UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-41160

ALLARITY THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**87-2147982**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
24 School Street, 2nd Floor, Boston, MA	**02108**
(Address of principal executive offices)	(Zip Code)

(401) 426-4664
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	ALLR	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act**: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the registrant's aggregate market value of its common stock held by non-affiliates as of such date was $10,592,706.

As of March 8, 2023, the registrant had 30,000,000 shares of common stock outstanding.

Documents incorporated by reference: None.

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When used herein, unless the context requires otherwise, references to the "Company," "we," "our" and "us" refer to Allarity Therapeutics, Inc., a Delaware corporation.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act, Section 21E of the Securities Exchange Act of 1934, as amended, and other federal securities laws. All statements, other than statements of historical fact, contained in this Annual Report. including statements regarding our strategy, future preclinical studies and clinical trials, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," 'will" "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. If one or more of these risk factors or uncertainties materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Furthermore, we operate in a competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements relating to Allarity in this Annual Report include, but are not limited to, statements about:

- our ability to continue as a going concern as addressed in the independent registered public accounting firm's report on our audited financial statements for the year ended December 31, 2022, included in this report;
- our ability to secure immediate substantial funding for our operations, working capital and to pursue our clinical trials. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our operations, product development, other operations or commercialization efforts;
- our ability to satisfy the Nasdaq continued listing requirements;
- our ability to amend our Certificate of Incorporation, as amended, to increase our authorized shares of common stock (which is subject to stockholder approval) since we currently do not have any authorized shares of common stock available for issuance;
- our ability to have effective disclosure controls and procedures and internal controls over financial reporting, and our ability to remediate the material weaknesses in our controls;
- our plans to develop and commercialize its drug candidates;
- our ability to generate any revenue or become profitable;
- the initiation, cost, timing, progress and results of our current and future preclinical studies and clinical trials, as well as our research and development programs;
- the impacts of the ongoing COVID-19 pandemic and related restrictions as they may related to our clinical trials;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the unknown consequences of a request for documents from the SEC;
- the market price of our common stock has been and may continue to be volatile;

- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of its current and future drug candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such drug candidates;
- our expectations regarding our ability to fund operating expenses and capital expenditure requirements with our existing cash and cash equivalents, and future expenses and expenditures;
- our ability to perform our contractual obligations we have under the transaction documents for financings relating to our Series A Preferred Stock, Series C Preferred Stock and bridge loan;
- our ability to enroll patients in our clinical trials, our clinical development activities;
- our ability to retain key employees, consultants and advisors;
- our ability to retain reliable third parties to perform the chemistry work associated with our drug discovery, preclinical activities and to conduct our preclinical studies and clinical trials in a satisfactory manner;
- our ability to secure reliable on third party manufacturers to produce clinical and commercial supplies of API for our therapeutic candidates;
- our ability to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our therapeutic candidates and technology;
- our anticipated strategies and our ability to manage our business operations effectively;
- the impact of governmental laws and regulations;
- the possibility that we may be adversely impacted by other economic, business, and/or competitive factors;
- any future currency exchange and interest rates; and
- other risks and uncertainties indicated in this report, including those set forth in the section titled “Risk Factors” as set forth in this report, which is incorporated herein by reference.

These forward-looking statements are based on information available as of the date of this report, and current expectations, forecasts and assumptions, and involve a number of risks and uncertainties. We do not assume any obligation to update any forward-looking statements, Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage, precision medicine pharmaceutical company actively advancing a pipeline of in-licensed oncology therapeutics for patients with difficult-to-treat cancers. Our clinical program includes three anti-cancer assets in mid-stage clinical development and one anti-cancer asset in early-stage clinical development. Our programs and partnerships leverage our proprietary, highly accurate Drug Response Predictor (DRP®) technology to refine patient selection and improve clinical outcomes. Our DRP® technology has been broadly validated across an extensive array of therapies and tumor types with a high degree of accuracy for matching the right patient to the right drug. By identifying those patients who will and who will not respond, the DRP® companion diagnostics have the potential to transform cancer therapeutic development across many indications by increasing clinical success rates with trials involving a fewer number of patients and improve patient outcomes by matching them to the right drug.

Our pipeline currently consists of three mid-stage clinical candidates for cancer and one anti-cancer asset in early-stage clinical development. We are focused on the clinical development of three priority programs: dovitinib in combination with stenoparib for the second-line or later treatment of metastatic ovarian cancer, stenoparib as a monotherapy for ovarian cancer, and IXEMPRA® as a monotherapy for metastatic breast cancer. In addition, Allarity is supporting the development of one additional clinical asset through business development activities. Each Allarity pipeline program is being co-developed with a drug specific DRP® companion diagnostic to select and treat patients most likely to benefit from treatment.

While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. By utilizing our DRP® platform to generate a drug-specific companion diagnostic for each of our therapeutic candidates, if approved by the FDA, we believe our therapeutic candidates have the potential to advance the goal of personalized medicine by selecting the patients most likely to benefit from each of our therapeutic candidates and avoid the treatment of non-responder patients. All of our therapeutic candidates are clinical stage assets and the FDA has not yet approved any of our therapeutic candidates or any of our DRP® companion diagnostics. As used in this report, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that a therapeutic candidate may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for any of our therapeutic candidates or DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Our clinical and commercial development team is advancing our pipeline of targeted oncology therapeutic candidates, all of which have previously succeeded at least through Phase 1 clinical trials demonstrating that the therapeutic candidate is well tolerated. Our three priority assets, dovitinib, stenoparib, and IXEMPRA® (ixabepilone) are all former drug candidates of large pharmaceutical companies.

Our most advanced therapeutic candidate, dovitinib, is a selective inhibitor of several classes of tyrosine kinases, including FGFR and VEGFR, and was formerly developed by Novartis Pharmaceuticals through Phase 3 clinical trials in numerous indications. We submitted an NDA with the FDA on December 21, 2021, for the third line treatment of metastatic renal cell carcinoma (mRCC or kidney cancer) in patients selected by our Dovitinib-DRP® companion diagnostic. Prior to submission of the NDA, we submitted a Pre-Market Approval (PMA) application to the FDA for approval of our dovitinib-specific DRP® companion diagnostic for use to select and treat patients likely to respond to dovitinib. On February 15, 2022, we received Refusal to File (RTF) letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA has asserted that neither our NDA or PMA meets the regulatory requirements to warrant a complete agency review. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint and superiority in connection with the DRP®-Dovitinib companion diagnostic. Based upon the reasons given in the RTF letters and a subsequent Type C meeting with the FDA on May 31, 2022, we anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dose optimization studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP for the treatment of third-line mRCC can be obtained. While we have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success, we continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. For example, subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies for mRCC will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer, as well as other indications.

Our second priority therapeutic candidate is stenoparib (formerly E7449), a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), which also has an observed inhibitory action against Tankyrases, another important group of DNA damage repair enzymes. Stenoparib was formerly developed by Eisai, Inc. (Eisai) through Phase 1 clinical trials, and we are currently advancing a Phase 2 clinical trial of this therapeutic candidate for the treatment of ovarian cancer at trial sites in the U.S. and Europe together with its stenoparib-specific DRP® companion diagnostic, for which the FDA has previously approved an Investigational Device Exemption (IDE) application. In addition, subject to funding, we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 Clinical Trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors.

Our third priority therapeutic candidate is IXEMPRA® (ixabepilone), a selective microtubule inhibitor, which has been shown to interfere with cancer cell division, leading to cell death. IXEMPRA® (ixabepilone) was formerly developed and brought to market by Bristol-Myers Squibb, is currently marketed and sold in the U.S. by R-PHARM US LLC, for the treatment of metastatic breast cancer treated with two or more prior chemotherapies. We are currently advancing IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in a Phase 2 European clinical trial for the same indication, with the goal of eventually submitting an application for Marketing Authorization (MA) with the European Medicine Agency (EMA) to market IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in the European market.

We have in-licensed the intellectual property rights to develop, use and market our two most advanced therapeutic candidates, dovitinib and stenoparib. Consequently, we must perform all of the obligations under these license agreements, including the payment of substantial development milestones payments and royalty payments on future sales in the event we receive marketing approval for dovitinib or stenoparib in the future. If we fail to perform our obligations under our license agreements, we may lose the intellectual property rights to these therapeutic candidates which will have a material adverse effect on our business.

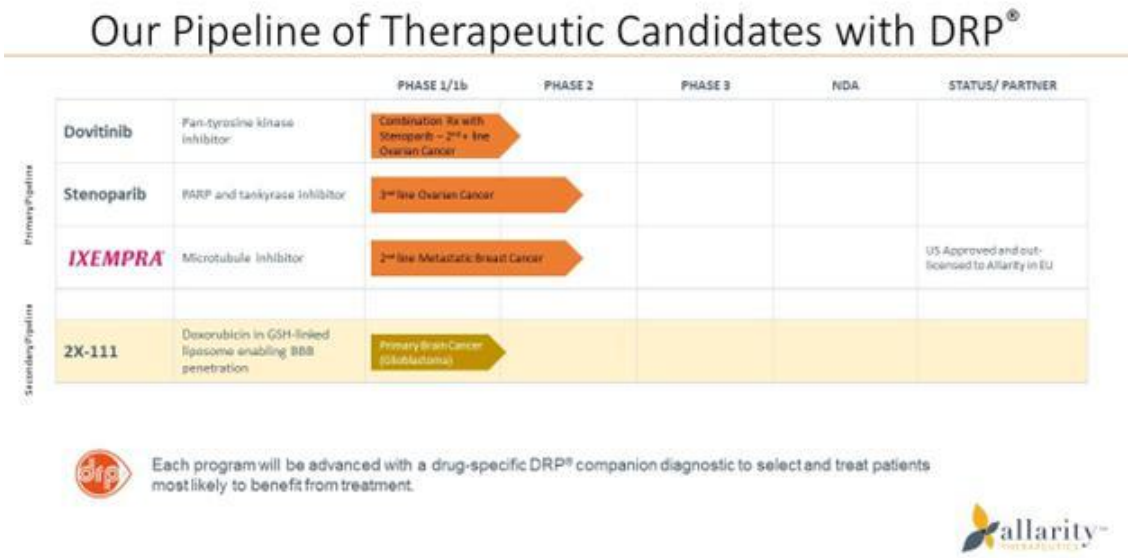
Our focused approach to address major unmet needs in oncology leverages our management's expertise in discovery, medicinal chemistry, manufacturing, clinical development, and commercialization. As a result, we have created substantial intellectual property around the composition of matter for our new chemical entities. The foundations of our approach include:

- ***The pursuit of clinical-stage assets:*** We strive to identify and pursue novel oncology therapeutic candidates that have advanced beyond Phase 1 clinical trials and are preferably Phase 2 to Phase 3 clinical stage assets. Accordingly, the assets we have acquired, and intend to acquire, have undergone prior clinical trials by other pharmaceutical companies with clinical data that helps us evaluate whether these candidates will be well tolerated in the tested patient population, and in some cases, have observed anti-cancer or anti-tumor activity that would support additional clinical trials using our DRP® platform. We often focus our acquisition efforts on therapeutic candidates that have been the subject of clinical trials conducted by large pharmaceutical companies. Further we intend to select therapeutic candidates for which we believe we can develop a drug-specific DRP® to advance together with the therapeutic candidate in further clinical trials as a companion diagnostic to select and treat the patients most likely to respond to the therapeutic candidate. We further consider whether the licensor or assignor can provide us substantial clinical grade active pharmaceutical ingredients (API) for the therapeutic candidate, at low-to-no cost, for our use in future clinical trials. The availability of API at low-to-no cost reduces both our future clinical trial costs and the lead time it takes us to start a new clinical trial for the therapeutic candidate. As an example, our therapeutic candidate, dovitinib, was developed by Novartis through Phase 2 clinical trials in numerous indications and in Phase 3 clinical trials for RCC before we acquired the therapeutic candidate, and it came with a substantial API.

- ***Our proprietary DRP® companion diagnostics:*** We believe our proprietary and patented Drug Response Predictor (DRP®) platform provides us with a substantial clinical and commercial competitive advantage for each of the therapeutic candidates in our pipeline. Our DRP® companion diagnostic platform is a proprietary, predictive biomarker technology that employs complex systems biology, bio-analytics with a proprietary clinical relevance filter to bridge the gap between in vitro cancer cell responsiveness to a given therapeutic candidate and in vivo likelihood of actual patient response to that therapeutic candidate. The DRP® companion diagnostic platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. We intend to develop and validate a drug-specific DRP® biomarker for each and every therapeutic candidate in our therapeutic candidate pipeline to serve as a companion diagnostic to select and treat patients most likely to respond to that therapeutic candidate. Although we are in the early stages of our companion diagnostic development and have not yet received a PMA from the FDA, our DRP® technology has been peer-reviewed by numerous publications and we have patented our DRP® platform for more than 70 anti-cancer drugs. While retrospective studies guide our clinical development of our companion diagnostics, prospective clinical trials may be required in order to receive a PMA from the FDA.

- ***A precision oncology approach:*** Our focused strategy is to advance our pipeline of therapeutic candidates, together with DRP® companion diagnostics, to bring these therapeutic candidates, once approved, to market and to patients through a precision oncology approach. Our DRP® companion diagnostic platform provides a gene expression fingerprint that we believe reveals whether a specific tumor in a specific patient is likely to respond to one of our therapeutic candidates and therefore can be used to identify those patients who are most likely to respond to a particular therapeutic treatment in order to guide therapy decisions and lead to better treatment outcomes. We believe our DRP® companion diagnostic platform may be used both to identify a susceptible patient population for inclusion in clinical trials during the drug development process (and to exclude the non-susceptible patient population), and further to select the optimal anti-cancer drug for individual patients in the treatment setting once an anti-cancer drug is approved and marketed. By including only patients that have tumors that we believe may respond to our therapeutic candidate in our clinical trials, we believe our proprietary DRP® companion diagnostics platform has the potential to improve the overall treatment response in our clinical trials and thereby improving our chances for regulatory approval to market our therapeutic candidate, while potentially reducing the time, cost, and risk of clinical development.

The following chart summarizes our therapeutic candidate pipeline:



Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Corporate Information

Our former parent, Allarity Therapeutics A/S, was founded in Denmark in 2004 by our chief scientific officer, Steen Knudsen, Ph.D., and our Director and Senior Vice President of Investor Relations, Thomas Jensen, both of whom were formerly academic researchers at the Technical University of Denmark working to advance novel bioinformatic and diagnostic approaches to improving cancer patient response to therapeutics. On May 20, 2021, we entered a Plan of Reorganization and Asset Purchase Agreement (the "Recapitalization Share Exchange"), between us, Allarity Acquisition Subsidiary, our wholly owned Delaware subsidiary ("Acquisition Sub"), and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark. Pursuant to the terms of the Recapitalization Share Exchange, our Acquisition Sub acquired substantially all of the assets and liabilities of Allarity Therapeutics A/S in exchange for shares of our common stock on December 20, 2021, and our common stock began trading on the Nasdaq Global Market on that same day. See section titled "*BUSINESS — Recapitalization Share Exchange, Asset Acquisition and Financing.*"

Our principal executive offices are located at 24 School Street, 2nd Floor, Boston, MA 02108 and our telephone number is (401) 426-4664. Our corporate website address is *www.allarity.com*. Information contained on or accessible through our website is not a part of this report, and the inclusion of our website address in this report is an inactive textual reference only.

Allarity and its subsidiaries own or have rights to trademarks, trade names and service marks that they use in connection with the operation of their business. In addition, their names, logos and website names and addresses are their trademarks or service marks. Other trademarks, trade names and service marks appearing in this report are the property of their respective owners. Solely for convenience, in some cases, the trademarks, trade names and service marks referred to in this report are listed without the applicable ®, ™ and SM symbols, but they will assert, to the fullest extent under applicable law, their rights to these trademarks, trade names and service marks.

BUSINESS

This Annual Report contains estimates, projections and other information concerning our industry, our business and the markets for our therapeutic candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this Annual Report from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe our internal research is reliable, such research has not been verified by any third party.

Overview

We are a clinical stage pharmaceutical company targeting some of the greatest unmet needs in oncology by developing differentiated and novel therapeutic candidates together with our proprietary DRP® companion diagnostics in a precision medicine approach. Our business strategy includes a focus on leveraging our proprietary DRP® companion diagnostics platform to streamline the drug development process and to identify patients that will benefit from therapeutic candidates that other biotechnology or pharmaceutical companies have abandoned or shelved after initiating clinical trials under an IND application filed with the FDA, including candidates that have failed to achieve statistical significance on the original endpoints established in their clinical trials. We use our proprietary DRP® companion diagnostics platform to advance therapeutic candidates by targeting and evaluating patient sub-populations having gene signatures, determined by our DRP® companion diagnostics platform, that will potentially correlate with drug efficacy and patient response to treatment. While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. By utilizing our DRP® platform to generate a drug-specific companion diagnostic for each of our therapeutic candidates, if approved by the FDA, we believe our therapeutic candidates have the potential to advance the goal of personalized medicine by selecting the patients most likely to benefit from each of our therapeutic candidates and avoid the treatment of non-responder patients. All of our therapeutic candidates are clinical stage assets and the FDA has not yet approved any of our therapeutic candidates or any of our DRP® companion diagnostics. As used in this report, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that a therapeutic candidate may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for any of our therapeutic candidates or DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Our Corporate History

We were founded in Denmark in 2004 by our chief scientific officer, Steen Knudsen, Ph.D., and our Director and Senior Vice President of Investor Relations, Thomas Jensen, both of whom were formerly academic researchers at the Technical University of Denmark working to advance novel bioinformatic and diagnostic approaches to improving cancer patient response to therapeutics. On May 20, 2021, we entered a Plan of Reorganization and Asset Purchase Agreement (the "Recapitalization Share Exchange"), between us, Allarity Acquisition Subsidiary, our wholly owned Delaware subsidiary ("Acquisition Sub"), and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark. Pursuant to the terms of the Recapitalization Share Exchange, our Acquisition Sub acquired substantially all of the assets and liabilities of Allarity Therapeutics A/S in exchange for shares of our common stock on December 20, 2021, and our common stock began trading on Nasdaq on that same day. See "*BUSINESS - Recapitalization Share Exchange, Asset Acquisition and Financing*." Concurrently, on December 21, 2021, we completed a private placement of our Series A Preferred Stock and a warrant to purchase additional shares of our common stock for an aggregate purchase price of $20.0 million.

Our Business

Our DRP® companion diagnostic platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. See, *Framework for FDA's Real-World Evidence Program,* page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two Investigational Device Exemption ("IDE") applications to conduct clinical trials, one with respect to LiPlaCis® and one with respect to stenoparib. However, while retrospective studies guide our clinical development of our companion diagnostics, prospective clinical trials may be required in order to receive a PMA from the FDA.

We submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for our therapeutic candidate, dovitinib, a second-generation "pan"-tyrosine kinase inhibitor (TKI), on December 21, 2021, for the third line treatment of mRCC in patients selected by our Dovitinib-DRP® companion diagnostic. Subsequently the FDA determined that our NDA was not sufficiently complete to permit a substantive review and therefore or NDA was not accepted for filing. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP® Dovitinib companion diagnostic. We anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP can be obtained. While we have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success, we continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. For example, subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies for mRCC will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer, as well as other indications.

While we have suffered delays due to the COVID-19 pandemic, we continue to expand patient enrollment in our ongoing Phase 2 clinical trials for our two other priority programs, stenoparib, a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), and IXEMPRA® (ixabepilone), a selective microtubule inhibitor. We also intend to opportunistically acquire other promising oncology assets, which have undergone prior clinical trials by other pharmaceutical companies with clinical data that helps us evaluate whether these candidates will be well tolerated in the tested patient population, and in some cases, have observed anti-cancer or anti-tumor activity that would support additional clinical trials using our DRP® platform.

Our clinical and commercial development team is advancing our pipeline of targeted oncology therapeutic candidates, all of which have previously succeeded at least through Phase 1 clinical demonstrating that the therapeutic candidate is well tolerated. Our three priority assets, dovitinib, stenoparib, and IXEMPRA® (ixabepilone) are all former drug candidates of large pharmaceutical companies.

Our most advanced therapeutic candidate, dovitinib, is a selective inhibitor of several classes of tyrosine kinases, including FGFR and VEGFR, and was formerly developed by Novartis Pharmaceuticals through Phase 3 clinical trials in numerous indications. As mentioned above, we submitted an NDA with the FDA on December 21, 2021, for the third line treatment of mRCC in patients selected by our Dovitinib-DRP® companion diagnostic. Prior to submission of the NDA, we submitted a Pre-Market Approval (PMA) application to the FDA for approval of our dovitinib-specific DRP® companion diagnostic for use to select and treat patients likely to respond to dovitinib. On February 15, 2022, we received RTF letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA has asserted that neither our NDA or PMA meets the regulatory requirements to warrant a complete agency review. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint and superiority in connection with the DRP®-Dovitinib companion diagnostic. We anticipate that it will be necessary to conduct a new prospective Phase 3 clinical trial, as well as additional dosing studies, to gain approval of dovitinib in the U.S. as a monotherapy for mRCC. While we have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success, we continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. For example, subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies for mRCC will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer, as well as other indications.

Our second priority therapeutic candidate is stenoparib (formerly E7449), a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), which also has an observed inhibitory action against Tankyrases, another important group of DNA damage repair enzymes. Stenoparib was formerly developed by Eisai, Inc. (Eisai) through Phase 1 clinical trials, and we are currently advancing a Phase 2 clinical trial of this therapeutic candidate for the treatment of ovarian cancer at trial sites in the U.S. and Europe) together with its stenoparib-specific DRP® companion diagnostic, for which the FDA has previously approved an Investigational Device Exemption (IDE) application. As mentioned above, subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors.

Our third priority therapeutic candidate is IXEMPRA® (ixabepilone), a selective microtubule inhibitor, which has been shown to interfere with cancer cell division, leading to cell death. IXEMPRA® (ixabepilone) was formerly developed and brought to market by Bristol-Myers Squibb, is currently marketed and sold in the U.S. by R-PHARM US LLC, for the treatment of metastatic breast cancer treated with two or more prior chemotherapies. We are currently advancing IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in a Phase 2 European clinical trial for the same indication, with the goal of eventually submitting an application for Marketing Authorization (MA) with the European Medicine Agency (EMA) to market IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in the European market.

We have in-licensed the intellectual property rights to develop, use and market our two lead therapeutic candidates, dovitinib and stenoparib. Consequently, we must perform all of the obligations under these license agreements, including the payment of substantial development milestones payments and royalty payments on future sales in the event we receive marketing approval for dovitinib or stenoparib in the future. If we fail to perform our obligations under our license agreements, we may lose the intellectual property rights to these therapeutic candidates which will have a material adverse effect on our business.

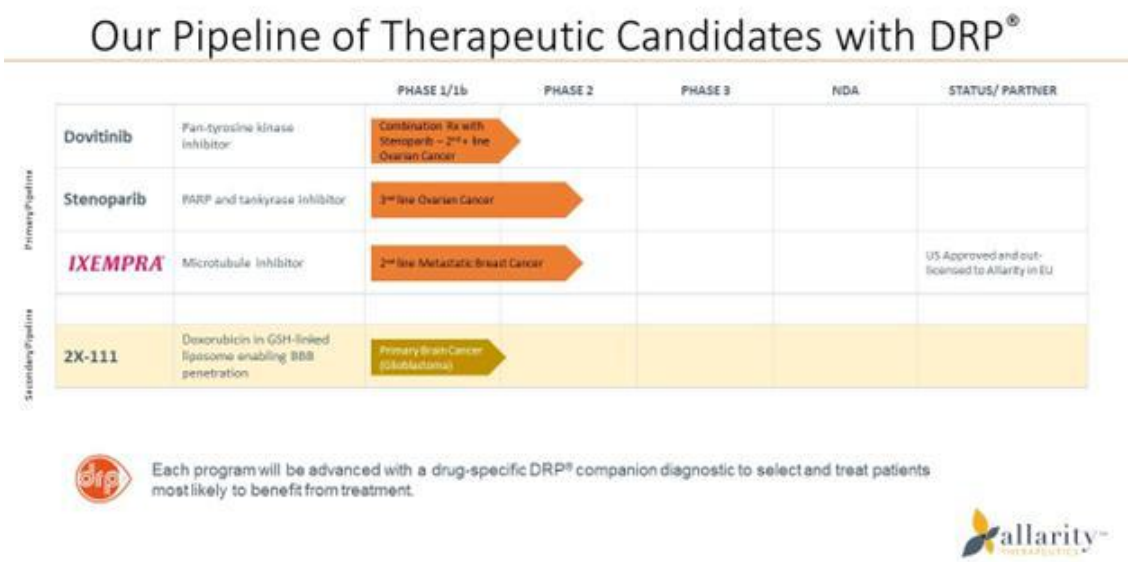
Our focused approach to address major unmet needs in oncology leverages our management's expertise in discovery, medicinal chemistry, manufacturing, clinical development, and commercialization. As a result, we have created substantial intellectual property around the composition of matter for our new chemical entities. The foundations of our approach include:

- ***The pursuit of clinical-stage assets:*** We strive to identify and pursue novel oncology therapeutic candidates that have advanced beyond Phase 1 clinical trials and are preferably Phase 2 to Phase 3 clinical stage assets. Accordingly, the assets we have acquired, and intend to acquire, have undergone prior clinical trials by other pharmaceutical companies with clinical data that helps us evaluate whether these candidates will be well tolerated in the tested patient population, and in some cases, have observed anti-cancer or anti-tumor activity that would support additional clinical trials using our DRP® platform. We often focus our acquisition efforts on therapeutic candidates that have been the subject of clinical trials conducted by large pharmaceutical companies. Further we intend to select therapeutic candidates for which we believe we can develop a drug-specific DRP® to advance together with the therapeutic candidate in further clinical trials as a companion diagnostic to select and treat the patients most likely to respond to the therapeutic candidate. We further consider whether the licensor or assignor can provide us substantial clinical grade active pharmaceutical ingredients (API) for the therapeutic candidate, at low-to-no cost, for our use in future clinical trials. The availability of API at low-to-no cost reduces both our future clinical trial costs and the lead time it takes us to start a new clinical trial for the therapeutic candidate. As an example, our therapeutic candidate, dovitinib, was developed by Novartis through Phase 2 clinical trials in numerous indications and in Phase 3 clinical trials for RCC before we acquired the therapeutic candidate, and it came with a substantial API.

- ***Our proprietary DRP® companion diagnostics:*** We believe our proprietary and patented Drug Response Predictor (DRP®) platform provides us with a substantial clinical and commercial competitive advantage for each of therapeutic candidates in our pipeline. Our DRP® companion diagnostic platform is a proprietary, predictive biomarker technology that employs complex systems biology, bio-analytics with a proprietary clinical relevance filter to bridge the gap between in vitro cancer cell responsiveness to a given therapeutic candidate and in vivo likelihood of actual patient response to that therapeutic candidate. The DRP® companion diagnostic platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. We intend to develop and validate a drug-specific DRP® biomarker for each and every therapeutic candidate in our therapeutic candidate pipeline to serve as a companion diagnostic to select and treat patients most likely to respond to that therapeutic candidate. Although we are in the early stages of our companion diagnostic development and have not yet received a PMA from the FDA, our DRP® technology has been peer-reviewed by numerous publications and we have patented our DRP® platform for more than 70 anti-cancer drugs. While retrospective studies guide our clinical development of our companion diagnostics, prospective clinical trials may be required in order to receive a PMA from the FDA.

- ***A precision oncology approach:*** Our focused strategy is to advance our pipeline of therapeutic candidates, together with DRP® companion diagnostics, to bring these therapeutic candidates, once approved, to market and to patients through a precision oncology approach. Our DRP® companion diagnostic platform provides a gene expression fingerprint that we believe reveals whether a specific tumor in a specific patient is likely to respond to one of our therapeutic candidates and therefore can be used to identify those patients who are most likely to respond to a particular therapeutic treatment in order to guide therapy decisions and lead to better treatment outcomes. We believe our DRP® companion diagnostic platform may be used both to identify a susceptible patient population for inclusion in clinical trials during the drug development process (and to exclude the non-susceptible patient population), and further to select the optimal anti-cancer drug for individual patients in the treatment setting once an anti-cancer drug is approved and marketed. By including only patients that have tumors that we believe may respond to our therapeutic candidate in our clinical trials, we believe our proprietary DRP® companion diagnostics platform has the potential to improve the overall treatment response in our clinical trials and thereby improving our chances for regulatory approval to market our therapeutic candidate, while potentially reducing the time, cost, and risk of clinical development.

The following chart summarizes our therapeutic candidate pipeline:



Recapitalization Share Exchange, Asset Acquisition and Financing

We were previously known as Oncology Venture A/S and changed our name to Allarity Therapeutics A/S on October 7, 2020. On April 6, 2021, we incorporated Allarity Therapeutics, Inc., a Delaware corporation, for the purposes of undertaking a recapitalization share exchange, a private placement of our preferred stock with an institutional investor (the "PIPE Financing"), and migrating the trading in our shares from the Nasdaq First North Growth Market: Stockholm to Nasdaq in the U.S. On May 20, 2021, we entered into a Plan of Reorganization and Asset Purchase Agreement (the "Recapitalization Share Exchange"), which was amended and restated on September 23, 2021, between us, Allarity Acquisition Subsidiary, our wholly owned Delaware subsidiary ("Acquisition Sub"), and Allarity Therapeutics A/S, an *Aktieselskab* organized under the laws of Denmark ("Allarity Therapeutics A/S, or Allarity A/S"), subject to the approval of the Recapitalization Share Exchange at an Extraordinary General Meeting (the "EGM") of the shareholders of Allarity A/S. The shareholders of Allarity A/S approved the Recapitalization Share Exchange at the EGM on November 22, 2021. On December 17, 2021 and in connection with the Recapitalization Share Exchange, we entered into the Asset Purchase Agreement with our Acquisition Sub and Allarity A/S, pursuant to which Allarity A/S agreed to sell, and our Acquisition Sub agreed to purchase, all of Allarity A/S' assets and certain specified liabilities in connection with Allarity A/S' Business (as defined in the Asset Purchase Agreement), for an aggregate purchase price of 8,075,824 shares of our common stock, plus the assumption of the specified liabilities.

On December 20, 2021, we consummated the transactions contemplated in the Asset Purchase Agreement, pursuant to which our Acquisition Sub acquired substantially all of the assets and assumed substantially all of the liabilities of Allarity A/S. In connection with the closing, our Acquisition Sub acquired substantially all of the assets and liabilities of Allarity A/S in exchange for shares of our common stock issued pursuant to a Registration Statement on Form S-4 (SEC File No. 333-258968), which was declared effective on November 5, 2021. Upon the closing of the Recapitalization Share Exchange, all of the shareholders of Allarity A/S became our shareholders, owning substantially the same percentage ownership in us as they owned in Allarity A/S. All of the business previously owned by Allarity A/S is owned and conducted by us through our Acquisition Sub.

Because we were formed as a "business combination related shell company" as defined in SEC Rule 405 for the purposes of undertaking our Recapitalization Share Exchange, Allarity Therapeutics A/S, our former parent who became our predecessor upon consummation of the Recapitalization Share Exchange, was deemed to be the accounting acquirer in the Recapitalization Share Exchange. While we are the legal acquirer of Allarity Therapeutics A/S in the Recapitalization Share Exchange, because Allarity Therapeutics A/S is deemed to be the accounting acquirer, the historical consolidated financial statements of Allarity Therapeutics A/S became our historical consolidated financial statements upon the consummation of the Recapitalization Share Exchange.

The Private Placement (PIPE Financing)

Concurrently with the execution of the Recapitalization Share Exchange on May 20, 2021, we entered into a Securities Purchase Agreement ("SPA") and related agreements with an institutional investor (the "Investor") wherein we agreed to sell, and the Investor agreed to purchase, 20,000 shares of our Series A Preferred Stock and a warrant to purchase additional shares of our common stock (the "PIPE Warrant") for an aggregate purchase price of $20 million with a closing conditioned upon the consummation of our Recapitalization Share Exchange and a listing of our common stock on Nasdaq. Simultaneously with the execution of the SPA, we also entered into a Registration Rights Agreement ("RRA") with the Investor wherein we agreed to register a number of shares of our common stock equal to the maximum number of shares of our common stock that could be issued upon conversion of the Series A Preferred Stock using a conversion price equal to 20% of $80,000,000 divided by the number of shares of common stock then outstanding (the "Floor Price") price plus 125% of the shares of common stock issuable upon exercise of the PIPE Warrant, or a maximum of 12,618,590 shares of our common stock. Such shares were registered for resale on a Registration Statement on Form S-1 originally filed with the SEC on September 13, 2021 (SEC File No. 333-259484), which was declared effective on December 20, 2021. Under the terms of the RRA, if we fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments equal to 2% of the Investor's investment upon our failure to maintain the effectiveness of the registration statement and every 30 days thereafter. Failure to maintain the effectiveness of the registration statement also constitutes a "triggering event" under the Certificate of Designations for the Series A Preferred Stock that would result in the accrual and payment of a dividend and provide the Investor the right to have its remaining Series A Preferred Stock redeemed for a premium of a minimum of 125% of the Conversion Amount of the Series A Preferred Stock, as more specifically described below.

Simultaneously with the closing of its Recapitalization Share Exchange, we closed on the PIPE Investment pursuant to the SPA. On December 20, 2021, we issued 20,000 shares of Series A Preferred Stock at $1,000 per share and a common stock purchase warrant to purchase 2,018,958 shares of common stock at an initial exercise price of $9.9061 to the Investor for an aggregate purchase price of $20 million. Each share of Series A Preferred Stock has a right to convert into shares of our common stock at an initial fixed conversion price of $9.9061. However, if (i) the price of our shares of common stock trade below $9.9061 (a "Price Failure") for a specified period of time; or (ii) in the event that the sum of (x) the aggregate daily dollar trading volume (as reported on Bloomberg) of our common stock on Nasdaq during the 10 trading day period ending on the trading day immediately preceding such date of determination, divided by (y) 10, is less than $1,500,000 (a "Volume Maximum Failure"), each share of Series A Preferred Stock is entitled to convert at a price equal to 90% of the sum of the two lowest VWAPs during the ten (10) trading day period immediately preceding delivery divided by two (the "90% Conversion Price"), but not less than the Floor Price, or, at the time of such Price Failure or Volume Maximum Failure, the sum of the average daily U.S. Dollar volume for our common stock during the 10 days previous to conversion divided by 10 is less than $2,000,000 (a "Volume Alternate Failure"), then each share of Series A Preferred Stock is entitled to convert at the lower of the fixed conversion price or a price equal to 80% of the sum of the two lowest VWAPs during the 10 trading day period immediately preceding delivery divided by two (the "80% Conversion Price"), but not less than the Floor Price (such 90% Conversion Price or 80% Conversion Price, as the case may be, the "Alternate Conversion Price"). If certain defined "Triggering Events" defined in the Certificate of Designations occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Series A Preferred Stock into common stock when a conversion right is exercised, failure to issue our common stock when the PIPE Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, certain defaults on our debts or contractual obligations, or upon a "bankruptcy triggering event" (as defined in the Certificate of Designations), then we may be required to pay a dividend that is added to the stated value on the Series A Preferred Stock in the amount of 18% per annum, but paid quarterly in cash, so long as the triggering event is continuing, or to redeem the Series A Preferred Stock for cash in an amount of a minimum of 125% of the Conversion Amount (as defined in the Certificate of Designations) of the Series A Preferred Stock or 125% of the Conversion Amount of the Series A Preferred Stock would be entitled to convert into our common stock at the Alternate Conversion Price. In the event that we experience a "Change of Control" (as defined in the Certificate of Designations) we may also be required to redeem the Series A Preferred Stock for cash at a minimum of 125% of their Conversion Amount. In addition, if thirty days after our common stock commences trading on Nasdaq the sum of the average daily dollar volume for the 10 days previous to conversion divided by 10 is less than $2,500,000, then the Series A Preferred Stock shall be entitled to a one-time dividend equal to an 8% increase in the stated value of the Series A Preferred Stock, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per share of Series A Preferred Stock. This dividend was paid during the first quarter of 2022. The Certificate of Designations of Series A Convertible Preferred Stock of Allarity Therapeutics, Inc. was filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1, as amended, filed with the SEC on September 13, 2021.

On May 4, 2022, the Company and the Investor entered into a Forbearance Agreement and Waiver, dated April 27, 2022, wherein the Investor confirmed that no Triggering Event as defined under the Certificate of Designations has occurred prior to April 27, 2022, that a Triggering Event under Section 5(a)(ii) will and has occurred on April 29, 2022, and that in consideration for the Registration Delay Payments the Company is obligated to pay under the RRA, and additional amounts the Company is obligated to pay under the Certificate of Designations and the Investor's legal fees incurred in the preparation of the Forbearance Agreement and Waiver in the aggregate of $538,823 paid upon execution of the Forbearance Agreement and Waiver, and so long as the Company pays the Registration Delay Payments that become due and payable under the RRA after the execution of the Forbearance Agreement and Waiver, the Investor has agreed to forbear exercising any rights or remedies that it may have under the Certificate of Designations that arises as a result of a Triggering Event under Section 5(a)(ii) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the Certificate of Designations (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022, which was subsequently extended to June 20, 2022 (such period, the "Forbearance Period"). Provided that the Company is not in breach of its obligations under Forbearance Agreement and Waiver, effective as of the Trading Day immediately following the Resale Availability Date, the Investor agrees to waive any rights or remedies that it may have under the Certificate of Designations that arises as a result of a Triggering Event under Section 5(a) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver. The Resale Availability Date was achieved on June 6, 2022, resulting in the Investor waiving any rights or remedies that it may have under the Certificate of Designations that arises as a result of a Triggering Event under Section 5(a) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver.

On June 6, 2022, we entered into that certain First Amendment to the Forbearance Agreement and Waiver with 3i, LP (the "Amendment") to extend the forbearance period date under subsection 5 of Section 2 of the Forbearance Agreement and Waiver dated April 27, 2022 (the "Original Agreement") from June 4, 2022, to June 20, 2022. In addition, the parties agreed that the forbearance period of June 20, 2022 may also be extended for an additional fifteen (15) days to July 5, 2022, provided that, on June 20, 2022 the Company will remove the restrictive legend on 441,005 shares of common stock of the Company issued in connection with the conversion of certain shares of Series A Preferred Stock ("Conversion Shares") by 3i, LP pursuant to the conversion notice dated May 2, 2022, and 3i, LP is able to sell the Conversion Shares free of restrictions (including volume restrictions) pursuant to SEC Rule 144(b)(1)(i).

On December 9, 2022, the Company and 3i, LP entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations for the Series A Preferred Stock, the parties agreed that the Conversion Price (as defined in such Certificate of Designations) was modified to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations) on the trading date immediately preceding the Conversion Date (as defined in the Certificate of Designations) and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Certificate of Designations) through and until the Company and 3i agree to terminate that definition.

Bridge Loan

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement with 3i, LP (the "Secured Note Purchase Agreement") for a bridge loan to extend the Company's cash runaway beyond December 31, 2022, in order to provide the Company with more time to complete the process of amending its Certificate of Incorporation to increase it authorized share capital and proposed reverse stock split to facilitate additional capital investments (the "Bridge Loan"). Under the Secured Note Purchase Agreement, the Company has authorized the sale and issuance of three 3i Promissory Notes, with the first note in an aggregate principal amount of $350,000 to be issued at closing (which was received in November 2022); the second note in the principal amount of $1,666,640 to be issued at closing and which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Certificate of Designations, that began to accrue on July 14, 2022; and the third note in an aggregate principal amount of $650,000 with respect to a new loan to be funded upon the Company filing a registration statement with SEC in connection with a registered offering. As of December 31, 2022, all of the notes have been issued and are outstanding. Each 3i Promissory Note matures on January 1, 2024, carries an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to the Security Agreement. In addition, 3i, LP may exchange the 3i Promissory Notes for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of the 3i Promissory Notes. In addition, each 3i Promissory Note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing.

Amendment to the Certificate of Designation of Series A Preferred Stock

On November 22, 2022, the Company amended Section 12 of the Certificate of Designation of Series A Preferred Stock to provide for voting rights. Subject to a 9.99% beneficial ownership limitation, the holders of Series A Preferred Stock were granted the right to vote on all matters presented to the stockholders for approval together with the shares of common stock, voting together as a single class, on an "as converted" basis using the "Conversion Price" (initially $9.9061 per share before any adjustment) (rounded down to the nearest whole number and using the record date for determining the stockholders of the Company eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in the Company's Certificate of Incorporation or the Certificate of Designations of Series A Preferred Stock. The voting rights described above expired on February 28, 2023.

Modification to Conversion Price of Series A Preferred Stock

On December 9, 2022, the Company and 3i, LP, the holder of outstanding shares of Series A Preferred Stock, entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations, the parties agreed that the Conversion Price (as defined in such Certificate of Designations) was modified to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations) on the trading date immediately preceding the Conversion Date (as defined in the Certificate of Designations) and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Certificate of Designations) through and inclusive of January 19, 2023. On January 23, 2023, the Company and 3i, LP amended the Letter Agreement to provide the term Conversion Price will be in effect until terminated by the Company and 3i, LP.

Establishment of Series B Preferred Stock

On November 22, 2022, the Company's Board of Directors established the Series B Preferred Stock, par value $0.0001 per share ("Series B Preferred Stock"). Each share of Series B Preferred Stock has 400 votes and is subject to certain redemption rights and voting limitations. See description in exhibit titled "*Description of Capital Stock – Series B Preferred Stock.*"

Issuance of Series B Preferred Stock Dividend

Effective December 5, 2022, the Company issued a stock dividend to be distributed as follows to stockholders of record as of close of business on December 5, 2022: (i) 0.016 shares of Series B Preferred Stock for each outstanding share of common stock; and (ii) 1.744 shares of Series B Preferred Stock for each outstanding share of Series A Preferred Stock. An aggregate of 190,786 shares of Series B Preferred Stock were issued as a stock dividend

Annual Stockholder Meeting and Redemption of Series B Preferred Stock

On February 3, 2023, we held our previously adjourned annual meeting of stockholders (the "Annual Meeting"). Nine proposals were submitted to our stockholders for a vote at the Annual Meeting including a proposal to increase the number of authorized shares and a proposal to effect a reverse stock split. Upon conclusion of the Annual Meeting, all of the 190,786 shares of Series B Preferred Stock were automatically redeemed, with the holders of the Series B Preferred Stock only having a right to receive the purchase price for the redemption, which was $0.01 per share of Series B Preferred Stock. In addition, the proposals to increase the number of authorized shares and to effect a reverse stock split did not pass by the requisite shareholder vote at the Annual Meeting. In light of our financing needs and our obligations to 3i, L.P., as holder of the Series A Preferred Stock and PIPE Warrant, we conducted a private placement offering pursuant to which we issued 50,000 shares of Series C Preferred Stock.

Establishment of Series C Preferred Stock and Sale of Series C Preferred Stock

On February 24, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock (the "Series C COD") with the Delaware Secretary of State designating 50,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock with a stated value of $27.00 per share. On February 28, 2023, the Company filed a Certificate of Amendment to the Series C COD (the "COD Amendment") to clarify the terms of conversion price and floor price based on definitions provided in the Series C COD (the COD Amendment, together with the Series C COD, the "COD"). Each share of Series B Preferred Stock has 620 votes and is subject to certain redemption rights and voting limitations. See description in exhibit titled "*Description of Capital Stock - Series C Preferred Stock.*"

On February 28, 2023, we entered into a Securities Purchase Agreement (the "SPA") with 3i, L.P. for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock, par value of $0.0001 per share of Series C Preferred Stock at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million (the "Series C Offering"). The Shares are convertible into shares of the Company's common stock, subject to the terms of the COD. The conversion price for the Series C Preferred Stock is initially equal the lower of: (i) $0.182, which is the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day (as defined in the COD) immediately preceding the Original Issuance Date (as defined in the COD); and (ii) the lower of: (x) the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Conversion Date or such other date of determination; and (y) the average of the official closing prices of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) for the five (5) Trading Days immediately preceding the Conversion Date (as defined in the COD) or such other date of determination, subject to adjustment herein (the "Conversion Price"), with the Conversion Price being no less than $0.0370 (the "Floor Price"). In the event that the Conversion Price on a Conversion Date would have been less than the applicable Floor Price if not for the immediately preceding sentence, then on any such Conversion Date the Company will pay the Holder an amount in cash, to be delivered by wire transfer out of funds legally and immediately available therefor pursuant to wire instructions delivered to the Company by the Holder in writing, equal to the product obtained by multiplying (A) the higher of (I) the highest price that the Common Stock trades at on the Trading Day immediately preceding such Conversion Date and (II) the applicable Conversion Price and (B) the difference obtained by subtracting (I) the number of shares of Common Stock delivered (or to be delivered) to the Holder on the applicable Share Delivery Date with respect to such conversion of Series C Preferred Stock from (II) the quotient obtained by dividing (x) the applicable Conversion Amount that the Holder has elected to be the subject of the applicable conversion of Series C Preferred Stock, by (y) the applicable Conversion Price without giving effect to clause (x) of such definition. The Offering closed on February 28, 2023.

In connection with the Series C Offering, concurrently with the SPA, the Company entered into a registration rights agreement with 3i, L.P. (the "RRA") pursuant to which the Company is required to file a registration statement with the SEC to register for resale the shares of Common Stock that are issued upon the potential conversion of the Shares. Under the terms of the RRA, if we fail file an Initial Registration Statement (as defined in the RRA) on or prior to its Filing Date (as defined in the RRA), or fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments, in cash and as partial liquidated damages and not as a penalty, equal to 2.0% of 3i, L.P.'s subscription amount of the Shares pursuant to the SPA. In addition, if we fail to pay any partial liquidated damages in full within seven (7) days after the date payment, we will have to pay interest at a rate of 18.0% per annum, accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The Company has also agreed to pay all fees and expenses incident to the performance of the RRA, except for any broker or similar commissions. In connection with the Series C Offering, the Company and 3i, L.P. entered into a limited waiver agreement pursuant to which 3i, L.P. confirmed that the sale and issuance of the Shares will not give rise to any, or trigger any, rights of termination, defaults, amendment, anti-dilution or similar adjustments, acceleration or cancellation under the existing agreements with 3i, L.P.

Special Meeting of Stockholders

Pursuant to a proxy statement filed with the SEC on or about March 6, 2023, (the "Proxy Statement"), the Company will be holding a Special Meeting of Stockholders (the "Special Meeting") virtually online on March 20, 2023. Stockholders of record of our outstanding shares of Common Stock and Series C Preferred Stock on March 3, 2023 (the "Record Date") will be entitled to notice of, and to vote at, the Special Meeting and any adjournments, continuations or postponements thereof that may take place At the Special Meeting, the stockholders of Common Stock and Series C Preferred Stock will be voting on the following proposals: (1) to approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares from 30,500,000 to 750,500,000, and to increase the number of our common stock from 30,000,000 to 750,000,000, in substantially the form attached to the Proxy Statement as Appendix A (the "Share Increase Proposal"); and (2) to approve an amendment to our Certificate of Incorporation, as amended, in substantially the form attached to the Proxy Statement as Appendix B, to, at the discretion of the Board of Directors of the Company (the "Board"), effect a reverse stock split with respect to the Company's issued and outstanding common stock, par value $0.0001 per share, at a ratio between 1-for-20 and 1-for-35 (the "Range"), with the ratio within such Range to be determined at the discretion of the Board (the "Reverse Stock Split Proposal") and included in a public announcement. Under the terms of the Series C Preferred Stock, the holders thereof may only vote on Proposal 1 (Share Increase Proposal) and Proposal 2 (Reverse Stock Split Proposal) and for no other matters. Each holder of one share of Series C Preferred Stock is entitled to six hundred twenty (620) votes representing 31,000,000 votes in the aggregate assuming 50,000 shares of Series C Preferred Stock is outstanding.

Our Therapeutic Candidates

Our most advanced therapeutic candidate, dovitinib (formerly TKI258), was designed to be a second-generation "pan"-tyrosine kinase inhibitor (TKI) with the ability to inhibit numerous classes of tumor-driving tyrosine kinases (both receptor and internal), including FGFR, VEGFR, PDGFR, c-Kit, Flt-3, and CSF-1. Numerous pan-TKIs are approved and in use for the treatment of cancers, including Sorafenib (NEXAR®, Bayer), Lenvatinib (LENVIMA®, Eisai), and Tivozanib (FOTIVDA® AVEO Oncology) and this class of drugs is increasingly showing promise in combination with immuno-oncology drugs, including checkpoint inhibitors. Dovitinib was previously developed by Novartis in 56 clinical trials, and through a Phase 3 clinical trial, where it showed therapeutic equivalence (with similar adverse events profile) to Bayer's Sorafenib for the third treatment of mRCC, but failed to show that it was statistically significantly superior to Sorafenib. Dovitinib also previously showed encouraging Phase 2 clinical trial results for the treatment of gastrointestinal stromal tumors (GIST), endometrial cancer, breast cancer, and liver cancer. We have retrospectively validated our DRP® companion diagnostic for dovitinib using clinical trial gene expression data (from patient biopsies) from prior Phase 2 and 3 clinical trials of this therapeutic candidate. In retrospective analysis of mRCC, patients selected with our Dovitinib-DRP® have an observed fifty percent (50%) increase in median overall survival when compared to DRP® negative patients. We plan to clinically advance dovitinib in combination with our therapeutic candidate stenoparib in future clinical trials for second-line or later treatment of metastatic ovarian cancer using our dovitinib-specific DRP® companion diagnostic to select and treat likely responder patients. We believe that dovitinib, if approved, could be broadly applicable and gain market share in the pan-TKI market as a combination therapy product in other indications as well. As discussed above, as a result of the FDA's determination that our NDA filed on December 21, 2021, was not sufficiently complete to permit a substantive review and therefore was not accepted for filing, we anticipate that we will need to conduct additional prospective clinical trials to support our retrospective analysis of prior clinical trials and have decided on advancing dovitinib in combination with our therapeutic candidate, stenoparib, or another approved drug, in future clinical trials. Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer.

Our second priority therapeutic candidate, stenoparib, is a selective inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), which also has, in clinically relevant doses, a unique inhibitory action against Tankyrases, another important group of DNA damage repair enzymes. DNA damage repair mechanisms are crucial to mammalian cell survival and replication, and so inhibition of key DNA damage repair enzymes, such as PARP, has clinically demonstrated to be therapeutically beneficial in the treatment of cancer. Tankyrases are enzymes involved in the stabilization and maintenance of telomeres (the ends of chromosomal DNA) during cell replication, and so disruption of Tankyrases is thought to provide an additional mechanism of impeding cancer cell growth. There are four PARP inhibitors currently approved and used for the treatment of cancers, primarily ovarian and breast cancers. Most of these approved PARP inhibitors use mutation of BRCA genes, which encode another important DNA damage repair enzyme as a biomarker for whether the patient will respond to a PARP inhibitor. The theory is that tumors already defective in BRCA, which are then treated with an inhibitor of PARP, will suffer higher cell/tumor death than tumors with active BRCA, effectively resulting from a synergistic inhibition of multiple DNA damage repair pathways. Stenoparib has demonstrated a superior therapeutic and toxicity profile compared to competitive PARP inhibitors and has the potential to be a beneficial drug, if approved. In addition to stenoparib's dual PARP and Tankyrase inhibitory activity, we believe stenoparib may cross the blood brain barrier (BBB) — potentially leading to treatment opportunities for primary brain cancers and brain metastases from tumors elsewhere in the body , and shows less myelotoxicity than the other approved PARP inhibitors.

Additionally, we have developed and retrospectively validated our Stenoparib-DRP® companion diagnostic using clinical trial biopsies from the prior Phase 1 clinical trial of this therapeutic candidate. In retrospective analysis of this trial, we have observed that patients selected with our Stenoparib-DRP® have a fourfold (4X) improvement in overall survival when compared to DRP® negative patients. Our putative Stenoparib-DRP® companion diagnostic identified a substantially broader responder patient subgroup than use of single biomarkers, including BRCA mutation, alone, thus potentially enabling the treatment of more patients. We plan to apply for initial market approval for stenoparib, in the U.S., for the treatment of advanced ovarian cancer, using our Stenoparib- DRP® companion diagnostic to select and treat likely responder patients or as a combination therapy with our therapeutic candidate, dovitinib. We are currently advancing a Phase 2 clinical trial for stenoparib for the treatment of advanced ovarian cancer at trial sites in the U.S. and Europe, together with its Stenoparib-specific DRP® companion diagnostic, for which the FDA has previously approved an Investigational Device Exemption (IDE) application. Subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 Clinical Trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors.

Our third priority therapeutic candidate, IXEMPRA® (ixabepilone), is a selective microtubule inhibitor, which interferes with cancer cell division, through mitotic arrest, leading to cell death. Microtubules are polymers of the structural protein tubulin that form part of the cytoskeleton and provide structure and shape to mammalian cells. They are involved in forming the mitotic spindle apparatus that ensures the proper segregation of duplicated chromosomes into daughter cells during cell division. IXEMPRA® was formerly developed and brought to market by Bristol-Myers Squibb (BMS) and is currently marketed and sold in the U.S. by R-PHARM US LLC for the treatment of metastatic breast cancer treated with two or more prior chemotherapies. There are numerous microtubule inhibitors currently approved and used for the treatment of numerous cancers such as ovarian and breast, including Halaven® (eribulin mesylate), Taxotere® (docetaxel), and Abraxane® (nanoparticle albumin-bound paclitaxel). Currently marketed microtubule inhibitors have generated significant sales in the past few years. For example, sales of Halaven® (Eisai) alone were about $400 million in 2019. We have previously developed and retrospectively validated our Ixabepilone-DRP® companion diagnostic using clinical trial gene expression data from a prior Phase 2 clinical trial of IXEMPRA® by BMS. In retrospective analysis of this trial, patients selected with our putative Ixabepilone-DRP® companion diagnostic have an observed 58% increase in complete remission when compared to randomly selected patients treated with ixabepilone. We are currently advancing IXEMPRA®, together with its DRP® companion diagnostic, in a Phase 2 European clinical trial in metastatic breast cancer treated with two or more prior chemotherapies, with the goal of eventually submitting for marketing approval with the EMA for the European market. R-PHARM US, LLC, holds a first buy-back option for this asset.

We are also developing, through external partnerships and out-licensing arrangements, several second priority therapeutic candidates, including a DRP® companion diagnostic for LiPlaCis® and Irofulven in combination with an Irofulven-specific DRP® companion diagnostic in order to improve therapeutic benefit and patient outcomes by selecting and treating the patients most likely to respond to each drug. LiPlaCis® is an advanced, targeted liposomal formulation of Cisplatin. While we previously had an exclusive in-license to develop this drug from LiPlasome Pharma ApS, on March 28, 2022, we agreed to transfer our exclusive development rights to Chosa ApS, an affiliate of Smerud Medical Research International AS and have out-licensed our DRP® companion diagnostic for LiPlaCis® to Chosa. The specific LiPlaCis® formulation utilizes a proprietary phospholipase A (sPLA2-IIA) cleavage substrate for controlled, selective hydrolyzation, disruption and release of drug payload in the presence of tumor cells. This delivery vehicle may result in drug accumulation directly at tumor site, thereby potentially increasing drug targeting at the tumor and reducing negative, off target drug effects and toxicity that is well known for cisplatin. We have previously developed and retrospectively validated a DRP® companion diagnostic specific for cisplatin, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate.

Our therapeutic candidate 2X-111 is an advanced, targeted liposomal formulation of Doxorubicin, that remains one of the world's most widely used chemotherapies. We exclusively in-licensed this therapeutic candidate from 2BBB Medicines, B.V. The specific 2X-111 formulation, which exploits a glutathione enhanced PEG-liposomal delivery system, we believe may allow 2X-111 to cross the blood-brain barrier (BBB), thereby potentially enabling the treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and secondary brain tumors that originated from cancers outside the brain, such as metastatic breast cancer. The treatment of such brain tumors is a significant unmet need in cancer care, given that patients with primary brain tumors and metastases have few or no meaningful therapy options. We have previously developed and retrospectively validated a DRP® companion diagnostic specific for epirubicin, which may enable us to identify and treat the patients most likely to respond to this therapeutic candidate. 2X-111 has previously shown encouraging results in a Phase 2 trial (without use of a DRP® companion diagnostic) for the treatment of both GBM and brain metastases of mBC. In June of 2020, we out-licensed this program to Smerud Medical Research International, our long-time CRO partner in Europe, which was subsequently terminated on March 28, 2022, in connection with our out-licensing of our DRP® companion diagnostic for LiPlaCis® to Chosa discussed above. We are currently in discussions with SMERUD about a revised agreement under which SMERUD, together with original drug owner 2BBB Medicines, B.V., will secure grant funding to advance this program, with DRP® companion diagnostic support from us.

Irofulven (6-hydroxymethylacylfulvene), is a unique DNA damaging agent, is a semi-synthetic sesquiterpene derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (*Omphalotus illudens*). Until July 23, 2021, we exclusively in-licensed this therapeutic candidate from Lantern Pharma, Inc. Irofulven has two primary anti-tumor mechanisms of action: first, it produces bulky single strand DNA adducts that are only repairable by the transcription coupled nucleotide excision repair (TC-NER) pathway; and second, it stalls RNA polymerase II leading to transcription and cell cycle arrest and apoptosis. The therapeutic candidate was formerly developed, between 1995 and 2007, in 41 different clinical trials, including through Phase 3 clinical trials, which demonstrated Irofulven's single agent activity in a range of indications, including castration-resistance prostate cancer (CRPC), ovarian, liver, and pancreatic cancer, and clinical activity in combination treatments targeting CRPC, colorectal and thyroid cancers. We have previously developed and patented a putative DRP® companion diagnostic specific for Irofulven, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate although we have not yet filed a PMA with the FDA for this companion diagnostic. In order to devote more of our development resources to our priority therapeutic candidates, on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of API, our clinical data and records, and our know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to Lantern Pharma to use our putative DRP® companion diagnostic specific for Irofulven in exchange for $1 million and future additional milestone and royalties. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

We retain exclusive worldwide rights to all the therapeutic candidates in our pipeline, with the exception of IXEMPRA® for which we have exclusive European rights and our putative DRP® companion diagnostic specific for Irofulven, which we have out-licensed to Lantern Pharma, Inc. and our DRP® companion diagnostic for LiPlaCis® which we have out-licensed to Chosa. We have a broad intellectual property portfolio comprised of more than 17 granted DRP® patents covering 70 different cancer drugs, and another 27 DRP® patent applications pending covering 2 additional cancer drugs. Our rolling patent strategy allows our DRP® patents to be listed in FDA's Orange Book for the drugs where they occur in the approval label. We also control remaining composition of matter, formulation, and methods of use patent coverage on dovitinib and stenoparib which extend out to 2028 or 2032 depending on the relevant patents.

Strategy

We strive to deliver meaningful benefit to patients with serious unmet medical needs in oncology by developing potentially breakthrough therapies, together with our proprietary DRP® companion diagnostics, in a personalized medicine approach. The core elements of our strategy include:

- ***Advance our therapeutic candidate, dovitinib, in combination with our therapeutic candidate, stenoparib, in a Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors, together with our Dovitinib-DRP® companion diagnostic.*** Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer.

- ***Accelerate enrollment in, and conclusion of, our ongoing Phase 2 clinical trials for stenoparib in ovarian cancer and IXEMPRA® in metastatic breast cancer.*** Our ongoing, DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at trial sites in the U.S. and Europe, has been adversely impacted by the COVID-19 pandemic. We anticipate accelerating enrollment in our stenoparib clinical trial and concluding the clinical trial, with data read out, sometime sometime in the second half of 2023. Similarly, the recent start of our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations in Europe, has been adversely impacted by the COVID-19 pandemic. As the regulatory agencies, the internal review boards and the clinical trial sites continue to emerge from COVID-19 pandemic, we anticipate accelerating enrollment in our IXEMPRA® clinical trial and concluding the clinical trial, with interim data read out, in the second half of 2023.

- ***Support the continuing, external clinical development of our secondary pipeline assets towards value inflection points***. We have previously out-licensed both LiPlaCis® and 2X-111, to our longtime CRO partner Smerud Medical Research International, in our efforts to advance the clinical development of these assets. In March 2022, we restructured our LiPlaCis® license agreements with Smerud and original drug owner LiPlasome Pharma ApS, in a way that will enable Smerud to step into the shoes of Allarity and assume full control of this program for further development in a Smerud affiliate, Chosa ApS, and to secure additional investment funding and collaborative development of the program through the affiliate. Allarity and SMERUD are currently in discussions about a revised agreement, together with original drug owner 2BBB Medicines, B.V., about future clinical advancement of 2X-111. We intend to support both of these clinical programs with our proprietary DRP® companion diagnostics and our clinical trial and regulatory expertise, and are in ongoing negotiations with SMERUD to extend the financing pathways and timeframe for these programs.

- ***Continue to leverage our deep insights in tumor biology and predictive diagnostics to pursue innovative clinical candidates.*** We have established, over many years, expertise, and capabilities in the evaluation of oncology therapeutics with coupled companion diagnostics utilizing our proprietary DRP® platform. We intend to leverage these capabilities to identify, acquire, and advance additional new, clinical stage assets that may benefit patients with serious unmet medical needs, through a precision medicine approach.

- ***Evaluate strategic opportunities to accelerate development timelines and maximize value of our therapeutic candidate pipeline.*** We currently own the exclusive worldwide development and commercial rights to each of our therapeutic candidates, with the exception of IXEMPRA®, for which we own exclusive European rights, LiPlaCis® which is now being developed by Chosa ApS, and Irofulven, which is now being developed by Lantern Pharma. We intend to evaluate collaborations that could maximize the value of our therapeutic candidate pipeline, either through the evaluation of our therapeutic candidates in combination with compounds owned by third parties or through geographic collaborations outside of the U.S. that allow us to leverage the existing infrastructure of other companies. For example, there are a number of pharmaceutical companies in oncology markets in the Asia-Pacific, Middle East, and Latin America markets that we believe are interested in partnering with us, and or acquiring license rights from us, in order to develop and commercialize our oncology products in those substantial oncology therapeutics markets.

Our Companion Diagnostics

Overview of Our DRP® Companion Diagnostic Platform

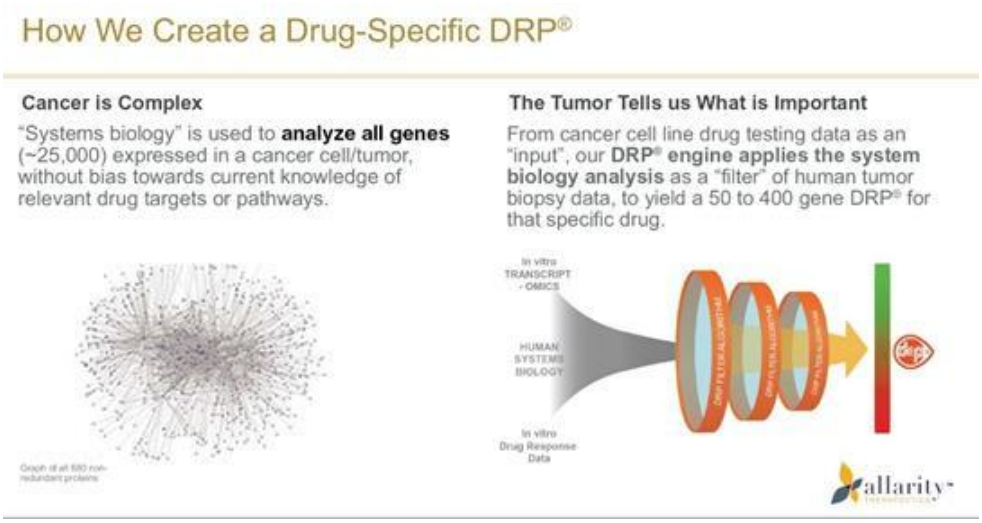
Our patented DRP® platform is a proprietary technology that enables the development of drug-specific companion diagnostics that are used to identify patients that will most likely respond to a particular cancer therapy. While our strategy is to use our DRP® platform to advance our own therapeutic candidates, we believe our DRP® platform could be used by many other cancer drugs, both in clinical development and those on the market.

A companion diagnostic is an *in vitro* diagnostic device or test that provides information that is essential for the safe and effective use of a corresponding therapeutic product. After the companion diagnostic is approved for use by the FDA, the use of the companion diagnostic with an approved therapeutic product is stipulated in the instructions for use in the labeling of both the companion diagnostic and the corresponding therapeutic product.

In cancer therapy, personalized medicine, also known as precision medicine, aims to match therapeutic products to those patients (and only those patients) who will positively respond to that therapeutic product, to maximize the benefits and minimize risks from the therapeutic product received. Personalized medicine in the field of oncology therefore depends on (1) understanding the molecular pathophysiology of cancer and (2) the ability of companion diagnostics to accurately and reliably detect and measure molecular biomarkers. Consequently, these companion diagnostics inform both the clinical development of therapeutic candidates and the approved use of therapeutic products.

Our DRP® platform facilitates personalized medicine in cancer patients by addressing the crucial fact that the specific cancer tumor biology within a patient that determines whether a patient will (or will not) respond to a particular cancer drug is largely unique to that patient:

We believe our DRP® platform addresses the great complexity of cancer, and is fundamentally different from classical or competitive approaches, in that we let the tumor tell us what cellular mechanisms are important to its response (or resistance) to a given cancer drug:

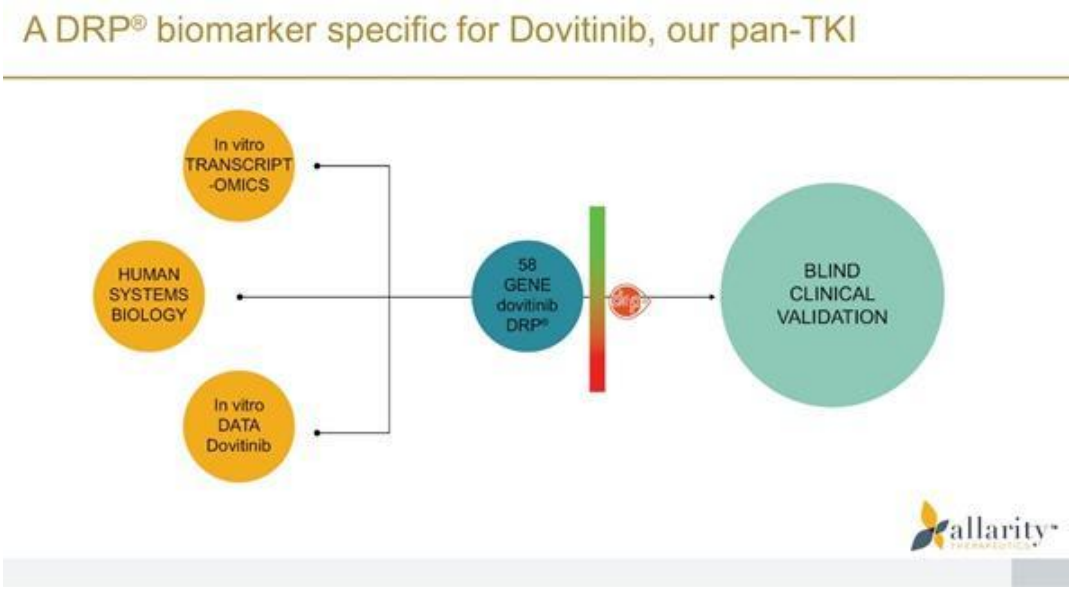


Our DRP® platform is a powerful bioinformatic engine that is based on advanced systems biology and transcriptomics, meaning that it analyzes all genes that are transcribed (*i.e.* expressed) as RNA and/or microRNA in a tumor and whether those transcribed genes are affected in response to treatment of the tumor (or cancer cells) with a given approved drug or therapeutic candidate. Our approach differs greatly from simple genetic tests, such as those for a critical mutation in a single gene, and provides a much deeper level of insight into a tumor's likelihood of responding to a particular approved drug or therapeutic candidate, that may not be observed by simply looking at a patient's DNA sequence information.

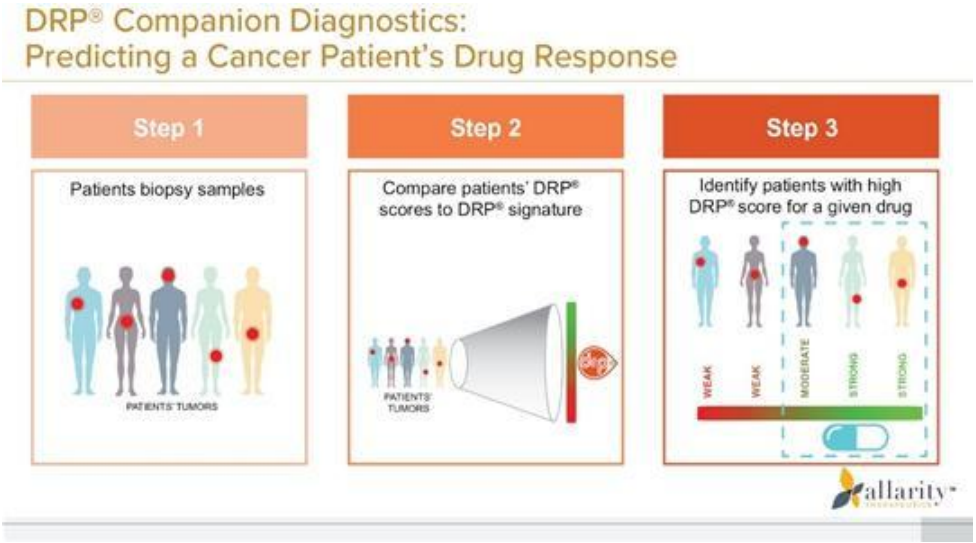
When we create a new, drug-specific DRP® companion diagnostic using our DRP® platform, we start with an established panel of cancer cell lines, which have been treated with the cancer drug or therapeutic candidate, to correlate the genetic expression profile of cell lines that are either sensitive or resistant to the drug or therapeutic candidate. In our development of a companion diagnostic, we usually use a well-known collection of 60 human tumor cell lines from the National Cancer Institute known as the "NCI-60" panel, however we also use proprietary cancer cell line panels. Gene expression profiles of the cancer cell lines are derived from a microarray (commercially available Affymetrix Gene Chips) to quantify the level of mRNA and/or microRNA that have been transcribed from genes in those cells. The advanced bioinformatic algorithm at the heart of our DRP® platform then identifies, from all mRNA, the specific ones that are correlated with either drug or therapeutic candidate response or resistance, and the collection of these biomarkers becomes a "fingerprint" of response (or resistance) to that drug or therapeutic candidate. Our DRP® platform then applies what we believe to be a unique "biological relevance filter" — created from analyzing more than 3,000 actual biopsy samples from human clinical trials across a broad range of cancer types and cancer drug and therapeutic candidate types — to remove biomarkers that are not relevant to actual clinical response of tumors (from patients) and thus reduce the background noise from our observations. This process generates a putative DRP® companion diagnostic, specific for the drug or therapeutic candidate, which identifies a subpopulation of cancer patients most likely to respond to the drug or therapeutic candidate. Typically, between 50 and 400 biomarkers (*i.e.* expressed genes) comprise a putative DRP® companion diagnostic for a specific drug or therapeutic candidate.

However, before we can confidently use the DRP® companion diagnostic with real cancer patients, either in clinical trials for a therapeutic candidate or for an approved and on market drug, we must retrospectively validate the predictive power of the DRP® for that drug or therapeutic candidate by accessing tumor biopsies (or gene expression data from such biopsies) from prior clinical trials of the drug or therapeutic candidate, and then retrospectively predicting which patients will respond to the drug or therapeutic candidate. When possible, we do our analysis in a "blinded" manner, meaning that we have no access to patient information and whether they did or did not respond to the drug or therapeutic candidate. Using this protocol of analysis, we believe we are able to retrospectively validate whether our putative DRP® companion diagnostic would have correctly identified those patients who did respond to the drug or therapeutic candidate. At this stage, we also establish a cutoff score for the putative DRP® companion diagnostic, in order to capture most of the responsive patients while excluding most of the nonresponsive patients in the tested population. Typically, we set a DRP® cutoff score for a given cancer drug at 50%, although we may use a more stringent cutoff score for certain cancer types or drugs.

The following image shows an exemplary process flow for creation of our Dovitinib-DRP® companion diagnostic:

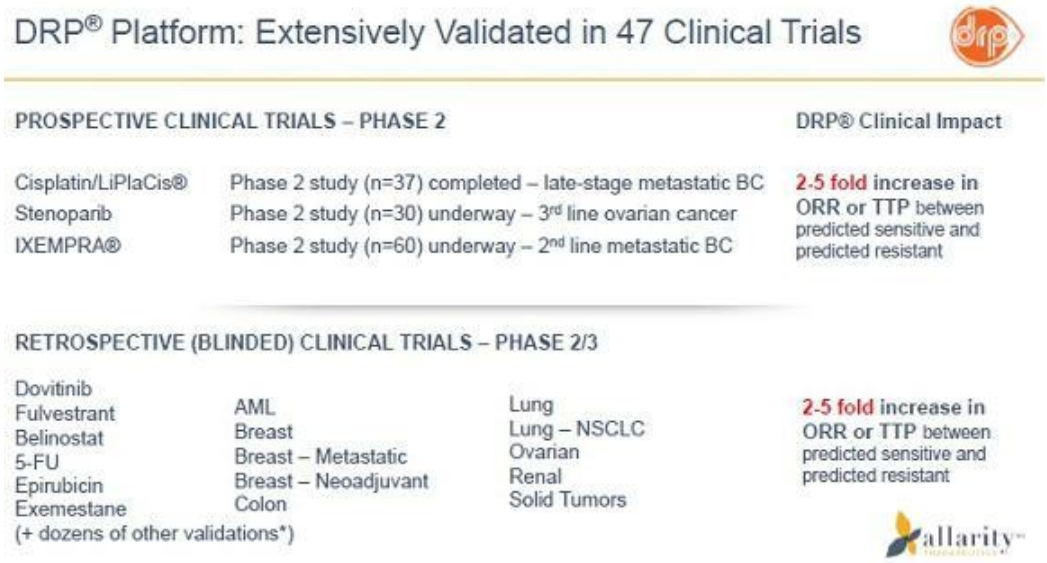


If we succeed with the final retrospective validation step, then our putative DRP® companion diagnostic is ready for submission as an IDE to the FDA and, if approved, use with actual patients in clinical trials. Depending on the outcomes of our clinical trials, a Pre-Marketing Authorization ("PMA") application may be made with the FDA and, if approved, our DRP® companion diagnostic may be used with an approved drug in cancer therapy. The following image shows how to use a drug-specific DRP® companion diagnostic, in practice, to test whether a patient will or will not respond to a given cancer drug:



For example, we may receive, at our diagnostic laboratory (or a partner diagnostic laboratory), a biopsy sample from a hospital or cancer center where a patient is being treated. Often, this biopsy sample is formalin-fixed paraffin-embedded (FFPE). Generally, we prefer a recent biopsy to an older (*e.g.* diagnostic) biopsy, since tumors may change, at the molecular biology level, with each round of therapy they are treated with. Gene expression in tumor cells from the biopsy is determined in the same manner as in the cell lines previously described above. The expression levels of the relevant biomarkers (that comprise the DRP® companion diagnostic) in the patient's tumor are compared to the DRP® reference in order to assess how closely the patient's biomarker expression levels match the reference. We then apply the relevant DRP® score cutoff (e.g. 50%) for that drug to determine whether the patient has a high enough DRP® score to be identified as a likely responder for the drug.

Our DRP® platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. *See, Framework for FDA's Real-World Evidence Program*, page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two IDE applications to conduct clinical trials, one with respect to LiPlaCis® and one with respect to stenoparib. We believe our DRP® platform has successfully generated drug-specific putative DRP® companion diagnostics for a broad range of cancer drugs and therapeutic candidates with different mechanisms-of-action (e.g. kinase inhibitors, chemotherapeutics, HDAC inhibitors, PARP inhibitors, hormone receptor inhibitors, etc.) and across both solid and hematological cancers. Although none of our putative DRP® companion diagnostics have yet been approved by the FDA for marketing, the following graphic illustrates some retrospective validations we have conducted (a strong clinical impact suggests that use of the putative DRP® companion diagnostic may result in a 3X to 5X increase in therapeutic benefit for DRP®-selected patients, while a moderate clinical impact suggests that the DRP® companion diagnostic may provide a 2X increase in therapeutic benefit):



While these retrospective observational studies validate the ability of the DRP® platform to predict likely responders, few of these retrospective studies meet the criteria for proof of efficacy and safety required by the FDA. Usually, the FDA requires a sufficiently powered phase III clinical trial before a PMA may be approved.

Although we believe our DRP® platform is very robust and retrospectively validated, we are not always successful in discovering a putative DRP® companion diagnostic in all cases. Generally, the limited number of failures we have encountered have been with cancer drugs with a mechanism-of-action that is not directly cytotoxic (*i.e.* it acts directly on the cancer cell leading to cell death), such as angiogenesis inhibitors that interfere with new blood vessel development to the tumor. Additionally, we have experienced some failures to develop a putative DRP® companion diagnostic for a given drug or therapeutic candidate when biopsy materials are too old, or when too many intervening treatments have taken place from the time of original biopsy to current treatment.

Our DRP® companion diagnostics have been patented for more than 70 anticancer agents across a broad range of cancer drugs. Studies involving our DRP® platform, and resulting putative DRP® companion diagnostics, have also been extensively published in peer reviewed literature and presented at major oncology conferences.

Advantages Over Other Biomarker Approaches

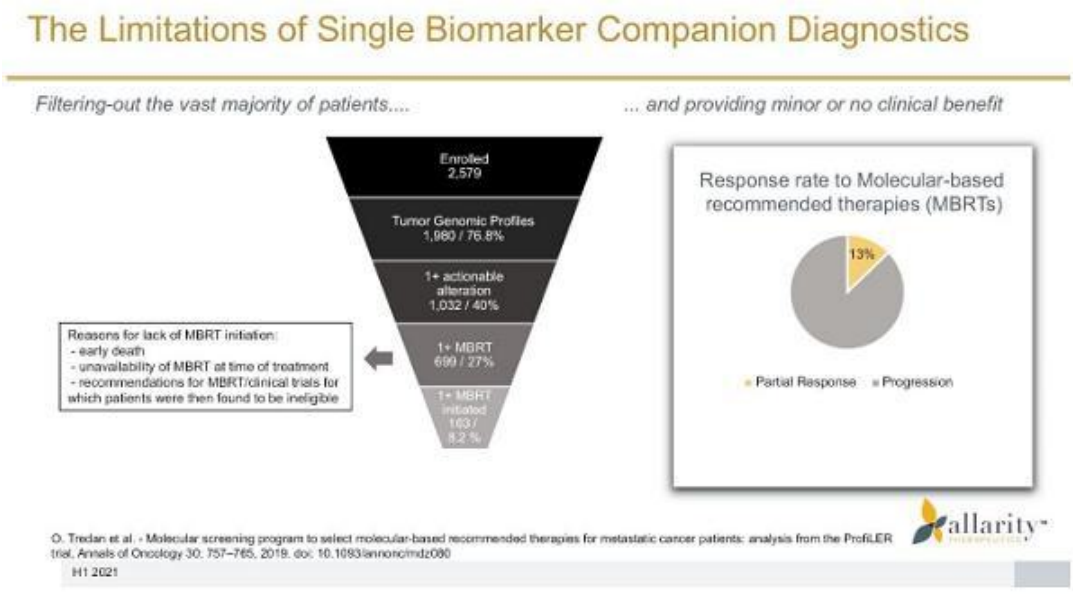
The realization of personalized medicine in cancer care has been hampered, in part, due to the general lack of FDA approved companion diagnostics to select and treat those cancer patients most likely to respond to a given drug (while avoiding treatment of those patients likely to not respond). This lack of suitable companion diagnostics we believe has largely resulted from an outdated and overly simplistic view of cancer, which fails to adequately address the great complexity of individual tumor responsiveness to a given drug or therapeutic candidate, and which relies entirely on what the oncology community knows about cancer biology without regard to the much greater body of what we do not know. Accordingly, historic and competitive companion diagnostic approaches mostly rely on a "knowledge-driven" approach that focus only on single biomarkers — and not on more informative and reliable, complex biomarker signatures — that rarely hold up in the clinic or on the market for use with actual patients.

Examples of competitive approaches and technologies and their shortcomings are:

- ***Gene Mutation Sequencing***. A number of gene mutations have been identified which leads to an alteration in the expressed protein or enzyme, targeted by a drug, which results in the drug no longer binding (or sufficiently binding) to and inhibiting the target. Such mutations are common in kinases, and thus can lead to failure of targeted kinase inhibitors binding to that target. Modern "Next Gen Sequencing" (NGS) of such genetic mutations is one current approach to identify patients who may or may not respond to a given cancer drug. NGS approaches have been commercialized by companies like Foundation Medicine and are also increasingly being used by large cancer centers with their own NGS capabilities. We believe this approach is largely limited by failing to address complex tumor biology and mechanisms of drug response/resistance, much of which is currently unknown, and, accordingly, can only partially identify patient therapeutic response if it is linked to a single gene mutation. This approach is also limited to drugs that target proteins or enzymes that have mutations and is thus not suitable for predicting response to drugs such as chemotherapeutics.

- ***Drug Target Expression Analysis***. This approach uses the level of expression of the actual drug target itself as a biomarker for whether a patient will (or will not) respond to a given drug. A common example is expression of the cell surface receptor tyrosine kinase HER2 used as a companion diagnostic for the HER2-targeting cancer drug Herceptin® for the treatment of breast cancer. We believe this approach is also largely limited by failing to address complex tumor biology and mechanisms of drug response/resistance, much of which is currently unknown. Indeed, many patients who are HER2 positive do not respond well to drugs targeting this receptor and/or patients that initially respond become resistant, indicating other, more complex underlying tumor biology.

- ***"Artificial Intelligence" (AI) or "Machine Learning" (ML) Approaches***. While there are many companies, including in the companion diagnostics space, currently employing technologies that leverage AI or ML, we believe these computer-based technologies are largely limited to the identification and/or design of potential new drug structures. Currently, we are not aware of any retrospectively or clinically validated, published, or approved companion diagnostic created by any AI-based or ML-based approach.



In contrast to other alternative companion diagnostics technologies, we believe our DRP® platform enjoys several, unique competitive advantages:

- ***Broadly Applicable***. We believe our DRP® platform can successfully generate a drug-specific companion diagnostic for most cancer drug types, including:
  - mechanisms-of-action as diverse as DNA damaging agents,
  - chemotherapeutics,
  - targeted kinase inhibitors, and
  - epigenetic enzyme inhibitors.
- ***Retrospectively Validated***. The ability of the DRP® platform to generate reliable and accurate predictive DRP® companion diagnostics has been retrospectively validated in more than 35 clinical trials and 1 prospective clinical trial.
- ***Extensively Published***. Studies of our DRP® platform and putative companion diagnostics have been extensively published in peer-reviewed literature, including publications such as the British Journal of Cancer, Journal of the National Cancer Institute, Plos One, and Breast Cancer Research and Treatment, and have been presented at major oncology conferences, including ASCO, ESMO, and EACR.
- ***Accepted for Use in Clinical Trials by Regulatory Agencies.*** Although none of our putative DRP® companion diagnostics has yet been approved by a regulatory agency for marketing, the U.S. FDA has previously granted 2 IDE applications approving the use of DRP® companion diagnostics for both stenoparib and LiPlaCis® in clinical trials. The Company previously filed a Pre-Market Approval (PMA) application, with the FDA, for the approval and use of the Dovitinib-DRP® companion diagnostic as a marketed companion diagnostic for dovitinib in mRCC. In February 2022 the FDA issued a RTF letter on review of this PMA, largely based on the FDA's issued RTF letter on the related NDA. Separately, the stenoparib, IXEMPRA® and LiPlaCis® DRP® companion diagnostics have been accepted for use in clinical trials by national regulatory agencies in the U.S. and/or Europe.
- ***Trusted by Clinicians***. Prominent oncologists at leading cancer centers where we were conducting our DRP®-guided clinical trials, including Guy's Hospital (London, England), and Rigshospitalet (Copenhagen, Denmark), have used our putative DRP® companion diagnostics to select and treat likely responder patients and improve patient outcomes in a personalized medicine approach in such trials.

Our Priority Therapeutic Programs

Overview of Dovitinib (pan-TKI)

Our most advanced therapeutic candidate, dovitinib (formerly TKI258), is a potent and selective small molecule inhibitor targeting multiple tyrosine kinases. It inhibits fibroblast growth factor receptors (FGFR), along with vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR), among others. During clinical development, with dovitinib's unique pharmacological profile, the focus was originally on FGFR driven diseases, and also on those diseases where the additional anti-angiogenesis properties of dovitinib would offer a therapeutic advantage. As used in this section of this report describing our therapeutic candidate dovitinib, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate dovitinib may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate dovitinib or our putative Dovitinib-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Dovitinib exhibits a dual mechanism of action including anti-tumor effects via its anti-proliferative activity as well as anti-angiogenic activity. Dovitinib is a potent inhibitor of the FGFR1 (inhibitory concentration 50% (IC50) of 8 nM), FGFR2 (IC50 of 40 nM) and FGFR3 (IC50 of 9 nM), as well as of the VEGFR 1, 2, and 3, PDGFRβ, c-Kit, RET, TrkA, CSF 1R, and FLT3 with IC50s of less than 40 nM. Stem cell factor (SCF), also termed KIT ligand or steel factor, has been shown to modulate tumor angiogenesis. In cultured human endothelial cells and c-Kit expressing cancer cells, dovitinib was observed to inhibit VEGF and SCF- stimulated mitogenesis; in a second model of angiogenesis driven by FGF-2, dovitinib was observed to potently inhibit neovascularization of Matrigel® plugs in vivo with an average effective dose (50% inhibition) (ED50) of 3 mg/kg. The effects on endothelial cells suggest that dovitinib may have potent anti-angiogenic activity. FGFR and PDGFR are also believed to play a role in the proliferation of certain tumor cells and supporting stromal cells. As a result of inhibition of target receptor tyrosine kinases (RTKs) by dovitinib, other ligand- stimulated cellular functions are blocked, including activation of downstream signaling molecules, cellular proliferation, and survival. Anti-tumor effects for this agent may therefore be secondary to anti-angiogenesis, anti-proliferative activity against tumor cells, and anti- stromal activity.

Receptor tyrosine kinases (RTKs) such as VEGFR1,2,3, FGFR1,2,3, and PDGFRβ have been shown to play an important role in tumor angiogenesis (Dvorak 2003). VEGF is produced by both the host and the cancer cells and VEGF has a direct effect on endothelial cells, causing their proliferation, migration, invasion, and growth (Nagy et al 2002). Sunitinib and sorafenib, both multi-tyrosine kinase inhibitors that target the VEGF pathways, have become the standard of care for patients with advanced kidney cancer. Subsequently, other anti-angiogenic agents including, bevacizumab in combination with interferon alpha, pazopanib, axitinib and cabozantinib have also been approved by the FDA for advanced RCC.

The mTOR pathway has been shown to play an important role in angiogenesis through regulation of the synthesis of HIF and proteins that control cell proliferation, such as c-myc and cyclin D1. (Jiang BH, Liu LZ. Role of mTOR in anticancer drug resistance: perspectives for improved drug treatment. Drug Resist Update 2008;11(3):63-76. doi:10.1016/j.drup.2008.03.001). Based on favorable risk benefit ratio FDA has approved mTOR inhibitors such as temsirolimus and everolimus for advanced RCC that have demonstrated anti-angiogenesis and anti-tumor activities via action on HIF and stopping the production of cell-cycle regulators. All of these targeted therapies have been established as the preferred first or second line of therapies in patients with advanced RCC, with a median overall survival of up to 26 months, although sorafenib, the original prototype receptor tyrosine kinase inhibitor (RTKi) has been relegated to the 3rd line setting following failure of targeting of the VEGF and mTOR pathways.

Dovitinib was previously developed by Novartis, through a Phase 3 trial, where it showed therapeutic equivalence (with similar adverse events profile) to Bayer's Sorafenib for the treatment of third line RCC, but failed its primary anti-cancer activity endpoint of superiority (to sorafenib) progression-free survival (PFS). Dovitinib also previously showed promising Phase 2 results in Novartis sponsored studies for the treatment of gastrointestinal stromal tumors (GIST), endometrial cancer, breast cancer, and liver cancer.

Pre-Clinical Studies

Dovitinib has demonstrated activity in a number of in vitro and in vivo models. It potently inhibits the activity of multiple receptor tyrosine kinases (RTKs) including PDGFRβ, CSF 1R, KIT, FLT3, VEGFRs 1-3, TrkA, RET, and FGFR (IC50 = 1-40 nM). Inhibition of these RTKs impedes tumor growth and progression through different mechanisms, including both direct anti- tumor effects and effects on host tissues, such as endothelial cells and supporting stromal cells, that are essential for tumor cell proliferation and metastasis.

The in vivo effects of dovitinib were shown to be a result of its direct anti-tumor effect and also its anti-angiogenic effect. Direct inhibition of RTK activation on tumor cells (PDGFRβ, FLT3, and FGFR3) was confirmed by a reduction in phosphorylation of these target RTKs, as well as signaling pathway components (ERK, STAT5, and AKT) in tumor xenografts. Target inhibition was observed for as long as 24 h after a single high dose of dovitinib. A decrease in tumor cell proliferation and induction of apoptosis, in combination with the anti-angiogenic effect of dovitinib, resulted in significant anti-tumor activity. The target RTK profile of dovitinib predicts for activity in many different types of solid and hematologic tumor models by acting on both endothelial cells and tumor cells. In the human tumor xenograft models tested, including colon, prostate, myeloma, AML, breast, and ovarian, dovitinib had anti-tumor effects on both small and large established tumor xenografts.

Studies in the RIP-Tag based experimental tumor model have shown that tumor angiogenesis can switch from VEGFR dependence to FGFR dependence under anti-VEGF therapy. This escape mechanism could explain treatment failure with agents targeting single angiogenic targets. Dovitinib combines potent anti-VEGFR2 and FGFR1-3 activity suggesting the possibility of enhanced response or duration of response in renal tumors compared to agents targeting VEGF only.

Dovitinib was evaluated in the mouse renal cell carcinoma Renca model. Renca cells (1 x 106 cells/mouse) were implanted s.c. into the right flank of Balb/c mice and treatment was started when the average tumor volume was ~70 mm3. Dovitinib was also evaluated in two models for human clear cell RCC: Caki-1, with VHLWT and 786-O with a deletion in the VHL gene and compared to sunitinib and sorafenib. In both human RCC models, dovitinib was at least as effective as the two clinically approved inhibitors at their MTDs.

Prior Clinical Trials

Dovitinib has been studied in 56 prior clinical trials, of which 23 were sponsored by Novartis, and 33 were investigator initiated. The sponsor initiated trials are summarized in the following table:

Study No. with CTKI258 as prefix	Indication/Design/ Country	Study drug dose/ schedule	N (total)	Comments	General Results
A1101	Advanced solid tumors P1 Dose escalation Japan	100 – 500 mg qd 5 days on/2 days off	28	6 patients treated at 500 mg in SCS	MTD determined to be the 500 mg dovitinib on an oral once daily, 5 days on, 2 days off schedule
A1201	Advanced scirrhous gastric carcinoma P2, single arm, multicenter Japan	500 mg qd 5 days on/2 days off	11	Evaluate the efficacy and safety Early termination. Acceptable safety profile	Primary endpoint DCR at 8 weeks: 0%
A2101	Advanced solid tumors P1 Dose escalation, multicenter UK	25 – 100 mg qd 7 days on/7 days off and 100 – 175 qd 7 days on/7 days off then 28 day cycles continuous qd dosing	35	Dose and schedule not similar to pivotal study	MTD defined at 125 mg daily, orally
A2102	Acute myloid leukemia P1/2 Dose escalation, multicenter UK & US	50 – 600 mg qd 7 days on/7 days off then 28 day cycles continuous qd dosing	32	Dose and schedule not similar to pivotal study	2 DLT in 600 mg group
A2103	Multiple Myeloma P1/2 Dose escalation, multicenter US	50 – 500 mg qd x 14 days then 7 day rest followed by continuous qd dosing	21	MM pts had neutropenic DLTs not seen in solid tumor pts	Report combined with A2104
A2104	Multiple Myeloma P1/2 Dose escalation, multicenter UK	50 mg BID, 100 mg BID, and 325 mg qd continuous dosing on 28 day cycles	7	Hematological tumor toxicities differ from solid tumors	A2103 and A2104 were discontinued due to time and dose dependent accumulation at daily doses above 500 mg
A2105	Melanoma P1/2 Dose escalation, multicenter US	200 – 500 mg qd continuous dosing	47		MTD reached at 400 mg daily Study discontinued due to no clinical benefit
A2106	Solid tumor P1, single center, ADME Netherlands	500 mg radiolabeled dose day 1 followed by 400 mg qd continuous dosing	13	ADME	Terminal half life about 32 hours. Elimination via oxidative metabolism
A2107	Metastatic RCC P1/2, Dose escalation and expansion, multicenter US, EU, Taiwan	500 – 600 mg qd 5 days on/2 days off	87 5 pts at 600 mg and 82 pts at 500 mg	Supportive P1/2 in SCS and SCE + renal impairment (TKI258 renal impairment report – Nov 19, 2013)	MTD was 500 mg 5 days on/2 days off Disease Control (CR, PR, SD) 73.3% in the dovitinib 500 mg group per central reading
A2112	Solid tumors P1, multicenter, crossover US	Arm 1 – Cycle 1: 500 mg single dose crossover Cycle 2+: CSF capsule 500 mg 5 on/2 off Arm 2 – Cycle 1: 300 mg daily, crossover for test meals Cycle 2+: FMI capsule 500 mg 5 on/2 off	60	Bioavailability Food Effect Capsules	Food had no effect on the systemic exposure of dovitinib (FMI capsules)
A2116	Solid tumors P1, multicenter, crossover US	Arm 1 – Cycle 1: 500 mg single dose crossover Cycle 2+: CSF capsule 500 mg 5 on/2 off Arm 2 – Cycle 1: 300 mg daily, crossover for test meals Cycle 2+: FMI tablet 500 mg 5 on/2 off	63	Bioavailability Food Effect Tablets	Food had no effect on the systemic exposure of dovitinib (FMI tablets)

Study No. with CTKI258 as prefix	Indication/Design/ Country	Study drug dose/ schedule	N (total)	Comments	General Results
A2119	Solid tumors P1, multicenter, drug-drug interaction (DDI) US	Cycle 1 DDI between dovitinib and the substrates of CYP1A2, CYP2C19, CYP2C9, and CYP3A4	39	DDI study	Dovitinib is a strong inducer of CYP1A2 and a moderate inhibitor f CYP2C19 and CYP3A4/5
A2120	Solid tumors, excluding breast cancer P1, multicenter, drug-drug interaction (DDI) US, EU	Cycle 1 DDI between dovitinib and the inhibitor of CYP1A2	45	DDI study	Fluvoxamine, a CYP1A2 inhibitor showed weak to moderate inhibition of dovitinib metabolism
A2124	Mild, moderate and severe hepatic impairment cohorts in Patients w/ Solid Tumors P1, multicenter, hepatic impairment US, EU	Single dose PK followed by multiple dose PK 400 mg or 500 mg	38 Normal 7 Mild 400 mg: 12 Mild 500 mg: 10 Moderate 400 mg: 9	Closure of the study before the tolerated dose was identified in any of the hepatic impaired group. In SCS	Dovitinib label: Excluding patients with moderate and severe hepatic impairment from treatment with dovitinib
A2128	Solid tumors P1, multicenter, crossover US	500 mg 5 on/2 off crossover in PK phase	175	Bioequivalence Capsules FMI vs. Tablets FMI	Bioequivalence established between capsules and tablets
A2201	Urothelial Cancer NA, EU Taiwan	500 mg qd 5 days on/2 days off	44	In SCS	ORR in FGR3 wildtype: 3.2% FGFR3 mutated: 0%
A2202	Metastatic Breast Cancer P2, multicenter NA, EU, Taiwan	500 mg qd 5 days on/2 days off	81	In SCS	No CR or PR SD: FGFR1+/HR+ 65.2% FGFR1-/HR+ 39.1%
A2204	Multiple myeloma P2, multicenter NA, EU, Australia, Turkey	500 mg qd 5 days on/2 days off	43	Hematological tumor toxicities differ from solid tumors	ORR 0% Terminated after stage 1 according to protocol
A2208	Hepatocellular carcinoma 1st line P2, multicenter Asia	500 mg qd X 5 days on/2 days off with Pop PK Vs Sorafenib 400 mg bid	165 (dovitinib 82, sorafenib 83)	Phase 2 randomized in SCS	HR 1.27
A2210	Metastatic breast cancer, HER2-, HR+ P2, randomized, double blind, placebo controlled Global	Fulvestrant + dovitinib 500 mg qd 5 days on/2 days off vs. Fulvestrant + Placebo	47 (fulvestrant+ dovitinib) 49 (fulvestrant+ placebo)	In SCS	PFS HR 0.681 (95% CI: 0.406, 1,143)
A2211	Endometrial cancer with or without FGFR2 mutation P2, multicenter, single arm Global	500 mg qd 5 days on/2 days off	53	In SCS	PFS at 28 weeks 31.8% in FGFR2 mutated 29.0% in FGFR2 wild type
A2302	Advanced RCC after failure of at least 1 VEGF and 1 mTOR targeted therapy	500 mg qd X 5 days on/2 days off with Pop PK Vs Sorafenib 400 mg bid	570 (dovitinib 284, sorafenib 286)	Phase 3, pivotal in SCS & SCE	
AIC02	GIST Progressed on imatinib EU	500 mg qd X 5 days on/2 days	38	Phase 2 Investigator initiated In SCS	DCR at 12 weeks 52.6%
KR01T	GIST Progressed on imatinib and sunitinib South Korea	500 mg qd X 5 days on/2 days	30	Phase 2 Investigator initiated No CSR only a publication Kang et. al., British Journal of Cancer (2013) 109, 2309 – 2315	DCR at 24 weeks 13%

We believe the clinical data in these trials justify further clinical trials for dovitinib in GIST, endometrial cancer, ovarian cancer, breast cancer, RCC, and hepatocellular carcinoma (HCC or liver cancer).

The studies in clear cell renal carcinoma, A2302 and A2107, were the pivotal and the supporting study, respectively, in the dovitinib NDA, as well as PD02-044, the Dovitinib-DRP® validation study. The indication for the NDA was treatment of patients with advanced RCC following two or more prior systemic therapies and who are selected for therapy with the Dovitinib-DRP® companion diagnostic. As discussed above, based upon the reasons given in the RTF letters and a subsequent Type C meeting with the FDA on May 31, 2022, we anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dose optimization studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP for the treatment of third-line mRCC can be obtained.

A2107 is a Phase I/II study on a 5-day on/2-day off treatment schedule in heavily pre-treated advanced RCC patients that are refractory to standard therapies. In the 20 patients treated in phase I with 500 mg (N = 15) or 600 mg (N = 5) dovitinib, the MTD was defined as 500 mg. Dovitinib was observed to be well tolerated and anti-tumor activity was observed after progression on both VEGF and mTOR inhibitors. In the Phase II portion of the study, 67 heavily pre-treated patients were enrolled and received 500 mg dovitinib on a 5 days on/2 days off schedule, and had measurable, histologically or cytologically confirmed progressive advanced or metastatic RCC with predominant clear cell histology. Thirty-five patients were previously treated with at least 2 prior VEGF inhibitors (most often sunitinib and sorafenib) and one mTOR inhibitor (most often everolimus), and 55 patients received at least one VEGF and one mTOR inhibitor. ORR of 3% (90% CI 0.5-9.1), Disease Control Rate (DCR; CR, PR, and SD) of 55.2% and a median progression free survival of 3.7 (95% CI 3.0- 5.6) months according to both independent central review and local review.

A further Phase III registration trial CTKI258A2302 (study A2302), also referred to as the GOLD trial, was conducted in RCC. The pivotal Phase III trial was an open-label, randomized, multi-center study to compare the toleration and anti-cancer activity of dovitinib versus sorafenib in patients (N = 570) with metastatic RCC after failure of anti-angiogenic (VEGF- targeted and mTOR inhibitor) therapies. Supportive data from a Phase I/II dose escalation maximum tolerated dose (MTD) and dose expansion study CTKI258A2107 (study 2107) in patients with advanced or metastatic RCC (N = 82 at 500 mg) was included in our NDA.

Initially, dovitinib was investigated with a continuous daily dosing schedule. However, preliminary PK data suggested that over-proportional drug accumulation might occur with daily administration. Therefore, a 5 days on/2 days off dosing schedule was proposed for study A2107. At the tested dose levels of 500 mg and 600 mg, no over-proportional drug- accumulation was observed on Day 15 (steady state) with the 5 days on/2 days off regimen. Two patients presented with dose-limiting toxicities at 600 mg, and the MTD was established at 500 mg. Accordingly, Novartis selected the 500 mg 5 days on/2 days off regimen for the Phase III registration trial in the advanced RCC indication (study A2302).

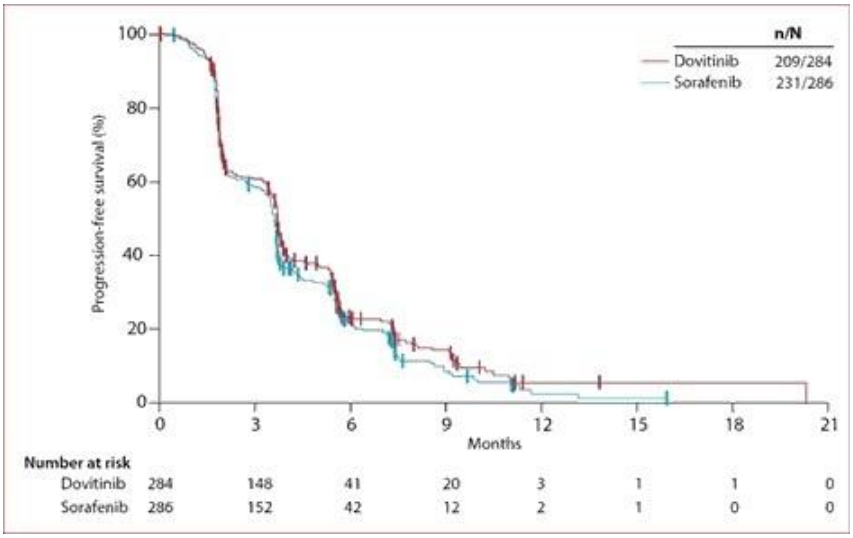
Based on the observed anti-tumor effect of dovitinib against advanced RCC in trial A2107 Novartis proceeded to a Phase III registration trial designed to show superiority over sorafenib. A2302 is the Phase III registration trial, also referred to as the GOLD trial. This pivotal Phase III trial was an open-label, randomized, multi-center study to compare the tolerability and anti-cancer activity of dovitinib versus sorafenib in patients (N = 570) with metastatic RCC after failure of anti-angiogenic (one VEGF- targeted and one mTOR inhibitor) and other therapies. The randomization was a 1:1 ratio to dovitinib 500 mg/day 5 days on/2 days off vs. sorafenib 400 mg BID. The trial failed its primary anti-cancer activity endpoint of superiority (to sorafenib) progression-free survival (PFS) as determined by central radiology assessment (the median PFS was 3.7 months and 3.6 months in the dovitinib and sorafenib arms, respectively and the HR 0.86 (95% CI: 0.72, 1.04)). The median overall survival was 11.9 months for the dovitinib arm and 11.2 months for the sorafenib arm, respectively (HR: 0.95; 95% CI: 0.78, 1.15). The study was published in *Lancet Oncology* in 2014 where it was concluded that "Dovitinib showed activity, but this was no better than that of sorafenib in patients with renal cell carcinoma who had progressed on previous VEGF-targeted therapies and mTOR inhibitors."

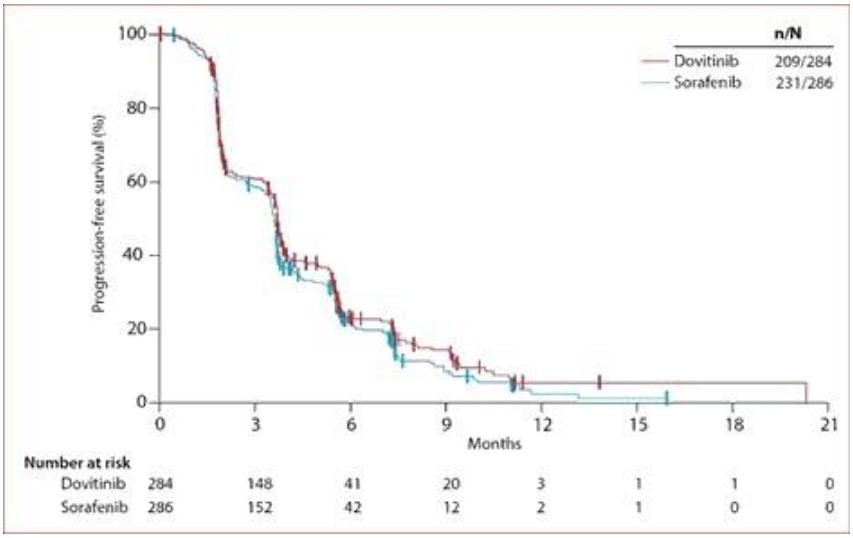
The A2302 trial had been designed to show superiority of dovitinib to sorafenib, and the superiority observed in terms of PFS and OS was not statistically significant. Subsequently, Novartis did not pursue further development. However, we believe the trial established that dovitinib is non-inferior to sorafenib with respect to PFS and OS. Non-inferior is the statistical term describing a drug that is a drug that shows equivalent therapeutic benefit to its comparator drug. However, in evaluating our NDA, the FDA determined that our application using a retrospective analysis to show dovitinib is non-inferior to sorafenib cannot be based on a Phase 3 clinical trial by Novartis designed to show that dovitinib is superior to sorafenib that failed its designed endpoints.

The two key requirements for the non-inferiority approach are (i) the presence of assay sensitivity of the pivotal study, a finding that is readily demonstrable for the A2302 study, and (ii) the choice of non-inferiority margin, based upon a combination of statistical reasoning and clinical judgement by RCC-subspecialized practitioners offering their clinical perspective on the retention of efficacy needed for the intervention to be considered "efficacious" in that particular malignancy and specific disease setting. The non-inferiority margin for the hazard ratio, i.e., 1.153, was determined using studies that are all phase 3, randomized controlled trials (RCTs) where sorafenib was administered as second-line, third-line, or fourth-line treatment. As mentioned above, in the A2302 study, the point estimate of the hazard ratio on PFS was 0.86, and its two-sided 95% confidence interval was (0.72, 1.04). Since the upper bound margin of 95% CI in the unstratified analysis of PFS was 1.04, we believe the non-inferiority of dovitinib to sorafenib is demonstrated because the upper limit (1.04) was less than the estimated margin of 1.153. Subgroup and sensitivity analyses of PFS were consistent with the primary analysis demonstrating the efficacy of dovitinib in this patient population. Patients with KPS ≥ 90 had a higher median PFS in the dovitinib group (median 18.4 months, 95% CI: 12.9, Not evaluable) than the sorafenib group (median 13.9, 95% CI:10.7, 15.5).

The post hoc non-inferiority analysis on the OS was performed using a hazard ratio (HR on OS; dovitinib/sorafenib as secondary endpoint) with a margin of 1.153 with the same hypothesis used for PFS. The OS between the dovitinib and sorafenib treatment groups, had a Hazard ratio of 0.94 with 95% CI: 0.779, 1.146%. Since the upper bound of the two-sided 95% confidence interval for the hazard ratio is <1.153, we believed that the results showed that dovitinib is non-inferior to sorafenib.

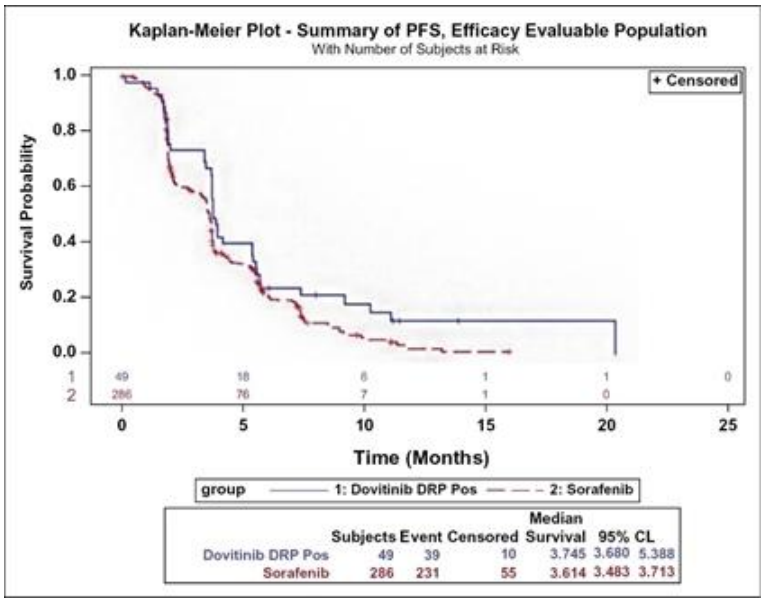
The figures below show the progression-free and overall survival from the A2302 Phase 3 trial):





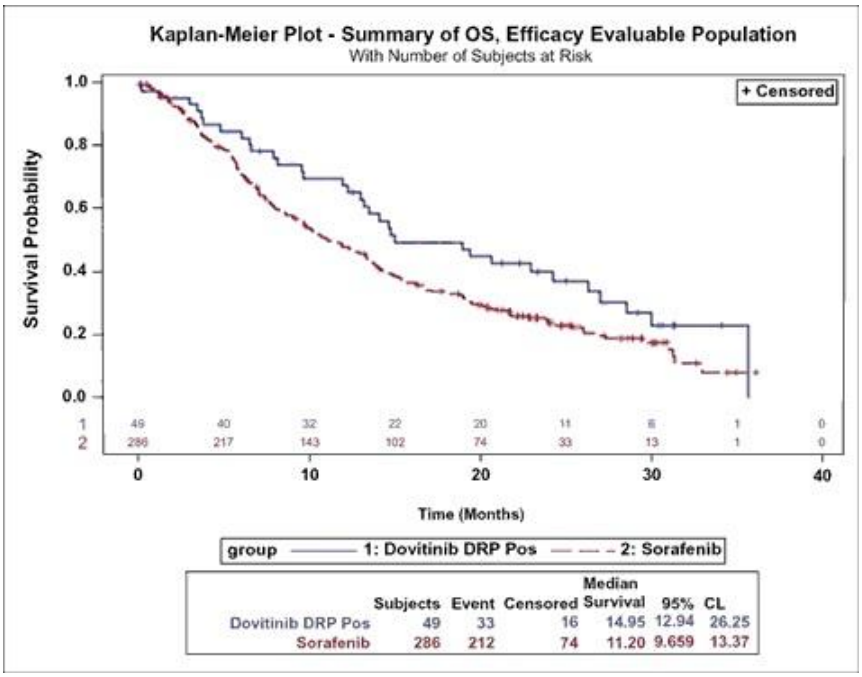
The PD02-044 study intended to identify patients who were more likely to benefit from treatment with dovitinib in the A2302 study and thus validating the Dovitinib-DRP®. 135 dovitinib-treated patients' renal biopsy tissue comprised the investigational arm of the "Dovitinib DRP Study". Of these 135 patients, 49 patients had a Dovitinib-DRP® score of> 50%. The key clinical outcomes of PFS, OS, and ORR were compared between the 49 patients with a tumor DRP® score >50% and the sorafenib-treated control arm comprised of 286 patients. The protocol for the "Dovitinib DRP Clinical Performance Evaluation Study" was submitted with the PMA submission. The outcome on the efficacy outcome measure, PFS, revealed a 3.75-month median PFS for DRP®-selected dovitinib-treated patients versus 3.6-month median PFS for sorafenib-treated patients, yielding an *unadjusted* HR of 0.714 (95% CI 0.5051, 1.0103; p = 0.0572). We believe these results show a marginal and non-significant improvement in median PFS for DRP®-selected dovitinib-treated patients. (Please refer to Figure 1 below.)

Figure 1: Kaplan Meier Plot — Summary of PFS, Efficacy Evaluable Population



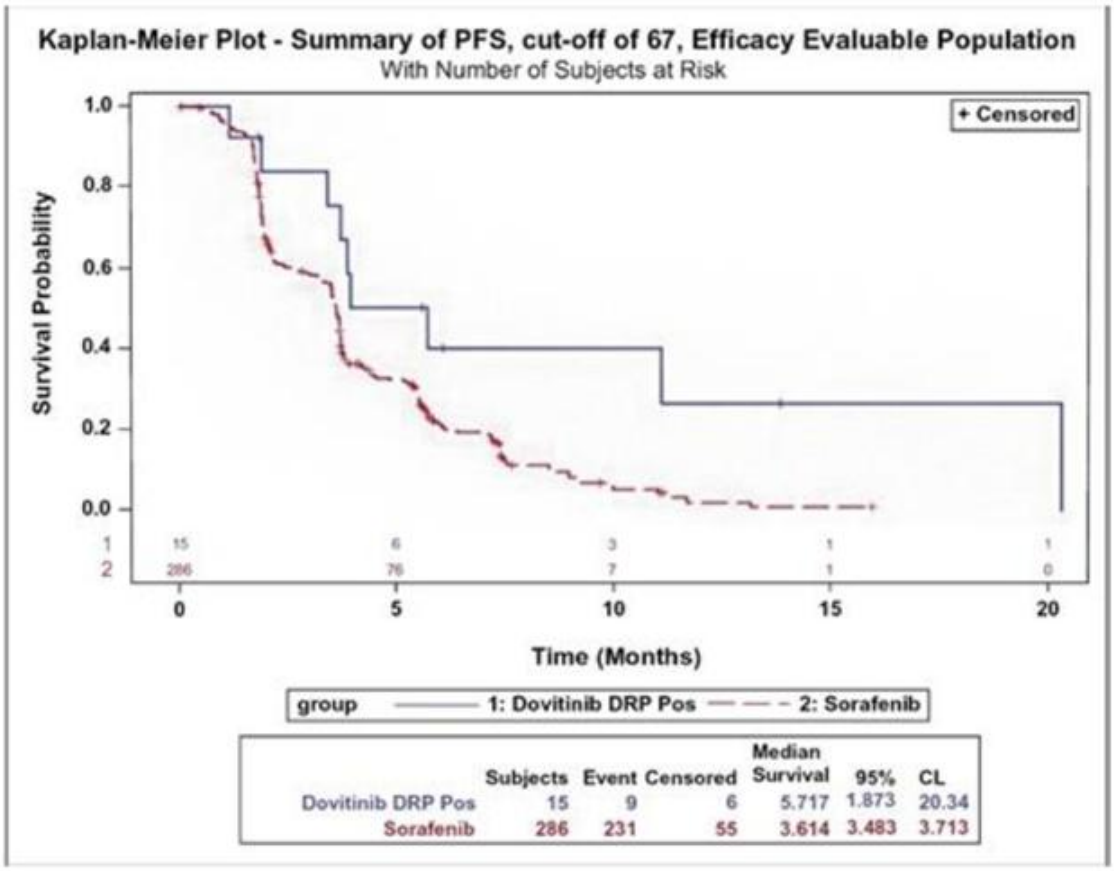
The results of the "Dovitinib DRP Study" on the other efficacy outcome measure OS, revealed a favorable outcome. It showed a 14.95-month median OS for DRP-selected dovitinib-treated patients versus an 11.20-month median OS for sorafenib-treated patients. Comparison of these medians yields an *unadjusted* HR of 0.685 (95% CI 0.4736, 0.9897; p = 0.0439) where the upper bound of the 95% CI does not cross unity, thereby revealing a statistically significant improvement in median OS for DRP-selected dovitinib-treated patients. (Please refer to Figure 2 below).

Figure 2: Kaplan Meier Plot — Summary of OS, Efficacy Evaluable Population



In an exploratory analysis of the effect of increasing DRP® score thresholds on clinical outcomes, it was shown that as the DRP® threshold increased, so did the clinical outcomes on PFS and OS. Specifically, when the DRP® score threshold increased from 50 to 67, the outcome on the primary efficacy endpoint, PFS, further improved to a 5.7-month median PFS for DRP®-selected dovitinib-treated patients versus 3.6-month median PFS for sorafenib-treated patients. Comparison of the median PFS values (resulting from this increase in the DRP threshold score) yields an *unadjusted* HR of 0.420 (95% CI 0.2054, 0.8585; p = 0.0174) and shows a statistically significant improvement in median PFS for DRP®-selected dovitinib-treated patients when the DRP® score threshold is increased. (Please refer to Figure 3 below). However, in evaluating our NDA, the FDA determined that our application using a retrospective analysis to show dovitinib is non-inferior to sorafenib cannot be based on a Phase 3 clinical trial by Novartis designed to show that dovitinib is superior to sorafenib that failed its designed endpoints.

Figure 3: Kaplan Meier Plot — Summary of PFS, Cut-Off of 67%, Efficacy Evaluable Population



The following tables summarize the adverse events observed in the prior Phase 3 trial in RCC:

Most frequently occurring AEs by MedDRA System Organ Class and Preferred Term:

ISS 6.2B TEAEs by MedDRA SOC and PT — Pooled RCC Studies, Safety Population (>5%)

System Organ Class[(1)] Preferred Term[(1)]	Dovitinib (500 mg/day) N=362 n (%)	Sorafenib N=284 n (%)	Total N=646 n (%)
Subjects With ≥ 1 TEAE	**357 (98.6)**	**276 (97.2)**	**633 (98.0)**
Total Number Of TEAEs	**6195**	**3770**	**9965**
Blood And Lymphatic System Disorders	**74 (20.4)**	**39 (13.7)**	**113 (17.5)**
Anaemia	49 (13.5)	31 (10.9)	80 (12.4)
Gastrointestinal Disorders	**325 (89.8)**	**233 (82.0)**	**558 (86.4)**
Abdominal Pain	51 (14.1)	42 (14.8)	93 (14.4)
Abdominal Pain	41 (11.3)	24 (8.5)	65 (10.1)
Upper			
Constipation	72 (19.9)	73 (25.7)	145 (22.4)
Diarrhoea	247 (68.2)	134 (47.2)	381 (59.0)
Dry Mouth	27 (7.5)	13 (4.6)	40 (6.2)
Dyspepsia	40 (11.0)	14 (4.9)	54 (8.4)
Nausea	204 (56.4)	84 (29.6)	288 (44.6)
Stomatitis	51 (14.1)	57 (20.1)	108 (16.7)

Vomiting	177 (48.9)	49 (17.3)	226 (35.0)

ISS 6.2B TEAEs by MedDRA SOC and PT — Pooled RCC Studies, Safety Population (>5%)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=362 n (%)	Sorafenib N=284 n (%)	Total N=646 n (%)
General Disorders And Administration Site Conditions	**285 (78.7)**	**187 (65.8)**	**472 (73.1)**
Asthenia	92 (25.4)	48 (16.9)	140 (21.7)
Fatigue	141 (39.0)	99 (34.9)	240 (37.2)
General Physical Health Deterioration	28 (7.7)	20 (7.0)	48 (7.4)
Non-Cardiac Chest Pain	39 (10.8)	21 (7.4)	60 (9.3)
Oedema Peripheral	44 (12.2)	20 (7.0)	64 (9.9)
Pain	16 (4.4)	16 (5.6)	32 (5.0)
Pyrexia	63 (17.4)	44 (15.5)	107 (16.6)
Investigations	**165 (45.6)**	**129 (45.4)**	**294 (45.5)**
Blood Alkaline Phosphatase Increased	30 (8.3)	5 (1.8)	35 (5.4)
Gamma-Glutamyltransferase Increased	35 (9.7)	8 (2.8)	43 (6.7)
Weight Decreased	81 (22.4)	90 (31.7)	171 (26.5)
Metabolism And Nutrition Disorders	**217 (59.9)**	**132 (46.5)**	**349 (54.0)**
Decreased Appetite	133 (36.7)	101 (35.6)	234 (36.2)
Hyperkalaemia	20 (5.5)	12 (4.2)	32 (5.0)
Hypertriglyceridaemia	71 (19.6)	2 (0.7)	73 (11.3)
Musculoskeletal and Connective Tissue Disorders	**203 (56.1)**	**138 (48.6)**	**341 (52.8)**
Arthralgia	41 (11.3)	30 (10.6)	71 (11.0)
Back Pain	53 (14.6)	36 (12.7)	89 (13.8)
Bone Pain	18 (5.0)	14 (4.9)	32 (5.0)
Muscle Spasms	25 (6.9)	25 (8.8)	50 (7.7)
Musculoskeletal Chest Pain	21 (5.8)	14 (4.9)	35 (5.4)
Musculoskeletal Pain	21 (5.8)	11 (3.9)	32 (5.0)
Myalgia	42 (11.6)	17 (6.0)	59 (9.1)
Pain In Extremity	52 (14.4)	33 (11.6)	85 (13.2)
Nervous System Disorders	**163 (45.0)**	**84 (29.6)**	**247 (38.2)**
Dizziness	37 (10.2)	8 (2.8)	45 (7.0)
Dysgeusia	48 (13.3)	9 (3.2)	57 (8.8)
Headache	45 (12.4)	25 (8.8)	70 (10.8)
Psychiatric Disorders	**64 (17.7)**	**47 (16.5)**	**111 (17.2)**
Anxiety	19 (5.2)	13 (4.6)	32 (5.0)
Insomnia	23 (6.4)	21 (7.4)	44 (6.8)
Respiratory, Thoracic and Mediastinal Disorders	**187 (51.7)**	**133 (46.8)**	**320 (49.5)**
Cough	74 (20.4)	52 (18.3)	126 (19.5)
Dysphonia	26 (7.2)	26 (9.2)	52 (8.0)
Dyspnoea	91 (25.1)	58 (20.4)	149 (23.1)
Pleural Effusion	19 (5.2)	13 (4.6)	32 (5.0)
Skin And Subcutaneous Tissue Disorders	**188 (51.9)**	**198 (69.7)**	**386 (59.8)**
Alopecia	5 (1.4)	61 (21.5)	66 (10.2)
Dry Skin	35 (9.7)	26 (9.2)	61 (9.4)
Palmar-Plantar Erythrodysaesthesia Syndrome	39 (10.8)	118 (41.5)	157 (24.3)
Pruritus	19 (5.2)	30 (10.6)	49 (7.6)
Rash	72 (19.9)	48 (16.9)	120 (18.6)
Vascular Disorders	**118 (32.6)**	**95 (33.5)**	**213 (33.0)**
Hypertension	76 (21.0)	79 (27.8)	155 (24.0)

(1) MedDRA Version 16.0.

Note: All percentages are based on the number of subjects in the population and treatment group (N).

ISS 6.2B2 TEAEs by MedDRA SOC and PT — Pooled 500 mg Dosing Regimen Studies, Safety Population (>5%)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=664 n (%)
Subjects With ≥ 1 TEAE	**657 (98.9)**
Total Number Of TEAEs	**12443**
Blood And Lymphatic System Disorders	**156 (23.5)**
Anaemia	96 (14.5)
Neutropenia	37 (5.6)
Thrombocytopenia	47 (7.1)
Eye Disorders	**135 (20.3)**
Lacrimation Increased	35 (5.3)
Gastrointestinal Disorders	**600 (90.4)**
Abdominal Pain	112 (16.9)
Abdominal Pain Upper	84 (12.7)
Constipation	132 (19.9)
Diarrhoea	462 (69.6)
Dry Mouth	68 (10.2)
Dyspepsia	74 (11.1)
Nausea	379 (57.1)
Stomatitis	80 (12.0)
Vomiting	353 (53.2)
General Disorders And Administration Site Conditions	**527 (79.4)**
Asthenia	194 (29.2)
Fatigue	250 (37.7)
General Physical Health Deterioration	33 (5.0)
Non-Cardiac Chest Pain	46 (6.9)
Oedema Peripheral	90 (13.6)
Pyrexia	119 (17.9)
Infections And Infestations	**224 (33.7)**
Urinary Tract Infection	51 (7.7)
Investigations	**331 (49.8)**
Alanine Aminotransferase Increased	77 (11.6)
Aspartate Aminotransferase Increased	73 (11.0)
Blood Alkaline Phosphatase Increased	87 (13.1)
Blood Bilirubin Increased	34 (5.1)
Gamma-Glutamyltransferase Increased	73 (11.0)
Weight Decreased	145 (21.8)
Metabolism And Nutrition Disorders	**401 (60.4)**
Decreased Appetite	255 (38.4)
Dehydration	40 (6.0)
Hypertriglyceridaemia	109 (16.4)
Hypoalbuminaemia	43 (6.5)
Musculoskeletal And Connective Tissue Disorders	**323 (48.6)**
Arthralgia	57 (8.6)
Back Pain	90 (13.6)
Muscle Spasms	37 (5.6)
Musculoskeletal Pain	34 (5.1)
Myalgia	67 (10.1)
Pain In Extremity	89 (13.4)

ISS 6.2B2 TEAEs by MedDRA SOC and PT — Pooled 500 mg Dosing Regimen Studies, Safety Population (>5%)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=664 n (%)
Nervous System Disorders	**314 (47.3)**
Dizziness	70 (10.5)
Dysgeusia	83 (12.5)
Headache	110 (16.6)
Psychiatric Disorders	**134 (20.2)**
Insomnia	61 (9.2)
Respiratory, Thoracic And Mediastinal Disorders	**321 (48.3)**
Cough	117 (17.6)
Dysphonia	40 (6.0)
Dyspnoea	145 (21.8)
Skin And Subcutaneous Tissue Disorders	**353 (53.2)**
Dermatitis Acneiform	40 (6.0)
Dry Skin	63 (9.5)
Palmar-Plantar Erythrodysaesthesia Syndrome	56 (8.4)
Pruritus	43 (6.5)
Rash	152 (22.9)
Vascular Disorders	**207 (31.2)**
Hypertension	135 (20.3)
Hypotension	35 (5.3)

(1) MedDRA Version 16.0.

Note: All percentages are based on the number of subjects in the population and treatment group (N).

Table: Adverse Events with Incidence ≥ 3.5% (Grade 3/4), Regardless of Study Drug Relationship, By Preferred Term, Maximum Grade and Treatment (Safety Set)

	Dovitinib N=280		Sorafenib N=284	
Preferred Term	All Grade n (%)	Grade 3/4 n (%)	All Grades n (%)	Grade 3/4 n (%)
Total	275 (98.2)	215 (76.8)	276 (97.2)	199 (70.1)
Diarrhoea	190 (67.9)	20 (7.1)	134 (47.2)	13 (4.6)
Nausea	147 (52.5)	9 (3.2)	84 (29.6)	7 (2.5)
Vomiting	125 (44.6)	10 (3.6)	49 (17.3)	3 (1.1)
Fatigue	115 (41.1)	29 (10.4)	99 (34.9)	24 (8.5)
Decreased Appetite	93 (33.2)	5 (1.8)	101 (35.6)	14 (4.9)
Asthenia	65 (23.2)	14 (5.0)	48 (16.9)	11 (3.9)
Dyspnoea	64 (22.9)	16 (5.7)	58 (20.4)	22 (7.7)
Weight Decreased	63 (22.5)	4 (1.4)	90 (31.7)	1 (0.4)
Hypertension	55 (19.6)	22 (7.9)	79 (27.8)	45 (15.8)
Hypertriglyceridaemia	55 (19.6)	38 (13.6)	2 (0.7)	1 (0.4)
Rash	54 (19.3)	3 (1.1)	48 (16.9)	6 (2.1)
Cough	52 (18.6)	4 (1.4)	52 (18.3)	3 (1.1)
Constipation	51 (18.2)	0	73 (25.7)	3 (1.1)
Pyrexia	46 (16.4)	2 (0.7)	44 (15.5)	3 (1.1)
Back Pain	42 (15.0)	7 (2.5)	36 (12.7)	8 (2.8)
Abdominal Pain	38 (13.6)	10 (3.6)	42 (14.8)	4 (1.4)
Pain In Extremity	36 (12.9)	6 (2.1)	33 (11.6)	4 (1.4)
Anaemia	34 (12.1)	17 (6.1)	31 (10.9)	19 (6.7)

Table: Adverse Events with Incidence ≥ 3.5% (Grade 3/4), Regardless of Study Drug Relationship, By Preferred Term, Maximum Grade and Treatment (Safety Set)

	Dovitinib N=280		Sorafenib N=284	
Preferred Term	**All Grade n (%)**	**Grade 3/4 n (%)**	**All Grades n (%)**	**Grade 3/4 n (%)**
Dyspepsia	33 (11.8)	0	14 (4.9)	1 (0.4)
Palmar-Plantar Erythrodysaesthesia Syndrome	32 (11.4)	3 (1.1)	118 (41.5)	18 (6.3)
Stomatitis	30 (10.7)	1 (0.4)	57 (20.1)	6 (2.1)
Abdominal Pain Upper	30 (10.7)	3 (1.1)	24 (8.5)	3 (1.1)
Arthralgia	28 (10.0)	6 (2.1)	30 (10.6)	6 (2.1)
Myalgia	28 (10.0)	3 (1.1)	17 (6.0)	0
Dizziness	28 (10.0)	3 (1.1)	8 (2.8)	0
Oedema Peripheral	27 (9.6)	1 (0.4)	20 (7.0)	0
Gamma-Glutamyltransferase Increased	27 (9.6)	16 (5.7)	8 (2.8)	2 (0.7)
Headache	26 (9.3)	2 (0.7)	25 (8.8)	1 (0.4)
Blood Alkaline Phosphatase Increased	25 (8.9)	6 (2.1)	5 (1.8)	0
Dermatitis Acneiform	23 (8.2)	1 (0.4)	6 (2.1)	0
Dysphonia	22 (7.9)	0	26 (9.2)	1 (0.4)
Non-Cardiac Chest Pain	22 (7.9)	5 (1.8)	21 (7.4)	2 (0.7)
General Physical Health Deterioration	19 (6.8)	13 (4.6)	20 (7.0)	16 (5.6)
Musculoskeletal Chest Pain	17 (6.1)	1 (0.4)	14 (4.9)	2 (0.7)
Pleural Effusion	17 (6.1)	10 (3.6)	13 (4.6)	9 (3.2)
Lipase Increased	17 (6.1)	13 (4.6)	11 (3.9)	9 (3.2)
Bone Pain	15 (5.4)	2 (0.7)	14 (4.9)	4 (1.4)
Hyperkalaemia	14 (5.0)	4 (1.4)	12 (4.2)	5 (1.8)
Muscular Weakness	14 (5.0)	1 (0.4)	6 (2.1)	1 (0.4)
Paraesthesia	13 (4.6)	2 (0.7)	9 (3.2)	1 (0.4)
Malaise	13 (4.6)	1 (0.4)	7 (2.5)	0
Alanine Aminotransferase Increased	13 (4.6)	3 (1.1)	6 (2.1)	3 (1.1)
Musculoskeletal Pain	12 (4.3)	0	11 (3.9)	1 (0.4)
Gastrooesophageal Reflux Disease	12 (4.3)	1 (0.4)	4 (1.4)	0
Pain	11 (3.9)	5 (1.8)	16 (5.6)	5 (1.8)
Pneumonia	11 (3.9)	6 (2.1)	15 (5.3)	10 (3.5)
Dehydration	11 (3.9)	7 (2.5)	12 (4.2)	5 (1.8)
Urinary Tract Infection	11 (3.9)	1 (0.4)	10 (3.5)	0
Aspartate Aminotransferase Increased	11 (3.9)	3 (1.1)	8 (2.8)	3 (1.1)
Hypotension	11 (3.9)	1 (0.4)	7 (2.5)	0
Blood Triglycerides Increased	11 (3.9)	8 (2.9)	1 (0.4)	0
Dysphagia	7 (2.5)	2 (0.7)	12 (4.2)	0
Haemoptysis	5 (1.8)	0	11 (3.9)	2 (0.7)
Alopecia	2 (0.7)	0	61 (21.5)	1 (0.4)
Erythema	1 (0.4)	0	15 (5.3)	1 (0.4)
Pain of Skin	1 (0.4)	0	11 (3.9)	1 (0.4)

— Preferred Terms Are Sorted In Descending Frequency Of All Grades Column, As Reported In Dovitinib Arm.

— A Patient with Multiple Occurrences Of An AE Under One Treatment Is Counted Only Once In The AE Category For That Treatment.

— A Patient with Multiple Adverse Events Is Counted Only Once In The Total Row.

— MedDRA Version 16.0 Has Been Used For The Reporting Of AEs. AEs Have Been Graded According To The CTCAE V4.03.

Overview of Renal Cell Carcinoma (RCC)

Globally, the incidence of RCC varies widely from region to region, with the highest rates observed in North America. Approximately 431,000 new cases of kidney cancer were diagnosed worldwide in 2020 and 179,000 patients died from this malignancy. In the United States, there are approximately 79,000 new cases each year and almost 14,000 deaths from RCC on an annual basis. In Europe, there were approximately 130,000 cases of RCC and 54,000 deaths due to kidney cancer in 2020.

Renal cell carcinomas arise from the proximal tubal epithelium. Alternatively known as clear-cell cancer or renal adenocarcinoma, RCC is characterized by a distinct clear or granular cell appearance visible by light microscopy.

The most common molecular abnormality in clear cell RCC is loss of Von Hippel-Lindau (VHL), which is found in about 50-70% of sporadic cases. Sporadic somatic and hereditary germ cell mutations cause the loss of the VHL protein 9Pvhl0 and VHL negatively regulates hypoxia inducible genes, such as those encoding Hypoxia-inducible factor (HIF 1)-alpha, vascular endothelial growth factor (VEGF), and platelet-derived growth factor (PDGF) ß and the glucose transporter GLUT-1.

Approximately 25% of the patients present with advanced disease at the time of diagnosis, including locally invasive or metastatic renal cell carcinoma, and 50% of the patients undergoing curative surgery can be expected to experience relapse at distant sites. Median survival for patients with metastatic disease is approximately 2 years with the 5-year overall survival < 10% that has only improved marginally to 11.7% in the 2007-2013 reporting period.

In the last decade and a half, the treatment of RCC has evolved from being predominantly cytokine-based to being grounded in the use of drugs targeting VEGF and PDGF, mammalian target of rapamycin (mTOR) pathways and immunotherapy.

Rationale for Targeting Multiple Kinases in RCC

In the first line setting of advanced RCC, the established therapeutic options include agents conferring VEGF pathway inhibition, (e.g., sunitinib, pazopanib, and cabozantinib), mTOR- pathway inhibition (everolimus, temsirolimus), high-dose interleukin (IL)-2, but more recently, this has shifted to a combination of immune-oncology agents or a combination of immunotherapy with a tyrosine kinase inhibitor.

In the second-line setting, following progression of disease on therapy, or intolerance of the first- line regimen, there are again a number of potential treatment options, including targeted drugs such as axitinib, cabozantinib, lenvatinib in combination with everolimus, and the checkpoint inhibitors nivolumab and iplimumab. The optimal sequence of therapy remains an area of active research, partially rooted in the observation that mRCC is a heterogeneous disease characterized by a variable natural history and response to initial and subsequent therapy.

In the third line RCC setting, there is an unmet need for companion diagnostics, like the Dovitinib-DRP®, to help guide therapeutic options and decisions in this patient group. Until recently, there was no newly approved drug in this setting. However, tivozanib was recently approved in March 2021 as a treatment option in the third-line RCC setting.

Although these newly approved targeted agents represent significant progress in the treatment of advanced kidney cancer, the majority of advanced RCC patients become resistant or refractory to these therapies. There remains a large and significant unmet medical need for patients whose cancer progresses despite treatment with VEGF and mTOR inhibitors and immunotherapies. Thus, the development of novel therapies, particularly in combination with a predictive biomarker is an unmet medical need in third-line advanced RCC.

Currently, there is just one novel therapy in patients who have failed two previous systemic therapies, namely, the recently approved TKI tivozanib. In a retrospective analysis of 34 patients, third-line sorafenib appears to be active and well tolerated in mRCC after first-line sunitinib and second-line everolimus or temsirolimus. In addition, the most recently approved agent, axitinib, in second-line advanced RCC was also based on a Phase III trial comparing axitinib vs. sorafenib. Sorafenib was selected as an appropriate active comparator for the dovitinib Phase III trial (A2302) in patients who failed both anti-VEGF and mTOR therapies.

Existing pan-TKIs and Our Opportunity

Numerous pan-TKIs, including Nexavar® (sorafenib), Sutent® (sunitinib), Votrient® (pazopanib), and Lenvima® (lenvatintib) are currently used in the treatment of RCC and numerous other indications. Fotivda® (tivozanib) was recently approved as a third line RCC treatment, however its use in clinical practice is yet to be established. The global kinase inhibitor market in 2019 was roughly $33 billion and, according to consensus estimates cited by Leerink, is poised to grow about 13% annually to surpass $50 billion by 2022. Sales of pan-TKIs substantially contribute to this total market. For example, sales of Sutent® were $1 billion in 2018, while sales of Nexavar® and Votrient® were each about $800 million that year. Additionally, sales of certain pan-TKIs, such as Lenvima®, are increasingly being driven, in part, by combination therapy with immune checkpoint inhibitors, such as PD-1 inhibitors (e.g. Merck's Keytruda®). In the RCC setting, sales of Nexavar® alone, for example, were $125 million in 2019. The global kidney cancer drugs market size was valued at $4.4 billion in 2016 and is expected to grow to $6.3 billion in 2022.

The table below lists the therapeutic benefit of pan-TKIs, as well as other agents, approved for the treatment of RCC:

Efficacy and MOA of currently available treatments for advanced renal cell carcinoma — FDA approved

Approval Date/pharma	Drug name	MOA	Trt Control/Line of treatment	ORR %	Median PFS	Median OS
Dec 2005 Bayer	Sorafenib	TKI: KIT, FLT3, RET, VEGFR1-3, PDGFRβ, c-CRAF, BRAF, mutantBRAF	Placebo 2nd-line	Not reported	5.5 M vs 2.8 M HR=0.44	HR=0.72 NS
Jan 2006 Pfizer	Sunitinib	TKI: VEGFR1-2, FLT3, IT, SCF, PDGFR<	IFN-alpha 1st-line Previously untreated	27.5 vs 5.3	10.8 M vs 5.1 M HR=0.42	26.4 vs 21.8 HR=0.72 NS
May 2007 Pfizer	Temsirolimus	m-Tor inhibitor	IFN-alpha 1st-line Previously untreated with poor prognostic factors	8.6 vs 4.8 NS	5.5 M vs 3.1 M HR=0.53	10.9 M vs. 7.3 M HR=0.73
March 2009 Novartis	Everolimus	m-Tor inhibitor	Placebo 2nd-line Previously treated with sunitinib or sorafenib	2 vs 0	4.9 M vs 1.9 M HR=0.33 P<0.0001	NS
July 2009 Genentech	Bevacizumab/IFNα	VEGF inhibitor/cytokine	IFN-alpha 1st-line	30 vs 12	9.2 M vs 4.2 M HR=0.60	23 M vs 21 M HR=0.86 NS
Oct 2009 Novartis	Pazopanib	TKI: VEGFR1-3, PDGFR<β, FGF1-3, Kit, Itk, Lck, c-Fms,	Placebo 1st or 2nd-line Trt naïve (54%) or one prior cytokine trt (46%)	30 vs 3	9.2 M vs 4.2 M HR=046	NS
Jan 2012 Pfizer	Axitinib	VEGFR1-3, PDGFRαβ, c-Kit	Sorafenib 2nd-line after failure of one prior systemic therapy	19.4 vs 9.4	6.7 M vs 4.7 M HR=0.67 p<0.0001	20.1 vs 19.2 HR=0.97 NS
Nov 2015 BMS	Nivolumab	PD-1 blocking AB	Everolimus 2nd or 3rd line treatment after 1 or 2 antiangiogenic therapies	21.5 vs 3.9	6.0 M vs 6.0 M HR=0.84 p<0.033 mostly 2nd line	25.8 M vs 19.7 M HR=0.73 p<0.0018
May 2016 Eisai	Lenvatinib + everolimus	TKI: VEGFR1-3, FGFR1-4, PDGFαβ, KIT, RET/m-Tor	Everolimus (monotherapy) or Lenvatinib (monotherapy) or Lenvatinib + Everolimus 2nd-line treatment after 1antiangiogenic therapy	19 vs 3	14.5 M (L+E) vs 5.5 M (E) vs 7.4 M (L) HR=0.37	18.5 M L+E) vs 16.5 M (E) and 17.8 M (L) Label Aug 2018: 25.5 M vs 15.4 M HR=0.67
Dec 2016 Exelixis	Cabozantinib	TKI: VEGFR1-3, KIT, TRBB, FLT-3, AXL, RET, MET, TIE-2	Everolimus 2nd-line treatment in patients with metastatic renal cell carcinoma who progressed after VEGFR-targeted therapy	17 vs 3 p<0.0001	7.4 M vs 3.8 M HR=0.58 p<0.0001	21.4 M vs 16.5 M HR 0.66 p<0.0003

Approval Date/pharma	Drug name	MOA	Trt Control/Line of treatment	ORR %	Median PFS	Median OS
Dec 2017 Exelixis	Cabozantinib	TKI: VEGFR1-3, KIT, TRBB, FLT-3, AXL, RET, MET, TIE-2	Sunitinib 1st-line treatment in patients with advanced renal cell carcinoma of intermediate or poor risk	20 vs 9	8.6 M vs 5.3 M HR=0.48 P<0.0008	26.6 M vs 21.2 M HR=0.80
Aug 2018 BMS	Nivolumab + ipilimumab	PD-1 blocking AB/CTLA-4 blocking AB	Sunitinib 1st-line treatment in patients with Intermediate- and Poor-Risk Advanced Renal Cell Carcinoma	41.6 vs 26.5 p<0.0001	11.6 M vs 8.4 M HR=0.82 NS	NR vs 26.6 M HR=0.63 p<0.0001
Apr 2019 Merck	Pembrolizumab + axitinib	PD-1 blocking AB/TKI	Sunitinib 1st-line treatment in patients with advanced renal cell carcinoma	59 vs 36 p<0.0001	15.1 M vs 11.1 M HR=0.69 p<0.0001	HR=0.53 p=0.0001
May 2019 EMD Serono Pfizer	Avelumab + axitinib	PD-L1 blocking AB/TKI	Sunitinib 1st-line treatment in patients with advanced renal-cell carcinoma	19.4 vs 9.4	13.8 M vs 7.2 M HR=0.67 p<0.0001	20.1 M vs 19.2 M HR=0.97 NS
Jan 2021 BMS Exelixis	Nivolumab + cabozantinib	PD-1 blocking AB/TKI	Sunitinib 1st line treatment in patients with advanced renal cell carcinoma	56 vs 27 P<0.0001	16.6 M vs 8.3 M HR=0.51 p<0.0001	Not reached yet HR=0.60 p<0.001
Mar 2021 Aveo	Tivozanib	VEGFR1-3 c-kit, PDGFR-β and others	Sorafenib ≥3 line Treatment in relapsed or refractory advanced RCC	18 vs 8 NS	5.6 M vs 3.9 M HR=0.73 P=0.016	16.4 M vs 19.2 M HR=0.97 NS

The commercial success of pan-targeted kinase inhibitors has resulted in the development and FDA approval of seven tyrosine kinases for the treatment of RCC over the last 15 years. Adverse grade 3 – 4 events from this class of drugs include hypertension, liver toxicity, GI problems (nausea, vomiting, diarrhea), anemia, lymphocytopenia, thrombocytopenia, and fatigue. Other common adverse reactions include anorexia, mucositis, abdominal pain, palmar-plantar erythrodysesthesia and skin rash. These adverse events vary in frequency and severity among the different tyrosine kinases approved for RCC.

Additionally, most patients develop resistance to pan-TKIs via a number of mechanisms (i.e. genetic alterations, activation of other signaling pathways) or are non-responsive to a given pan-TKI. Accordingly, there continues to be a need for the development and approval of additional, new pan-TKIs, both for the treatment of RCC and other indications.

We believe that our pan-TKI, dovitinib, together with its DRP® companion diagnostic — which enables us to select and treat patients most likely to respond to this drug (while excluding those who will not), uniquely overcomes many of the limitations of current pan-TKIs and, once it is approved with its DRP® companion diagnostic by the FDA, has the potential to be a unique drug that can succeed and compete in the marketplace in numerous cancer indications. If approved by the FDA, the treating oncologist will have a novel diagnostic tool, the Dovitinib-DRP®, to evaluate a cancer patient's likelihood of responding to treatment with dovitinib and thus individualize the risk/benefit of this drug, versus other therapeutic options, for the patient.

Future Opportunities & Development Plans for Dovitinib

We have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success. We continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. For example, subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies for mRCC will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer, as well as other indications. In addition, one of dovitinib's mechanisms of action is to block the formation of new blood vessels that supply a tumor with nutrients and oxygen (i.e. inhibition of angiogenesis). This causes cancer to enter into a state of homologous recombination deficiency. Homologous recombination plays an essential role in the repair of DNA double-strand breaks and collapsed replication forks. Cancer cells that are deficient in homologous recombination become hypersensitive to single strand breaks that, if not repaired, lead to double strand breaks. PARP1 is essential for repair of single strand breaks and PARP1 is inhibited by stenoparib. Therefore, a combined treatment with an antiangiogenic agent and a PARP inhibitor may cause a synthetic lethality, which is a type of genetic interaction where the combination of two genetic events results in cell death. Because we hold exclusive, global commercial rights to both dovitinib and stenoparib, we believe that we can efficiently initiate clinical trials to study the possible synergistic activity achieved by combining dovitinib and stenoparib.

Additionally, we are developing a Protocol for a DRP®-guided Phase 2 trial of dovitinib for the treatment of pediatric osteosarcoma. This will be preceded by a Phase 1B dose escalation study in solid tumors in pediatric patients >=2 years of age. Current FDA regulations require, under The RACE for Children Act (Title V, Sec. 504, FDA Reauthorization Act (FDARA), enacted August 18, 2017) as part of an NDA submission for a drug, the concomitant submission of a clinical development plan for the drug in at least one pediatric cancer. Our planned study for pediatric osteosarcoma is based on previously conducted, pre-clinical animal model studies of dovitinib showing that the drug has promising activity in this pediatric indication, which is the most common primary malignant bone tumor in children and young adults. These pre-clinical studies were carried out in collaboration with the University of Illinois (Champaign, IL USA). Clinical development of dovitinib for pediatric indications will be advanced by OncoHeroes Biosciences, with which we announced a development license and partnership on January 3, 2022. On September 23, 2022, OncoHeroes announced that it had received a Rare Pediatric Disease Designation (RPDD) from the U.S. FDA for the development of Dovitinib for treatment of pediatric osteosarcoma. This RPDD qualifies OncoHeroes to receive fast track review and a priority review voucher (PRV) at the time of marketing approval of Dovitinib for a pediatric cancer indication. We continue to support OncoHeroes in this pediatric cancer development partnership.

The purpose of the pre-clinical studies was to investigate the capacity of dovitinib alone, and in combination with a specific checkpoint inhibition strategy (anti-PD-1), for slowing the progression of experimental pulmonary metastases in animal models of osteosarcoma. Two separate studies, performed contemporaneously in a syngeneic, mouse model of experimental pulmonary osteosarcoma metastases in mice using the K7M2 cell line, generated the following key results:

- Treatment with dovitinib, compared to control treatment (sucrose solution lacking dovitinib), increased the median survival time by 50%.
- Anti-tumor growth activity was also observed for dovitinib as a single agent in this model.

In addition, it was found that no significant anti-tumor activity was observed in mice treated with single-agent anti-PD-1 antibody at the investigated dosage and dosing schedule. Furthermore, the combination of dovitinib and anti-PD-1 antibody did not generate additive or synergistic anti-tumor activities equal or greater than observed by dovitinib alone in the mouse osteosarcoma model.

DRP® Companion Diagnostic for Dovitinib

We are developing dovitinib together with a DRP® companion diagnostic, which we believe will enable us to select the patients most likely to respond to the drug in our clinical trials. A Pre-Market Approval (PMA) application for our Dovitinib-DRP® companion diagnostic was filed with the FDA on April 1, 2021. On February 15, 2022, we received RTF letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA has asserted that neither our NDA or PMA meets the regulatory requirements to warrant a complete agency review. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP®-Dovitinib companion diagnostic. The primary basis for the RTF of our PMA for the DRP®-Dovitinib companion diagnostic was the RTF of our NDA for dovitinib, to which our PMA relates. Allarity anticipates that it may be necessary to conduct a new, prospective Phase 3 study, to gain approval of dovitinib in the U.S.

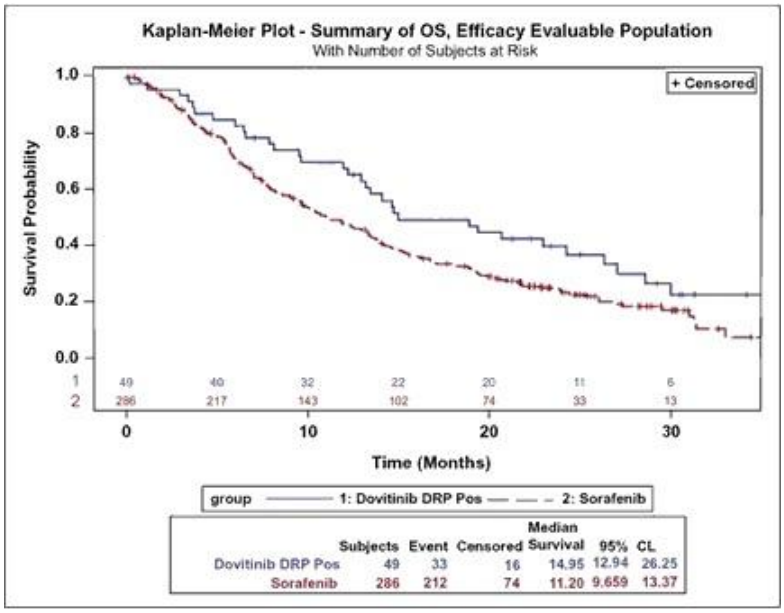
The Dovitinib-DRP® companion diagnostic, which comprises 58 expressed genes, was initially developed using cell line testing in the NCI60 panel. The sensitivity of the 60 cell lines to dovitinib was determined. The observed difference in sensitivity was correlated to the observed baseline gene expression in the 60 cell lines and 58 genes were identified as positively correlated or negatively correlated.

The putative Dovitinib-DRP® companion diagnostic, developed through our DRP® platform using gene expression data from cancer cell line testing data, was positively observed using biopsy materials from five Phase 2 trials of the drug and single Phase 3 trial of the drug, sponsored by Novartis AG, that were conducted worldwide from 2010-2015 (clinicaltrial.gov numbers NCT01223027, NCT01379534, NCT01232296, NCT01478373, NCT00958971, NCT01528345).

The following table shows the primary and secondary endpoints, respectively, in our analysis using a DRP® score cut-off of 50% is a single Phase 3 trial sponsored by Novartis AG. All observed measures show an improvement in the DRP® selected patients from the dovitinib arm when compared to the sorafenib arm:

Efficacy Parameter	**Dovitinib Dovitinib Score > 50% N = 49**	**Sorafenib Unselected N = 286**	**p-value**	**HR**
Median PFS, Months	3.75	3.61	0.0572	0.71
(95% CI)	(3.68,5.39)	(3.48,3.71)		(0.51,1.01)
Median OS, Months	15.0	11.2	0.04	0.69
(95% CI)	(12.94,26.25)	(9.66,13.37)		(0.48,0.99)

188 patients consented in the dovitinib group, of these, 135 passed established biomarker quality criteria. The DRP-dovitinib divided the patients into two groups, sensitive (n=49, DRP score >50%) or resistant (n=86, DRP score < 50%) to dovitinib. The DRP sensitive population was compared to the unselected sorafenib group (N=286). The graphic below shows a Kaplan-Meier curve of overall survival in these two groups.



A statistically significant improvement in overall survival of patients selected with Dovitinib-DRP® and treated with Dovitinib, when compared to patients treated with Sorafenib, is considered a strong argument in favor of regulatory approval of Dovitinib as a monotherapy together with its companion diagnostic Dovitinib-DRP®. However, we anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP

We additionally observed that, as expected, the Dovitinib-DRP® does not select responders or patients with longer PFS or OS in the sorafenib arm of the Phase 3 RCC study. This demonstrates that the DRP® is highly drug specific, and thus the Dovitinib-DRP® cannot be used to select responders to sorafenib. Certain details of our Dovitinib-DRP® were published as an e-Poster at the European Association for Cancer Research (EACR) 2021 Virtual Congress held from June 9 to June 12, 2021, and at the European Society for Medical Oncology (ESMO) 2021 Virtual Congress held from September 16 to September 21, 2021.

We further tested the predictive power of the Dovitinib-DRP® companion diagnostic in other Phase 2 study cohorts from which pre-treatment or diagnostic biopsies have been obtained, as follows:

- HCC (NCT01232296): Trial A2208 consisted of 82 patients treated frontline with dovitinib and 82 patients treated frontline with sorafenib. Archival tumor slides or fresh biopsy slides were available for 8 patients from the dovitinib arm and 10 patients from the sorafenib arm.

- Endometrial (NCT01379534): Trial A2211 consisted of 53 patients treated second-line with dovitinib. Archival tumor slides or tumor blocks were available for 44 patients, of which 35 met the QC criteria during lab analysis.

- GIST (NCT01478373): Trial AIC02 consisted of 38 enrolled patients treated second line dovitinib, biopsies were available and met QC for 16 patients.

- Breast cancer combination trial of fulvestrant +/- dovitinib in locally advanced or metastatic breast cancer patients who had evidence of disease progression (NCT01528345, A2210). 47 patients were randomized to fulvestrant+dovitinib, of which 21 had available biopsies that met QC.

- Breast cancer monotherapy (NCT00958971, A2202): 1–3 prior therapies in the metastatic setting, N=57 biopsies of which 19 meet QC.

In cohorts from GIST trial IC02 (second line dovitinib, N=16 biopsies) and breast cancer trial A2202 (1–3 prior therapies in the metastatic setting, N=57 biopsies of which 19 meet QC) there was no positive association between clinical outcome and DRP®-Dovitinib prediction. But the 95% confidence interval of the OS and PFS hazard ratios included those hazard ratios observed for the other cohorts and the RCC phase III cohort.

In summary, based on these studies, we believe our putative Dovitinib-DRP® companion diagnostic accurately and reliably identifies responder patients (with mRCC, HCC, breast cancer (ER positive) and endometrial cancer) to this therapeutic candidate, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance clinical development of dovitinib for these indications including mRCC. As discussed above, based upon the reasons given in the RTF letters and a subsequent Type C meeting with the FDA on May 31, 2022, we anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dose optimization studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP for the treatment of third-line mRCC can be obtained. While we have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success, we continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. For example, subject to funding we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. Our decision to advance dovitinib as a combination therapy and not as a monotherapy is based on our belief that both the science and the market for oncology therapies has shifted towards combination therapies and away from monotherapies for multiple indications of cancer. We further believe that our DRP®-Dovitinib companion diagnostic is tumor agnostic and our retrospective analysis of the clinical data generated in the Novartis clinical studies for mRCC will also support a companion diagnostic for dovitinib in second-line or later treatment of metastatic ovarian cancer, as well as other indications.

Overview of Stenoparib (PARP inhibitor)

Mechanisms of Action

PARP is an enzyme discovered more than 40 years ago that produces large, branched chains of poly (ADP) ribose (PAR) from NAD. In humans, there are 17 members of the PARP gene family, but most of these are poorly characterized. Of the 17 PARP family members, only PARP1 and PARP 2 are known to be involved in DNA repair. PARP is an abundant nuclear enzyme that is activated by DNA strand breaks to synthesize poly (ADP-ribose) from NAD. The main function of PARP is the maintenance of genomic integrity by facilitating DNA repair through the BER pathway. BER is one mechanism by which cancer cells counteract the DNA damage elicited by cytotoxic agents or radiation and thus develop resistance to chemo-or radiation therapies. PARP inhibition may provide a novel mechanism to sensitize refractory tumors to chemotherapy and radiotherapy.

PARP inhibition has shown anti-tumor activity in homologous DNA repair-defective tumors, such as those with BRCA1 and BRCA2 mutations. Also, it is well established that cells deficient in homologous recombination are particularly sensitive to DNA-crosslinking agents, including the platinum salts (cisplatin and carboplatin); their BRCA-selective effects are mediated by a similar mechanism to that of PARP inhibitors. Therefore, as platinum salts are frequently used for the treatment of ovarian cancer, including some individuals with BRCA1 or BRCA2 mutations, the combination with PARP inhibitors and DNA agents is an interesting combination that should be explored in clinical trials.

As used in this section of this report describing our therapeutic candidate stenoparib, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate Stenoparib may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate Stenoparib or our putative Stenoparib-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Stenoparib is a potent inhibitor of both PARP1 and PARP2 enzymes, as demonstrated in both *in vitro* and *in vivo* studies. Development of stenoparib as single agent and in combination is supported by preclinical studies. Stenoparib inhibited proliferation in subsets of cells in cell line panels derived from a variety of tumors. Stenoparib, administered as a monotherapy, demonstrated potent tumor growth inhibition in several animal models with tumors featuring underlying defects in DNA repair, including BRCA mutant breast cancer. In addition, stenoparib demonstrated *in vivo* activity as a single agent in models of B cell lymphoma and AML.

Apart from being a potent PARP1/2 inhibitor, stenoparib also inhibits PARP5a/5b, otherwise known as tankyrase1 and 2 (TNKS1 and 2), important regulators of canonical Wnt/Beta-catenin signaling and maintenance of chromosomal telomerase integrity. Thus, stenoparib inhibited Wnt/Beta-catenin signaling in colon cancer cell lines, likely through TNKS inhibition. Consistent with this possibility, stenoparib stabilized axin and TNKS proteins resulting in Beta-catenin de-stabilization and significantly altered expression of Wnt target genes. This indicates a potential for treating several cancers where aberrant activation of Wnt/Beta-catenin signaling can be part of the carcinogenesis and tumor progression.

Temozolomide (TMZ) is a chemotherapeutic agent with an activity that can be enhanced by PARP inhibition. PARP inhibition has also been shown to overcome resistance of cells to TMZ. Potentiation of TMZ activity was observed in orthotopic models of melanoma and glioblastoma. In xenograft models, stenoparib inhibition of PARP was observed in tumor tissue by using the PARP pharmacodynamic assay to measure PAR levels.

The predictive biomarker Ataxia-Telangiectasis Mutated (ATM) was selected for use in B cell lymphoma by demonstrating that stenoparib sensitivity was increased through ATM loss in these cells. Certain hematological indications are known to up-regulate P-glycoprotein (P-gp), which is implicated in the development of multidrug resistance leading to therapeutic failure and poor outcome. Stenoparib activity is not affected by P-gp over-expression, thus offering a potential advantage in the clinic.

Pre-Clinical Studies

PARP utilizes nicotinamide adenine dinucleotide (NAD) as substrate to catalyze the polymerization and transfer of poly (ADP-ribose) (PAR) to acceptor proteins. The posttranslational modification through addition of PAR results in modulation of target protein function. Stenoparib is a nicotinamide mimetic, competitive PARP inhibitor that inhibits PARP1 and PARP2 equipotently.

In cell-based assays, stenoparib potently inhibited proliferation of the BRCA1 mutant human breast cancer cell line MDA-MB-436. Additionally, stenoparib inhibited proliferation in the human hematologic cell lines: SR (B cell lymphoma) and MV-4-11-luc2/AcGFP (acute myeloid leukemia (AML)). In the murine leukemia cell line P388, P-glycoprotein (P-gp) overexpression had very little impact on inhibition of proliferation by stenoparib.

Oral administration of stenoparib for 28 days significantly inhibited tumor growth in vivo in the subcutaneous MDA-MB-436 xenograft model without any significant body weight loss. A dose- responsive pharmacodynamic effect on PARP activity in MDA-MB-436 xenograft tumor tissue was observed following administration of a single stenoparib dose. The decrease in PARP activity was sustained over several hours. These results demonstrate monotherapy activity of stenoparib in a BRCA mutant breast cancer model. Single agent activity was also observed in the AML MV-4-11-luc2/AcGFP survival model. Treatment with stenoparib resulted in decreased tumor burden as measured by luciferase signal, and reduction in disease translated to a statistically significant survival benefit.

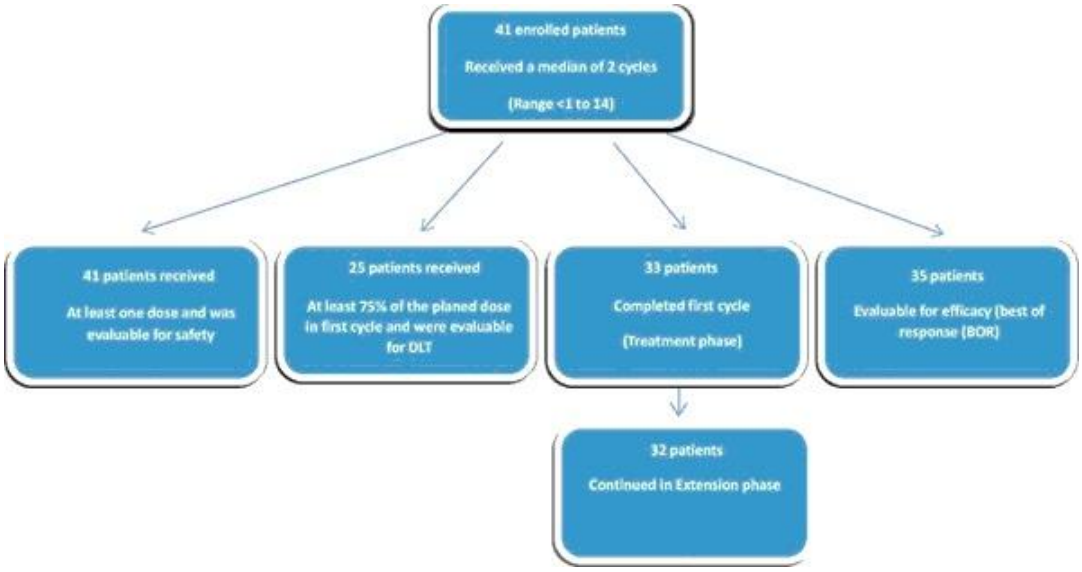
In addition to activity as monotherapy, stenoparib demonstrated potentiation of the anti-tumor effects of temozolomide (TMZ), eribulin mesylate (E7389) and carboplatin. In intracranial survival models of melanoma (murine melanoma B16 cell line) and glioblastoma (human glioblastoma multiforme SJGBM2 cell line), the addition of stenoparib to TMZ resulted in a significantly increased survival benefit versus that derived from TMZ alone.

Prior Clinical Trials

The initial planned first-in-human study of stenoparib (conducted by Eisai, Inc.) was an open-Label, Multi center, Phase 1 study of PARP Inhibitor stenoparib (formerly E7449) as single agent in subjects with advanced solid tumors or with B-cell malignancies and in combination with TMZ or with Carboplatin and Paclitaxel in Subjects with Advanced Solid Tumors. The first part (Phase 1) of the study started on January 31, 2012, and was completed with the last patient visit July 14, 2015. Further clinical evaluation was stopped, as it was decided to stop the clinical development for the reasons described below. Preliminary data after treating the first 28 patients have been presented at ESMO conference 2014. The final data including the retrospective/prospective Stenoparib-DRP® selection results were presented at ASCO 2018.

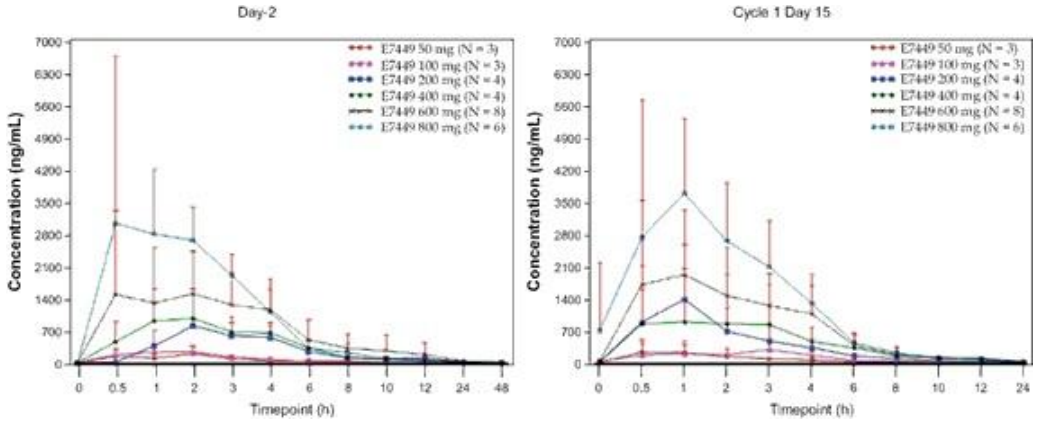
The study was conducted as Phase 1 single-agent arm (Arm 1) and standard 3+3 dose escalation was performed. During dose escalation, sequential cohorts of 3 to 6 subjects (dose escalation cohorts) were administered increasing doses of 50 mg, 100 mg, 200 mg, 400 mg, 600 mg, and 800 mg (Table 5-1). 41 subjects were enrolled and 33 completed the 'Treatment phase' (received first cycle of treatment) while 8 subjects discontinued. 32 subjects continued in the 'Dose Extension Phase'. During the Dose Extension Phase, the primary reason for discontinuation of study treatment was disease progression (27 subjects due to objective disease progression, which was defined as treatment completion). Two subjects in the 600 mg dose group discontinued study treatment due to AEs with AE being the primary reason for discontinuation as recorded from the disposition page of the Case Report Form (CRF).

All 41 subjects received at least 1 dose of stenoparib and were included in the safety, PK, and pharmacodynamics analyses. 12 subjects who received the 600 mg dose of stenoparib in both fed and fasted states were analyzed for food effect.



After a single or multiple oral dose, stenoparib was moderately well absorbed with tmax ranging from 0.5 to 4 hours across subjects and dose groups. The elimination half-life was approximately 8 hours with less than 1.5% of the administered dose recovered in urine. Accumulation based on AUC was minimal (less than 1.2 fold) upon 15 days of dosing across the range of doses.

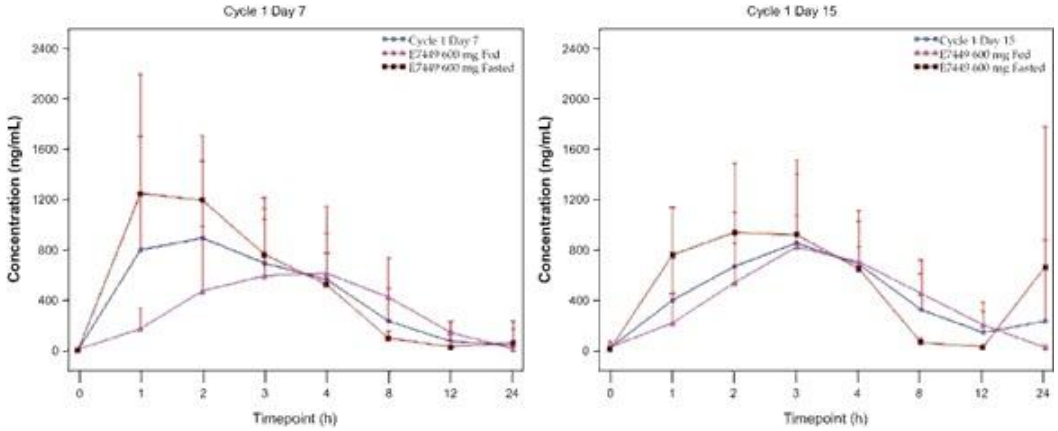
Stenoparib exposure (both Cmax and AUC) appeared to be approximately dose proportional following single or multiple oral doses between 50 mg and 800 mg, with slight deviation at the 400 mg and 600 mg doses. At the 600 mg dose, food delayed stenoparib absorption as evidenced by a shift in tmax by 2 hours, reduced Cmax by 60%, and increased AUC by 10%. The interpatient pharmacokinetic variability is large both with and without food. Thus, the effect of food with the decrease in Cmax, and increase in AUC.



The above figure shows a Linear Plot of Mean (+SD) E7449 plasma concentration versus nominal time (hours) by treatment fasting and after food intake.

Dose dependent inhibition of PARP activity, as demonstrated by percent change in PAR levels, was observed. Maximal inhibition of PARP activity was observed at the MTD dose (600 mg) of single agent stenoparib. Evaluation of PAR levels at the MTD dose of stenoparib (600 mg) in the food effect cohort demonstrated that PAR levels show maximal decrease at 2 to 4 hours post-dose with up to 90% inhibition in PAR levels (from baseline) observed. Sustained PARP inhibition was observed with a 70% or greater decrease in PAR levels observed at 24 hours post-dose. Greater decrease in PAR levels was observed with increasing plasma concentration of stenoparib and with the maximal inhibition observed corresponding to the peak plasma concentration in measurements obtained at Day-2 and Cycle 1 Day 15. A greater decrease in PAR levels was observed with a corresponding higher Cmax when stenoparib was administered without food than when administered with food. No significant changes in percent DNA in tail were observed.

In the finalized Phase 1 study, the majority of subjects (35/41; 85.4%) received up to 8 cycles of treatment with 26 subjects (63.4%) who received up to 2 cycles (<1 cycle = 7, 1 cycle = 5, and 2 cycles = 14); mean number of treatment cycles overall were 3.8 (median = 2 cycles, range: 0 i.e. <1 to 14). The overall median duration of treatment for all dose groups was 57 days (range: 1 to 392 days) with an overall median dose intensity of 11% (range: 1% to 111%) in terms of percentage of planned dose.



In the completed Phase 1 study the following safety results were reported:

- DLTs were reported in 5 of the 25 DLT evaluable subjects, 4 of these occurred at the 800 mg QD dose (1 Grade 3 fatigue and 3 Grade 2 fatigue resulting in administration of less than 75% of the planned dosage of stenoparib) and 1 occurred at the 600 mg QD dose (Grade 3 anaphylactic reaction). Based on assessment of DLTs, the MTD and RP2D of single agent stenoparib treatment was 600 mg administered orally QD in 28-day cycles.

- The mean number of treatment cycles received by the 41 subjects treated at the different dose levels of stenoparib was 3.8 (median = 2 cycles, range: <1 to 14). The overall median duration of treatment for all dose groups was 57 days (range: 1 to 392 days).

- No deaths due to AEs were reported during the study. Nonfatal SAEs were reported in 58.5% subjects overall. The majority of SAEs were considered not related to stenoparib treatment and were reported in not more than 1 subject overall; SAEs reported in more than 2 subjects overall were fatigue (n=3) and lower respiratory tract infection (n=3). Treatment related SAEs included fatigue (n=3), anemia (n=1), anaphylactic reaction (n=1), drug hypersensitivity (n=1), depression (n=1), pyrexia (n=1), and transaminases increased (n=1).

- TEAEs occurred in all study subjects. The most frequently reported (>30% of subjects overall) TEAEs were fatigue, chromaturia, decreased appetite, nausea, diarrhea, constipation, and vomiting. The majority of TEAEs were reported to be Grade 1 or 2 in severity. Overall, Grade 3 events were reported in 27 subjects (65.9%) and the most frequently reported Grade 3 event was fatigue (n=7, 17.1%). A single Grade 4 AE of non-treatment-related hypokalemia was reported in a subject in the 200 mg dose group. No Grade 5 (fatal) events were reported. (Table 5-3)

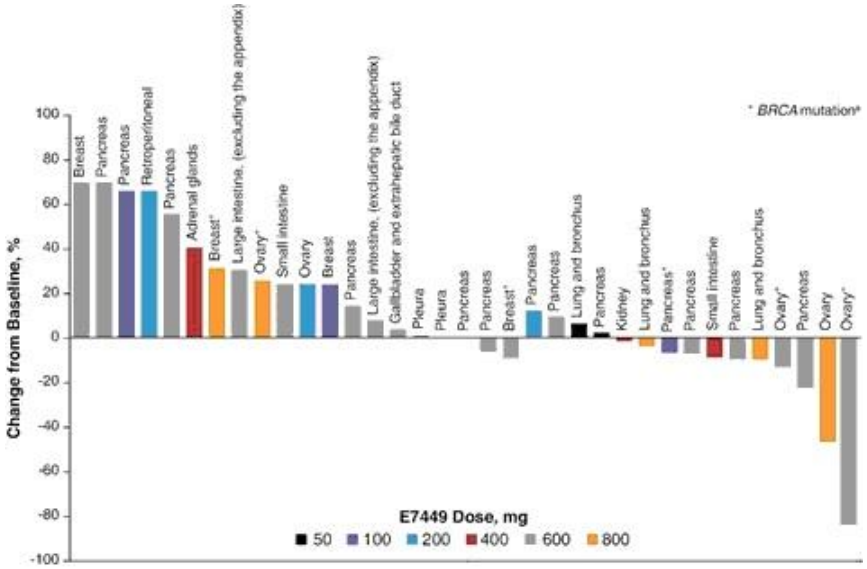
- The most common treatment-related TEAE was fatigue (63%), followed by chromaturia (49%), nausea (34%), diarrhea (29%), and maculo-papular rash (27%). The majority of treatment-related AEs were Grade 1 or 2 in severity. With the exception of treatment-related fatigue that was reported to be Grade 3 in severity for 4 subjects (2 subjects each in the 600 mg and 800 mg dose groups), all other Grade 3 treatment-related events were reported in not more than 2 subjects overall (Table 5-4).

- The study treatment was discontinued due to AEs in 17% subjects (1/3 subjects in 50 mg, 4/21 subjects in 600 mg, and 2/6 subjects in 800 mg dose groups). The events leading to treatment discontinuation included fatigue (n=3), diarrhea (n=2), muscular weakness (n=2), nausea (n=1), photosensitivity reaction (n=1), decreased appetite (n=1), paresthesia (n=1), and anaphylactic reaction (n=1). A total of 24 of 41 subjects (59%) required dose interruptions to manage treatment emergent toxicity. Dose reductions due to AEs were required in 14.6% subjects overall (1/4 subjects in 400 mg, 2/21 subjects in 600 mg, and 3/6 subjects in 800 mg dose groups).

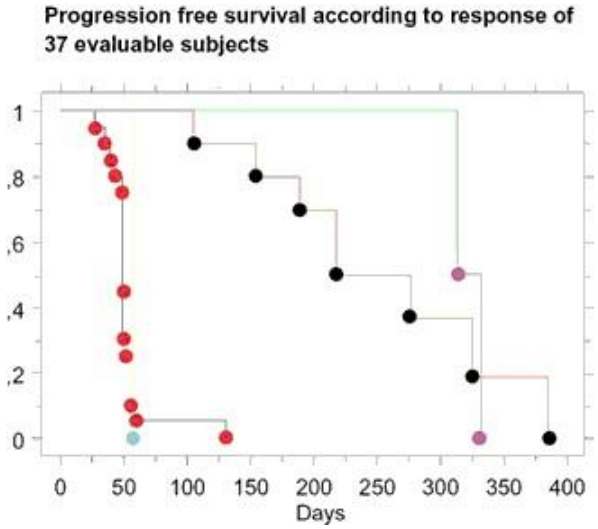
- Skin rash was considered as an event of special interest for stenoparib. Overall, 41.5% experienced AEs of skin rash with the highest incidence observed in the 800 mg dose group (66.7%) followed by the 600 mg dose group (47.6%). No serious events of skin rash were reported. All but 1 event of Grade 3 erythematous rash reported with the 600 mg dose group.

Preliminary anti-cancer activity assessment was a secondary objective of Phase 1. Of the total 41 subjects who received single agent stenoparib treatment, best overall response (BOR) could not be assessed for 6 subjects including 5 subjects who discontinued study treatment prior to the first posttreatment tumor evaluation and 1 subject who did not have any target lesion (i.e., measurable disease). None of the 35 subjects assessed had a BOR of CR based on investigator assessment using RECIST 1.1. The overall objective response rate (ORR; CR + PR) was 4.9% (n=2) with 2 PR out of 41 (both in ovarian cancer), and 31.7% SD (13 out of 41), and disease control rate lasting more than 23 weeks was 24.4% (CR+PR+SD: N=10). Both PRs were predicted by the DRP® for stenoparib after analyzing biopsies from 13 of the patients. A waterfall plot of the individual responses of 35 subjects from the safety cohort is presented below:

Anti-cancer activity according to dose groups



PFS for the whole population was 55 days. A Kaplan Meier plot of progression free survival of subjects with PR (green line), SD (orange line), NE (yellow line) and PD (blue line) is below:



The study was published in the British Journal of Cancer in 2020. It concluded that the drug stenoparib "showed good tolerability, promising antitumor activity and significant concentration-dependent PARP inhibition," and that "The results support further clinical investigation." Nevertheless, Eisai decided to pursue other priorities and for undisclosed reasons offered the therapeutic candidate to us because we had developed a Stenoparib-DRP® response predictor that we believe could identify the infrequent responding patients.

DRP®-Guided Phase 2 Trials

We have previously conducted an open label, single arm Phase 2 study to investigate the toleration and anti-cancer activity of stenoparib in patients with metastatic breast cancer. Patients were selected by having a Stenoparib-DRP® score of >80%. Stenoparib was administered as a once daily oral dose of 600 mg in 21-days cycles (study SMR-3475/2X-1001). The study was initiated in June 2018 and discontinued in June 2020 due to inconclusive results. Fourteen patients were enrolled and received at least 1 dose of stenoparib. The median of number of previous chemotherapies were 6. There were 3 patients with 'stable disease' response after receiving the treatment, and 1 patient maintained stable disease for more than 26 weeks until the date of disease progression. The overall CBR in evaluable population was 9.1%, PFS was 6 weeks, and OC was 8 months. The most common AE was Fatigue (n = 11; 79%), the second most common AE was decreased appetite and nausea, respectively (n = 8; 57%). There were 8 SAEs reported by 5 patients, 6 events were unrelated, 1 was unlikely to be related, and 1 event (urinary tract infection) was possibly related to the treatment. The data from this mBC trial suggest that a diagnostic biopsy cannot be used for predicting likelihood of drug response, using the Stenoparib-DRP® companion diagnostic, in heavily pre-treated mBC patients, and that new biopsies are needed. By terminating the mBC study, Allarity has decided to focus on advancing stenoparib in indications with a higher likelihood of success, including ovarian and pancreatic cancer.

We are further currently conducting a DRP®-guided Phase 2, open label, single arm study to investigate the toleration and anti-cancer activity of the PARP inhibitor, stenoparib in patients with advanced ovarian cancer. The protocol (2X-1002) addresses unmet medical needs in ovarian cancer patients that have progressed on previous PARPi therapy without requiring repeat platinum treatment and in selecting both HR proficient and HR mutated patients/tumors with high likelihood of responding. The primary endpoint is ORR as determined by RECIST 1.1. Secondary endpoints are CBR, PFS and OS. This study is being conducted at Guy's Hospital (London, England), in addition to other trials sites in the U.S. and Europe. Patients are selected by using the Stenoparib-DRP® with a score of >50%. Stenoparib is administered as a once daily oral dose of 600 mg in a 28-days cycle (study 2X-1002). The study was initiated in April 2019 and 10 subjects that were required to be enrolled independent of DRP® score have received at least 1 dose of stenoparib and are included in the safety SAE reporting. Stenoparib-DRP®-selected patients commenced enrollment in June 2021. The delay in enrolling Stenoparib-DRP®- selected patients has mainly been due to COVID-19 pandemic issues. Since the Phase 2 studies currently are ongoing, anti-cancer activity data from these are too early to report.

Overview of Ovarian Cancer

Ovarian Cancer (OC) is a lethal disease with a 5-year survival rate of 20-30% for advanced OC. It is the second leading cause of cancer related deaths in women. A large proportion of patients with OC are diagnosed at an advanced tumor stage. The outcome after chemotherapy for advanced OC becomes poorer and poorer each time a new treatment is introduced following progression on the previous treatment. Approximately 14,000 OC patients die each year due to disease progression.

Treatment of OC (as well as breast cancer (BC)) advanced when the genes BRCA1 and BRCA2 were cloned in the early 1990s and allowing identification of high-risk individuals. These genes encode proteins that are involved in DNA homologous recombination (HR). Patients harboring germline BRCA1/2 mutations carry a defective copy of the gene in every cell, which increases the likelihood of cancer developing if the remaining copy becomes defective through somatic mutation or epigenetic inactivation. However, there are also patients with germline mutations in other HR pathway genes and patients who do not carry an inherited germline mutation but have tumors with sporadic HRD mutations. Data from the Cancer Genome Atlas (TCGA) demonstrates that approximately fifty percent of high grade serous ovarian cancers have aberrations in HR repair.

Epidemiological studies have shown an association between germline BRCA1/2 (gBRCA1/2) mutations and the development of OC, (BC), and to a lesser extent pancreatic and endometrial cancers. Mutation frequencies are estimated to be approximately 15-20% for those diagnosed with OC and 5% for those diagnosed with BC (15). In a recent publication it was shown that for BRCA1 and 2 carriers, cumulative risk for BC by age 80 was 72% and 69%, respectively. For OC, cumulative risk was 44% and 17%, respectively.

The peak incidence of BC occurred in the 41-50-year age group (28.3 per 1000 person-years) for BRCA1 and in the 51-60-year group (30.6 per 1000) for BRCA2 mutation carriers. The incidence of OC was 3.6 times higher for BRCA1 than BRCA2 carriers, with the peak incidence of cancer occurring regardless of mutation type among women in the 61-70-year age group (29.4 per 1,000 in BRCA1 carriers). For BRCA1 and 2 carriers, BC risk increased with the number of first- and second- degree relatives with breast cancer. In contrast, OC risk did not vary with respect to family history of this disease. DNA repair pathways involving BRCA1/2 engage in single or double stranded DNA breaks, which can occur from damage caused by ultraviolet light, the generation of reactive oxygen species, ambient or therapeutic irradiation, day- to-day replication errors or chemical exposure. Cells lacking a functional BRCA1/2 are also deficient in HR and show a high-degree of chromosomal instability as well as increased sensitivity to ionizing radiation and chemotherapeutic agents that lead to double-stranded breaks.

Rationale for Targeting PARP in Ovarian Cancer

Poly (ADP-ribose) polymerases (PARPs) are a family of DNA-dependent nuclear enzymes catalyzing the transfer of ADP-ribose moieties from cellular nicotinamide-adenine-dinucleotide (NAD+) to a variety of target proteins. There are 17 PARP family member proteins identified through sequence homology of the catalytic domain. PARP1, 2 and 3 have all been implicated in DNA repair, with PARP1 being the most abundant. PARP inhibitors are designed to compete with NAD+ for the substrate binding to PARP and inhibit PARP activity. Cells containing dysfunctional BRCA1 or BRCA2 have been shown to become profoundly sensitized to the inhibition of PARP enzymatic activity, resulting in chromosomal instability, cell cycle arrest and subsequent apoptosis. PARP inhibition is thought to induce synthetic lethality, which describes a process where at least two genetic lesions that individually are not lethal become lethal when combined in the same cell. For example, cells that are deficient in HR, which is not lethal in itself, are hypersensitive to a reduction in PARP activity by PARP inhibitors. However, disruption to other proteins involved in HR DNA repair other than in BRCA may have the same effect on PARP inhibitor sensitivity.

A further important mechanism of action for PARP inhibition is the trapping of the PARP1 and PARP2 enzymes at damaged DNA causing cytotoxicity and cell death. Recent studies have revealed a more complex web of fundamental cellular processes that PARP1 is involved in crucial cell processes other than in DNA damage repair, such as chromatin remodeling and transcription or regulation of the cell cycle.

There are currently three PARP inhibitors approved, in a number of countries but not all yet, for either monotherapy or maintenance therapy or both in patients with advanced OC. Two are approved in patients with BRCA 1 and 2 mutations with advanced OC having undergone therapy with >3 chemotherapies (Olaparib) or >2 chemotherapies (Rucaparib). Two PARPi (niraparib and olaparib) are approved as maintenance therapy in patients with advanced OC who are in complete or partial response to platinum-based chemotherapy.

The effectiveness of PARP inhibitors as monotherapy or as maintenance therapy has substantially improved the progression free survival and may be promising for overall survival in OC patients. PARP inhibitors as single agents or as potential enhancers of cytotoxic agents that provoke DNA damage, such as alkylating agents and chemotherapy, have been investigated in a number of studies, including olaparib, rucaparib, niraparib, veliparib, and talazoparib, where the two latter PARPi are still under development.

There is a current unmet need for treatment of patients with OC who have progressed on PARPi treatment. Our ongoing Phase 2 study in ovarian cancer allows for enrollment of patients previously treated with a PARPi. We intend to use our Stenoparib-DRP® to select patients from this group that will have a high likelihood of responding to our PARPi, Stenoparib.

Future Opportunities & Development Plans for Stenoparib

Overview of Pancreatic Ductal Adenocarcinoma (PDAC) & Rationale for Targeting PARP in PDAC

PDAC is the third leading cause of cancer related death in the United States (2018). Initial presentation of the disease is typically with metastasis, and the overall 5-year survival for all stages combined is 8%. Molecular analysis has revealed four subtypes of PDAC giving clinicians further insight into treating this deadly disease. One subtype that has been elucidated and termed "unstable" is significant for the presence of DNA damage repair deficiency and can be targeted by several old and emerging therapies. One such therapy that may be considered are PARP inhibitors.

There have been reports of responses seen to PARP inhibitors in individuals with pancreatic cancer, and there are clinical trials currently (NCT03140670, NCT02184195, NCT01585805) for this patient population. One PARPi (olaparib) was approved by the FDA in December 2019 for the treatment of BRCA1/2 mutated PDAC. Due to the relatively common DNA repair pathway mutations in PDAC tumors, PARP inhibition may be a potential therapeutic option in individuals with advanced PDAC with the HRD phenotype.

Development Plan for Stenoparib in PDAC

This study would be performed as an open, uncontrolled Phase II study of stenoparib in up to 30 advanced PDAC patients. Patients with predicted high likelihood of responding to stenoparib, after inclusion in the pre-screening protocol using the Stenoparib-DRP® companion diagnostic will be included in the study. In this study, a high likelihood of response to stenoparib will be defined as the patient having a Stenoparib-DRP® score of at least 80% or greater. However, this DRP® cutoff can be modified depending on the clinical outcome.

The study will be performed in accordance with the Simon two-stage design (Simon 1989). The patients will come to a screening visit within 2 weeks prior to first administration of stenoparib. Patients will receive a daily dose of 600 mg stenoparib as hard gelatin capsules administered in a 28-day cycle. The treatment will continue until disease progression or unacceptable toxicity. The clinical endpoint will be objective response rate (ORR), as determined by RECIST 1.1.

Patients will continue the treatment until the occurrence of: (i) disease progression, or (ii) unacceptable toxicity, or (iii) patient refusal/withdrawing of consent, or (iv) non-compliance to the protocol, or (v) physician decision to discontinue treatment, or treatment delay > 2 weeks (except in the case of perceived patient benefit). An End of Treatment visit will be conducted when administration of stenoparib is stopped. Patients with CR, PR or SD where treatment have been stopped will continue follow-up by phone every 12 weeks until death.

Anticipated clinical trials sites and Principal Investigators would include Dr. Dan Von Hoff (U.S.) and Dr. Deb Sarker (UK).

Development for Additional Indications

We have developed a protocol for a Phase II, open label clinical study to investigate anti-tumor effect and tolerability of stenoparib in docetaxel-pre-treated metastatic castration-resistant prostate cancer (mCRPC) patients selected by the Stenoparib-DRP® companion diagnostic. Patients would receive 600 mg stenoparib as single oral agent in a 21-days cycle in in mCRPC patients who progressed on AR-targeted therapy (abiraterone acetate, enzalutamide or investigational AR-targeted agent) and docetaxel-pre-treated metastatic castration-resistant prostate cancer patients selected by the Stenoparib-DRP® companion diagnostic. Up to 30 mCRPC patients with predicted high probability of response to stenoparib, as determined by a Stenoparib-DRP®) score of >80%, will be enrolled and treated. Anti-tumor effect of stenoparib is based on objective response rate defined as complete response (CR), partial response (PR) or stable disease (SD) of > 9 weeks according to RECIST 1.1 for patients with measurable disease and defined as stable disease > 9 weeks including PSA and bone metastases according to PCWG3. This Phase II trial would likely have trial sites in the U.S. and in the EU/Denmark.

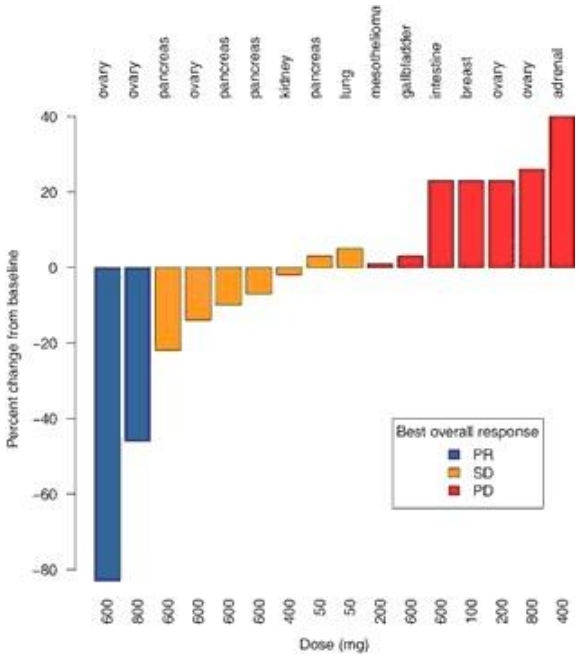
DRP® Companion Diagnostic for Stenoparib

We are developing stenoparib together with its validated DRP® companion diagnostic, which enables us to select the patients most likely to respond to the drug in our clinical trials. An Investigation Device Exemption (IDE) for our Stenoparib-DRP® was granted by the FDA (G180165) in 2018. The Stenoparib-DRP®, which comprises 414 expressed genes, was initially developed using a panel of 61 cancer cell lines (provided by Eisai) treated with stenoparib. This putative DRP® contains biomarkers that reflect the mechanism of action of PARP and Tankyrase inhibition by stenoparib, as well as capturing much unknown tumor biology, and is largely independent of BRCA mutation.

The putative Stenoparib-DRP®, developed through our DRP® platform using gene expression data from cancer cell line testing data, was retrospectively validated using biopsy materials from the Phase 1 trial of the drug (formerly E7449), sponsored by Eisai, that was conducted in the United Kingdom (UK) from 2012-2015 (clinicaltrial.gov number NCT01618136). Of 41 patients enrolled in the Phase 1 study, 35 had response assessment. Of these, 2 had PR (5% ORR) and 13 had SD. Biopsies and BRCA analysis were voluntary and available from 16, and 7 patients, respectively. Of the 16 patients with biopsies, 13 passed our QC in the lab and were assayed on the Affymetrix HG-U133Plus2 array.

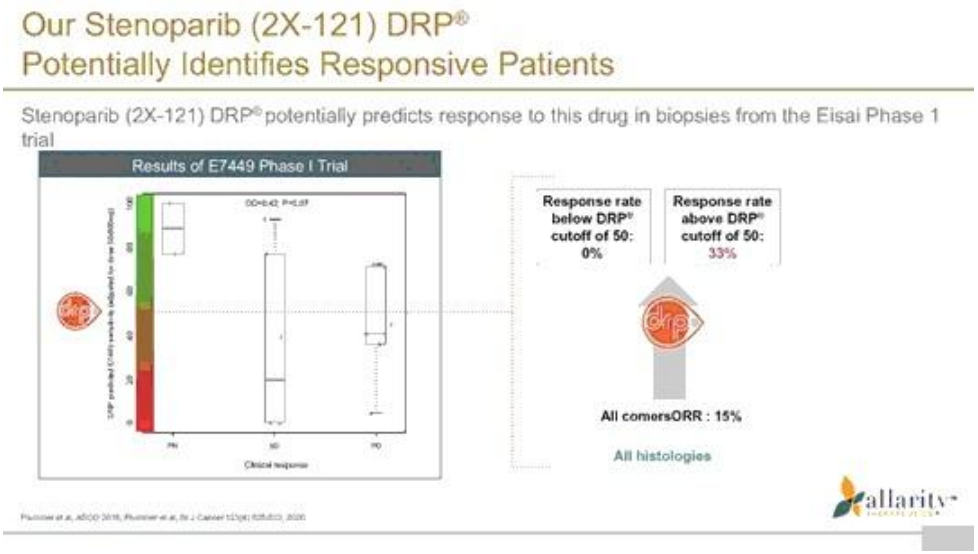
A statistical analysis plan was completed before initiation of retrospective blinded prediction of stenoparib sensitivity on the 13 samples.

Waterfall plot of 16 Phase 1 patients for which biopsies were available



Before blinded retrospective analysis of mixed histology biopsies from the Phase I trial of stenoparib, two crucial choices were made: 1) to use a reference population of 819 breast cancer biopsies, and 2) to use as cutoff the population median of the Phase 1 biopsies. Both choices turned out to be excellent, because the population median of the Phase 1 biopsies was very close to the population median of the breast cancer reference population, and when applied to the Phase 1 biopsies both medians separated the samples in identical populations with a clear difference in response rate and PFS.

It was decided that the breast cancer reference population with a cutoff of 50% would be used for the proposed Phase II trial. This has the added advantage of being the exact same parameters used for the blinded analysis of the Phase I trial. The only difference is that DRP has been locked and retrospectively validated between Phase I and proposed Phase II. The following figure shows the unblinded comparison of dose-adjusted predicted sensitivity to stenoparib and clinical response to stenoparib (the highest scoring SD patient is actually a long-term progression-free pancreatic cancer survivor (still alive at last check at 406 days, and progression-free at last evaluation at 321 days):



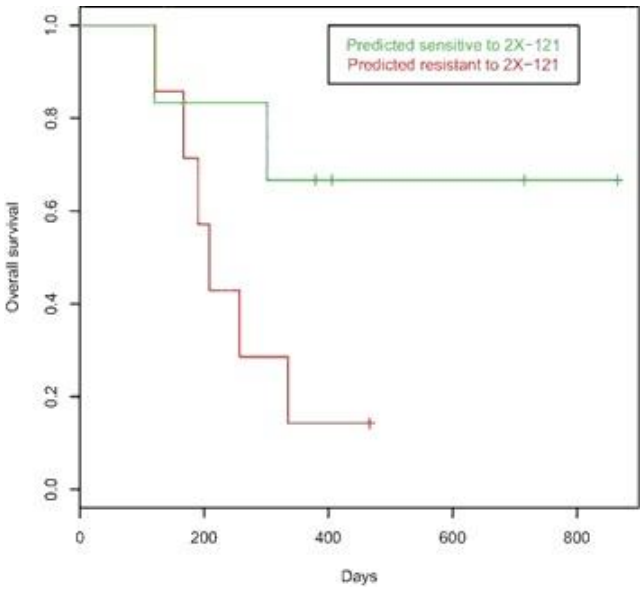
Clinical performance of the Stenoparib-DRP® at the pre-specified cutoff of 50 in ovarian cancer

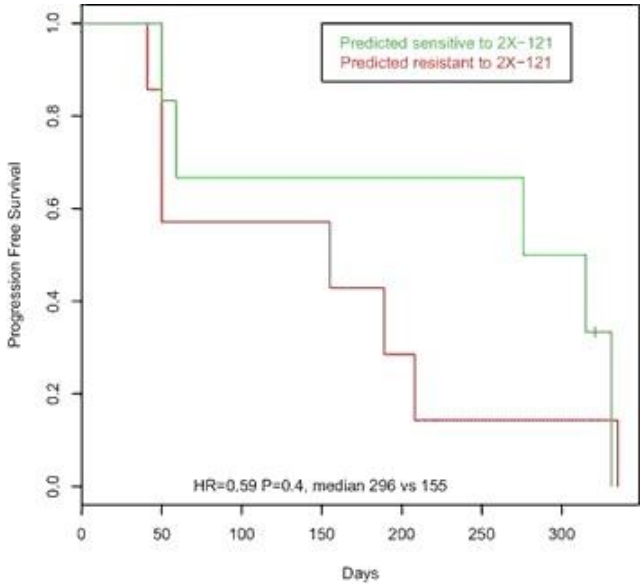
Ovarian only (N=3)	**Responders (PR)**	**Non-responders (SD+PD)**
DRP® positive (top 50%)	2	0
DRP® negative (bottom 50%)	0	1
Overall precision: 100% correct prediction		
Sensitivity: 100% of responders correctly predicted		
Specificity: 100% of non-responders correctly predicted		

Clinical performance of the Stenoparib-DRP® at the pre-specified cutoff of 50 for all histologies

All histologies (N=13)	**Responders (PR)**	**Non-responders (SD+PD)**
DRP® positive (top 50%)	2	4
DRP® negative (bottom 50%)	0	7
Overall precision: 69% correct prediction		
Sensitivity: 100% of responders correctly predicted		
Specificity: 64% of non-responders correctly predicted		

The following figures show Kaplan-Meier curves of overall survival (OS) and progression free survival (PFS) in two populations, those above a dose-adjusted cutoff of 50 (N=6), and those below a cutoff of 50 (N=7). The hazard ratio is 0.26 (P=0.04 one sided) and the median survival in the predicted resistant group (below cutoff) is 208 days. More than half of the patients remain alive in the group predicted sensitive.





Additionally, BRCA mutation status considered, but was only available for 7 patients in the trial (NCT01618136), of which 6 are BRCA mutated. Of these 6, 1 responded to stenoparib, giving a response rate of 1/6 or 16% in the BRCA mutated population. This equals the response rate observed in the unselected 13 patients analyzed with DRP® score. Thus, BRCA mutation does not appear to be a predictor of response in this small trial.

In sum, our retrospectively validated Stenoparib-DRP® companion diagnostic correctly identifies responder patients to stenoparib and we plan use this DRP® companion diagnostic for all of our clinical programs to advance stenoparib, including our ongoing Phase 2 ovarian cancer study.

Existing PARP Inhibitors and Our Opportunity

Numerous PARP inhibitors, including Lynparza® (olaparib), Rubraca® (rucaparib camsylate), Zejula® (niraparib) and Talzenna® (talazoparib tosylate) have been approved by the FDA for multiple oncology indications, including ovarian, breast, prostate, and pancreatic cancer. Sales of these FDA-approved PARP inhibitors were approximately $1.7 billion in 2019 and are forecasted to be over $7.0 billion in 2025, with Lynparza (olaparib) accounting for $1.2 billion and over $4.0 billion in the 2019 and 2025 totals, respectively.

Despite the commercial success of PARP inhibitors, broader adoption is limited by their high rates of GI and bone marrow toxicity which is largely a result of off-target cell killing. Adverse grade 3–4 events from this class of drugs include anemia, thrombocytopenia, neutropenia and alopecia. Other common adverse reactions include nausea, vomiting, diarrhea, fatigue, and decreased appetite.

We believe Stenoparib is distinguished among the PARP class of drugs by the following features and advantages:

- It is a dual inhibitor of Tankyrases 1 and 2, which provides a likely dual cancer cell killing mechanism by interference with Wnt signaling pathways and chromosomal telomerase maintenance and stability.
- It lacks myelotoxicity, a common limiting adverse event among PARP inhibitors, at the established MTD.
- It is resistant to P-glycoprotein (PgP) mediated export from target cancer cells, resulting in higher accumulation of drug in target cells.
- It can cross the Blood-Brain Barrier (BBB), enabling the potential treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and brain metastases from other body tumors, such as malignant breast cancer.

Additionally, the use of our Stenoparib-DRP® companion diagnostic to identify and treat only those patients most likely to respond to the drug (while excluding those patients most likely to be unresponsive to the drug), gives us a substantial advantage in increasing patient response rates, avoiding adverse events in patients that are not likely to benefit from our drug, and providing health economics advantages.

Furthermore, our DRP® for stenoparib identifies a broader group of potential responder patients than can be identified by the competitive biomarker approach of only assessing BRCA 1 and 2 mutation status in order to select and treat patients. The DRP® for stenoparib comprises 414 genes, including Wnt-beta-catenin and a number of DNA repair pathways, and thus is a broader assessment of the tumor responsiveness to the drug than determining mutation in one or two BRCA genes.

Overview of IXEMPRA® (microtubule inhibitor)

Mechanisms of Action

Ixabepilone (IXEMPRA®) is a semisynthetic derivative of epothilone B, with improved in vitro metabolic stability. It is a novel antineoplastic agent that stabilizes microtubule dynamics, resulting in blockade of cancer cells in mitosis during cell division, leading to cell death. Ixabepilone induces a distinct pathway of cellular apoptosis via activation of caspase-2, whereas other tubulin agents, such as the taxanes, act via caspase-9. Ixabepilone is a poor substrate for efflux transporters such as the multidrug resistance-related protein (MRP1) and P-glycoprotein (P-gp) that are involved in drug-resistance mechanisms. Epothilones have a tubulin-binding mode distinct from that of other microtubule- stabilizing agents. Ixabepilone's tubulin-binding mode affects the microtubule dynamics of multiple ®-tubulin isoforms, including the class III isoform of ®-tubulin (®-III tubulin), the expression of which has been implicated in clinical taxane resistance. As used in this section of this report describing our therapeutic candidate IXEMPRA®, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate IXEMPRA® may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate IXEMPRA® or our putative IXEMPRA®-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Ixabepilone has anti-tumor activity in vivo against a broad spectrum of tumor types, including tumors that overexpress P-gp and are resistant to multiple agents including taxanes, anthracyclines, and vinca alkaloids. Ixabepilone demonstrated synergistic in vivo activity in combination with capecitabine. In addition to direct anti-tumor activity, ixabepilone demonstrated antiangiogenic activity in vivo.

The nonclinical pharmacokinetic (PK) studies performed with ixabepilone were directed toward the preliminary assessment of the absorption, distribution, metabolism, and excretion of the drug. Ixabepilone was (a) orally bioavailable with bioavailability ranging from 8 to 40% in mice, rats, and dogs; (b) extensively distributed extravascularly; (c) moderately bound to serum protein; (d) extensively metabolized to many metabolites and the metabolite profile was similar among species including humans; I metabolized by CYP3A4/5; (f) cleared primarily via oxidative metabolism and then mostly excreted in the feces; (g) neither a CYP inhibitor nor a CYP inducer at clinically relevant concentrations.

Pre-Clinical Studies

The results from the in vitro cytotoxicity studies against extensive panels of human-tissue specific, taxane-sensitive and taxane-resistant (including MDR, ®-III tubulin over- expression, and tubulin mutation mechanisms), cancer cell lines demonstrate that ixabepilone has potent and broad-spectrum antineoplastic activity. The effectiveness of ixabepilone in vitro is paralleled by equally broad-spectrum activity observed in vivo. Ixabepilone demonstrated a broad spectrum of in vivo anti-tumor activity in taxane- sensitive and taxane-resistant human cancer xenograft models. Less frequent dosing schedules allowed higher doses of ixabepilone to be given and performed better than the more frequent dosing schedules. Against a total of 35 human tumor xenografts grown in mice, representing a wide array of tumor types, ixabepilone demonstrated anti-tumor activities, producing 1 LCK or greater anti-cancer activity in 33 of 35 tumors. Ixabepilone demonstrated the ability to overcome drug resistance due to the Pgp-mediated multidrug resistance (MDR) phenotype in vivo, reversing the MDR resistance of 2 established MDR models: the 16C/ADR breast carcinoma models and the HCT116/VM46 human colon carcinoma model. Ixabepilone also demonstrated anti-tumor activity both in vitro and in vivo against a human tumor model that over expresses MRP1 (Pat-7), producing in vitro IC90 values of 7.4 nM (compared with 150 nM for paclitaxel) and an in vivo activity of 2.9 LCK (compared with 0.8 LCK for paclitaxel).

Ixabepilone suppresses the dynamic instability of < ®-III microtubules and< ®-II microtubules. This is in contrast to paclitaxel which had no suppressive effect on the dynamic instability of < ®-III microtubules, but suppressed the dynamic instability of < ®-II microtubules. Thus, ixabepilone should be more effective than paclitaxel at inhibiting proper formation of the mitotic spindle and disrupting mitosis in tumor cells with high expression of ®-III tubulin. On this basis, ixabepilone is expected to be more active on tumors that are resistant to paclitaxel because of over expression of ®-III tubulin.

The in vitro and in vivo cardiovascular safety pharmacology studies conducted with ixabepilone indicated that it is unlikely that ixabepilone will affect electrocardiographic parameters at anticipated plasma concentrations in patients. Ixabepilone induced drug- related clinical signs consistent with peripheral neuropathy in rodents. In a comparative study in rats, ixabepilone and paclitaxel induced peripheral neuropathy that was similar in nature and characterized by decreases in sensory and motor maximal nerve conduction velocities and reductions in sensory and compound nerve-response amplitudes. There were no ixabepilone-related CNS or respiratory findings.

The combination of ixabepilone with a number of approved anticancer therapeutic agents produced anti-tumor activities that were markedly greater than the best achievable responses from the individual single agents administered at their MTD alone. Such therapeutic synergism was observed with capecitabine, cetuximab, bevacizumab, or trastuzumab. Modest anti-cancer activity enhancement was observed when combined with irinotecan. However, no therapeutic advantage was observed when combined with gefitinib, gemcitabine, or paclitaxel).

The pharmacokinetic characteristics of ixabepilone in mice, rats, and dogs are comparable to those in humans, indicating the acceptability of those species for the toxicological assessment of ixabepilone. Serum protein binding of ixabepilone was moderate in rat, dog, and human serum.

In both animals and humans, ixabepilone was extensively metabolized via oxidative metabolism and eliminated mainly through fecal excretion. Only metabolites formed through oxidation of ixabepilone were found in animals and humans. All of the metabolites identified in humans were present in the species used in the toxicological evaluation of ixabepilone. The total amount of metabolites, as a percentage of the total radioactive dose in excreta (urine and feces), was high in all species studied. The known degradants of ixabepilone, BMS-249798, BMS-326412, and BMS-567637, were detected in plasma and excreta across species. The metabolite and degradant profiles in plasma are similar among humans, rats, and dogs, with unchanged ixabepilone being the most abundant drug-related component. Although the pharmacologic activity of individual metabolites is not known, a mixture of in vitro metabolites of ixabepilone was not active in in vitro cytotoxicity assays.

Ixabepilone is a substrate of CYP3A4 and CYP3A5. The PK of ixabepilone may be affected by the co-administration of agents that inhibit or induce CYP3A4. Ixabepilone is an inhibitor of CYP3A4, but it does not inhibit any of the other common CYP enzymes. Ixabepilone is not an inducer of CYP enzymes in vitro. Based on the efficacious plasma concentration and the in vitro inhibition and induction characteristics, ixabepilone is not expected to affect the PK of co-administered agents that are metabolized by CYP enzymes.

Nonclinical toxicity studies identified the principal target-organ, genetic, and developmental toxicities of ixabepilone. Ixabepilone principally affected tissues having rapid-cell division, including the GI, hematopoietic and lymphoid systems, and the male reproductive system. In mice and rats, peripheral neuropathy was also a prominent effect. Ixabepilone-induced toxicities were generally reversible following a 1-month, post dose recovery period, except for delayed testicular effects in rats and dogs and peripheral neuropathy in rats and mice. In rats, females were generally more severely affected than males, consistent with higher systemic exposures in females. When administered daily for 2 weeks or once every 21 days for 6 or 9 months, ixabepilone toxicity was similar to that observed in the single-dose, 5-day, and 1-month intermittent dose (QWx5) toxicity studies, with the exception of loss of bony trabeculae of the femoral growth plate in rats, which was not seen in any other studies. The increased growth-plate thickness observed in the rat is not likely to be a safety risk for the treatment of cancer in adult human populations, because in the rat, unlike humans, the growth plates do not fuse upon reaching sexual maturity.

Ixabepilone was not mutagenic in the Ames bacterial mutation assay. Ixabepilone was not clastogenic in the in vitro cytogenetics assay in primary human lymphocytes, but did increase the incidence of polyploid lymphocytes at high concentrations. However, ixabepilone was clastogenic (induction of micronuclei) in the in vivo rat micronucleus study. These findings were similar to other microtubule-stabilizing drugs and result in a benefit-risk analysis in the indicated patient population that supports the use of these drugs for a cancer indication. Ixabepilone did not affect mating or fertility in a rat reproduction study, and induced embryo-fetal toxicity in rats and rabbits only at doses that also caused maternal toxicity. Since clinical administration of ixabepilone occurs at doses associated with minimal to mild clinical side effects, administration during pregnancy may pose a risk for fetal toxicity.

The single- and repeat-dose IV toxicity studies with ixabepilone adequately predicted the clinical toxicities that were subsequently observed in humans. In both experimental animals and humans, ixabepilone toxicities were primarily manifested in the GI, hematopoietic, and peripheral nervous systems. These effects were expected and consistent with the toxicity produced by other microtubule-stabilizing anticancer drugs. In general, the nonclinical species were more sensitive to ixabepilone-induced toxicity than human subjects. In vitro, vincristine and paclitaxel were more potent than ixabepilone in inhibiting mitochondrial axonal transport in fetal dorsal root ganglion culture, whereas in mice and rats, paclitaxel and ixabepilone induced axonal degeneration or decreases in nerve conduction velocities that were similar in nature and severity. Based on the intended use of ixabepilone in treating advanced breast cancer and other solid tumors, the scope and results of the nonclinical pharmacology, pharmacokinetics, toxicity, and exposure studies support the continuous IV administration of ixabepilone on a once every 21-day cycle in this patient population.

Prior Clinical Trials

Ixabepilone (IXEMPRA®) was originally developed through Phase 3 clinical trials and brought to market by Bristol-Myers Squibb (BMS). In Phase 1 clinical trials of ixabepilone as monotherapy, objective responses were demonstrated in a variety of tumor types, including breast, colon, head and neck, ovarian, endometrial, vulvar, and peritoneal cancers, melanoma, and non-Hodgkin's lymphoma.

Dose-limiting toxicities observed in Phase 1 clinical trials of ixabepilone as monotherapy included sensory neuropathy, neutropenia, myalgia, and fatigue. Adverse events (AEs) reported in Phase 1 studies in which ixabepilone was used in combination with other chemotherapy agents (*e.g.*, carboplatin [CA163007], doxorubicin [CA163008], and irinotecan [CA163025]) were similar qualitatively and in frequency to that observed in monotherapy studies; no toxicities unique to combination therapies were reported.

The PK of ixabepilone are linear, based on consistent total body clearance and apparent terminal elimination half-life across doses from 15 mg/m^2 to 57 mg/m^2. The coadministration of ketoconazole increases ixabepilone exposure in patients. Ketoconazole or other potent CYP3A4 inhibitors such as itraconazole, clarithromycin, atazanavir, nefazodone, saquinavir, telithromycin, ritonavir, amprenavir, indinavir, nelfinavir, delavirdine, or voriconazole should be avoided. If alternative treatment cannot be administered, a dose adjustment should be considered, and patients should be monitored closely for acute toxicities. Pharmacokinetics results indicate that exposure to ixabepilone is increased by 22%, 30%, and 81% in patients with mild, moderate, or severe hepatic dysfunction, respectively. After coadministration of ixabepilone and capecitabine, PK differences are minor and are not expected to affect the toleration profile or anti-cancer activity of either ixabepilone or capecitabine.

In a Pha½1/2 clinical trial (CA163031) evaluating ixabepilone in combination with capecitabine for the treatment of metastatic breast cancer (MBC), common toxicities included fatigue, nausea, hand-foot syndrome, and sensory neuropathy.

Phase 2 clinical trials demonstrated the activity of ixabepilone in advanced breast cancer, non- small cell, small-cell lung cancers, prostate cancer, gastric, and other malignancies. The most notable toxicities reported in Phase 2 trials of ixabepilone as monotherapy are peripheral neuropathy, neutropenia, myalgia, arthralgia, alopecia, and fatigue. The peripheral neuropathy has been predominantly sensory, cumulative in nature, and reversible upon discontinuation of ixabepilone.

In a large, international Phase 3 clinical trial (CA16304612) in patients with taxane-resistant and anthracycline-pre-treated or resistant metastatic or locally advanced breast cancer, ixabepilone in combination with capecitabine resulted in a statistically significant improvement in progression-free survival (PFS) and response rate (RR) compared to capecitabine monotherapy, per the independent radiology review committee (IRRC). Another similar, large, multicenter, international randomized, Phase 3 clinical trial (CA16304813) compared ixabepilone in combination with capecitabine to capecitabine alone in patients with metastatic or locally advanced breast cancer previously treated with anthracyclines and taxanes. CA163048, in which OS was the primary endpoint, demonstrated statistically significant and clinically meaningful superiority in PFS and improved RR over capecitabine alone that translated into a modest improvement in overall survival (OS) favoring the combination which did not meet statistical significance. These studies were conducted in 29 countries, with more than 300 clinical investigators and over 1,200 treated patients. The studies included dozens of trial sites spread throughout European countries.

Based on the Phase 3 clinical trials, ixabepilone was approved by the FDA in 2007 for the treatment of metastatic breast cancer in the following settings:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.

- As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

Despite the positive Phase 3 clinical trial results leading to approval of Ixabepilone in the U.S., the drug has not yet been approved in Europe, due to the EMA's determination of insufficient risk-benefit for Ixabepilone under the European socialized medicine pricing structure. Subsequently, IXEMPRA® was out-licensed to us to pursue approval in Europe using our IXEMPRA®-DRP®-selected patient population in order to show statistical significance in further clinical trials that the therapeutic candidate has sufficient risk-benefit under European standards to support a pricing structure that would be appropriate.

As of March 2009, more than 3,144 patients have been treated with ixabepilone in BMS- sponsored Phase 1, 2, and 3 clinical trials. In addition, the Cancer Therapy Evaluation Program (CTEP) program of the U.S. National Cancer Institute (NCI) independently conducted a number of clinical studies. These studies demonstrated the activity of ixabepilone in a variety of tumor types, including breast, hormone-refractory prostate, pancreatic, renal cell, non-small cell and small-cell lung cancers, and non-Hodgkin's lymphoma.

DRP®-Guided Phase 2 Clinical Trial

We are currently conducting a DRP®-guided, Phase 2, open label, single arm clinical trial — in Europe — to investigate the toleration and anti-cancer activity of IXEMPRA® as monotherapy in patients with metastatic or locally advanced breast cancer after failure of an anthracycline, a taxane, and capecitabine. This clinical trial, with an enrollment target of 60 IXEMPRA®-DRP®-selected patients, is being conducted at numerous sites in Europe, including Belgium, England, Finland, Poland and Germany. Patients are selected by using the putative IXEMPRA®-DRP® companion diagnostic at a cut-off score of sixty-seven percent (67%), and IXEMPRA® is administered at 40 mg/m^2 infused intravenously over 3 hours every 3 weeks (in accordance with the U.S. label of the drug). Dose reduction is required in certain patients with elevated AST, ALT, or bilirubin. The trial was initiated in April 2021. Thus far, several DRP®-selected patients have been enrolled and dosed in the trial, despite delays resulting from the ongoing COVID-19 pandemic. The clinical trial's goal is to provide a superior clinical benefit to DRP®-selected patients receiving IXEMPRA®, as compared to historical clinical data from breast cancer patients treated with IXEMPRA® but not selected with the putative DRP® companion diagnostic for the drug. Since the Phase 2 clinical trials currently are ongoing, data from these trials is not yet available to report. We have entered into a cost sharing arrangement with Smerud Medical Research International, our CRO for the Phase 2 clinical trial, where Smerud has agreed to accept a single digit share of any proceeds we generate from the commercialization or disposition of IXEMPRA® in exchange for the anticipated costs our CRO would incur in conducting the Phase 2 clinical trial up to an agreed upon maximum amount of costs incurred.

Overview of Metastatic Breast Cancer

Breast cancer is the most frequent malignancy in women worldwide, and the second most common cancer worldwide, with an estimated 1.8 million new diagnoses per year. In the U.S., breast cancer has the highest prevalence among all cancers. The Surveillance, Epidemiology, and End Results ("SEER") Program at National Cancer Institute estimates that in 2020, there will be 276,000 new cases of breast cancer in the U.S. alone, and more than 40,000 deaths. Treatment options for breast cancer depend on many factors, including the stage of cancer. Breast cancer is a heterogeneous disease which is grouped into several clinical subtypes based on the expression of three proteins: ER, progesterone receptor ("PR") and HER2. Both ER and PR are hormone receptors, and tumors that express either of these receptors are referred to as hormone receptor-positive. The American Cancer Society estimates that approximately 75-80% of all breast cancers express estrogen receptor ("ER+") highlighting the central role of ER signaling in driving a large majority of breast cancer. Although early-stage non-metastatic disease is curable in approximately 70-80% of patients, advanced breast cancer with distant organ metastases is considered incurable with currently available therapies. Advanced breast cancer comprises inoperable locally advanced breast cancer, which has not spread to distant organs, and metastatic (stage IV) breast cancer; common sites of spread are bone, lungs, liver, and brain. Currently, it is a treatable but virtually incurable disease, with metastases including to the brain being the cause of death in almost all patients, and a median overall survival of two to three years. Patients with metastatic breast cancer receive treatments that aim to relieve their symptoms and to prolong quality-adjusted life expectancy.

Treatment often continues until the cancer starts growing again or until side effects become unacceptable. If this happens, other drugs might be tried. The types of drugs used for stage IV (metastatic) breast cancer depend on the hormone receptor status and the HER2 status of the cancer. Women with hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive) cancers are often treated first with hormone therapy (tamoxifen or an aromatase inhibitor). This may be combined with a targeted drug such as a CDK4/6 inhibitor, everolimus or a PI3K inhibitor. Women who haven't yet gone through menopause are often treated with tamoxifen or with medicines that keep the ovaries from making hormones along with other drugs. Because hormone therapy can take months to work, chemo is often the first treatment for patients with serious problems from their cancer spread, such as breathing problems. Chemotherapy is the main treatment for women with hormone receptor-negative (ER-negative and PR-negative) cancers. These breast cancers are either HER2 positive or triple negative.

Trastuzumab (Herceptin®) may help women with HER2-positive cancers live longer if it's given along with chemo or with other medications such as hormonal therapy or other anti-HER2 drugs. Pertuzumab (Perjeta®), another targeted drug, might be added as well. Other options might include targeted drugs such as lapatinib (which may be given with certain chemo drugs or hormone therapy) or ado-trastuzumab emtansine (Kadcyla®). For HER2-negative patients, treatment depends on specific gene mutation status. Women who have a BRCA mutation are typically treated with chemotherapy (and hormone therapy, if the cancer is hormone receptor-positive). An option after getting chemotherapy is treatment with a PARP inhibitor, such as olaparib or talazoparib. Women who have a PIK3CA mutation are typically treated with alpelisib, a targeted PI3K inhibitor that can be used along with fulvestrant to treat postmenopausal women with advanced hormone receptor positive breast cancer.

For women that have triple-negative breast cancer (TNBC) — HER2 negative, ER negative, and PR negative — the immunotherapy dug atezolizumab (Tecentriq®) if often used, along with albumin-bound paclitaxel (Abraxane®) in patients with advanced triple-negative breast cancer with tumors expressing the PD-L1 protein (which is expressed is about 20% of triple-negative breast cancers.) For women with TNBC and a BRCA mutation whose cancer no longer responds to common breast cancer chemo drugs, platinum drugs (like cisplatin or carboplatin) may be considered.

According to the current estimates, the global therapeutics market for treatment of breast cancer was valued at over $19 billion in 2018 and is expected to reach over $40 billion by the year 2026, at a CAGR of 10.6%. By way of example, in 2019, worldwide sales for endocrine and targeted therapies treating ER+ breast cancer patients totaled $9.6 billion. Given the incidence rate and cost of treatment, by 2027 the market size for adjuvant therapy, first line treatments and second line treatments could total $25 billion, $8 billion and $4 billion, respectively. Accordingly, the potential market for treatment of mBC, including treatment of brain metastases (for which there is currently no approved therapy) is large and growing.

Rationale for Targeting Microtubules in mBC

IXEMPRA® is approved and on market in the U.S. as third- or fourth-line treatment of metastatic breast cancer in the following settings:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.

- As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

Accordingly, the clinical benefit of IXEMPRA®, a microtubule inhibitor, in these patient groups is already established. We seek to gain approval of this drug in Europe, for the same mBC patient groups, in connection with our putative IXEMPRA®-DRP® companion diagnostic, used to select and treat the most likely responder patients for the drug, in order to yield a superior therapeutic benefit in selected patients. Further, use of our putative DRP® companion diagnostic is expected to provide an improved benefit versus risk ratio, which we believe should support an EMA approval. IXEMPRA® was previously rejected by the EMA on basis of the risk versus benefit ratio.

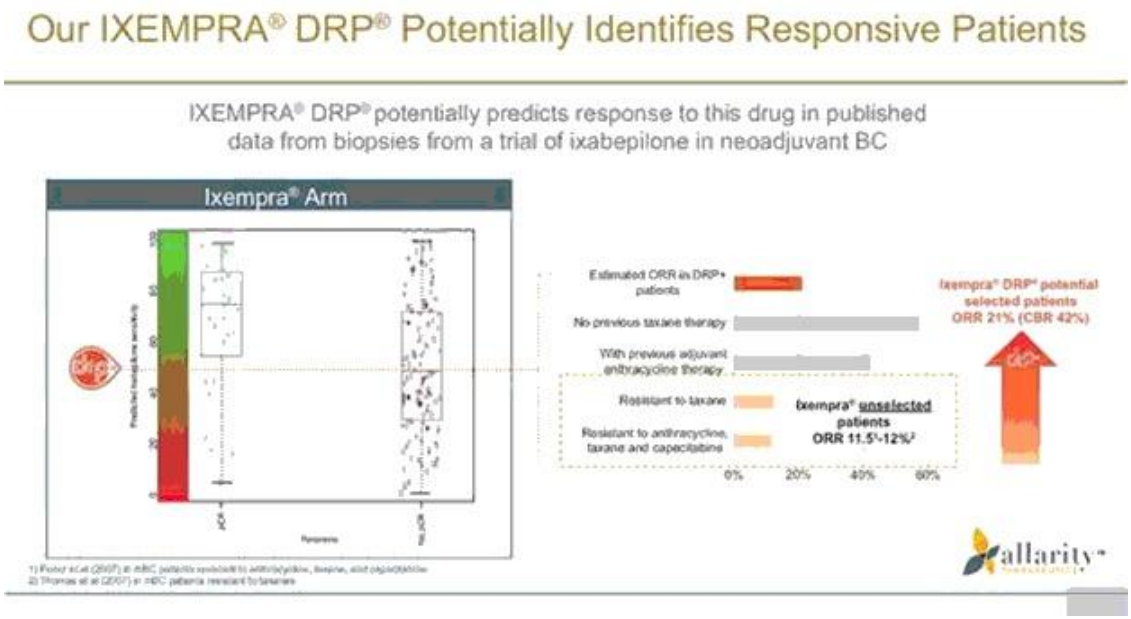
Future Opportunities & Development Plans for IXEMPRA®

Potential Development for Neoadjuvant mBC Setting

Since the retrospective validation of the IXEMPRA®-DRP® companion diagnostic showed a 58% increase in complete remission of patients treated with IXEMPRA® (see below) as adjuvant therapy, there is a potential to expand the IXEMPRA® drug plus a DRP® companion diagnostic combination to this setting as an attractive alternative to the commonly used paclitaxel. The neoadjuvant mBC setting is a substantially larger market opportunity than the third- or fourth-line mBC setting.

DRP® Companion Diagnostic for IXEMPRA®

We are developing IXEMPRA® together with its retrospectively validated DRP® companion diagnostic, which we believe enables us to select the patients most likely to respond to the drug in our clinical trials. Our Phase 2 clinical trial protocol, including use of the putative IXEMPRA®-DRP® companion diagnostic is in process of being approved by the regulatory agencies in the countries where we are conducting the clinical trial, and is already approved for use in clinical trials in Belgium, Finland, UK and Poland. The putative IXEMPRA-DRP® companion diagnostic, which comprises 198 expressed genes, was initially retrospectively validated using gene expression data from patient biopsies in the prior Phase 2 clinical trial of ixabepilone in neoadjuvant breast cancer setting that was conducted by BMS (NCT00455533). In retrospective analysis of this trial, patients selected with our putative IXEMPRA®-DRP® companion diagnostic was observed to have a 58 percent (58%) increase in complete remission when compared to randomly selected patients treated with ixabepilone.



In sum, we believe our retrospectively validated putative IXEMPRA®-DRP® companion diagnostic accurately and reliably identifies responder patients to this drug, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance IXEMPRA®, including our ongoing Phase 2 clinical trial for mBC.

Existing Microtubule Inhibitors & Our Opportunity

A number of microtubule inhibitors are approved and on market for the treatment of multiple cancer types. These approved drugs include docetaxel (Taxotere®), eribulin (Halaven®), ixabepilone (IXEMPRA®), paclitaxel (Taxol®, Abraxane®), and vinorelbine (Navelbine®). Docetaxel, paclitaxel, and albumin-bound paclitaxel are also called taxanes. Currently marketed microtubule inhibitors have generated several $billions of sales in the past few years. For example, sales of Halaven® (Eisai) alone were about $400 million in 2019, and sales of vinorelbine exceeded $110 million in 2018. The following table (2019) summarizes many of the approved microtubule inhibitors:

Drug	Main indications	Dose	Combinations
Vinblastine 1961*	Hodgkin's disease, non-Hodgkin lymphoma, histiocytic lymphoma, mycosis fungoides, testis, Kaposi's sarcoma, choriocarcinoma, breast, kidney	3.7 mg/m^2 – 18.5 mg/m^2	Monotherapy, mechlorethamine, doxorubicin, vincristine, bleomycin, etoposide, dacarbazine, brentuximab, cisplatin, ifosfamide, methotrexate, mitomycine
Vincristine 1963*	Leukemias, lymphomas, myeloma, breast, lung, head & neck, sarcomas, Wilms' tumor, neuroblastoma, retinoblastoma, medulloblastoma,	0.8 mg/m^2 – 2 mg	Monotherapy, doxorubicin, carboplatin mechlorethamine, vinblastine, bleomycin, etoposide, cyclophosphamide, procarbazine, topotecan, dactinomycin, leucovorin, actinomycin D
Vindesine 1982***	ALL, CML, melanoma, breast	3 mg/m^2 – 4 mg/m^2	Monotherapy, cisplatin
Vinorelbine 1994*	NSCLC, Hodgkin's disease, non-Hodgkin lymphoma, rhabdomyosarcoma, Wilm's tumor, neuroblastoma	25 mg/m^2 – 30 mg/m^2	Monotherapy, cisplatin
Vinflunine 2009**	Urothelial carcinoma	280 mg/m^2 – 320 mg/m^2	Monotherapy
Vincristine Liposomal 2012*	Philadelphia chromosome-negative ALL	2.25 mg/m^2	Monotherapy
Paclitaxel 1992*	Ovarian, breast, lung, gastric, Kaposi's sarcoma	100 mg/m^2 – 210 mg/m^2	Monotherapy, cisplatin, doxorubicin
Docetaxel 1996*	Breast, lung, prostate, gastric, head & neck	75 mg/m^2 – 100 mg/m^2	Monotherapy, cyclophosphamide, cisplatin, 5-fluorouracil
Nab-Paclitaxel 2005*	Breast, lung, pancreas	100 mg/m^2 – 260 mg/m^2	Monotherapy, carboplatin, gemcitabine
Cabazitaxel 2010*	Prostate	20 mg/m^2 – 25 mg/m^2	Monotherapy
Ixabepilone 2007*	Breast	40 mg/m^2	Capecitabine

Anti-tubulin agents first approved by FDA (*), EMA (**) or in other countries (***). ALL: acute lymphoblastic leukemia; CML: chronic myelogenous leukemia; NSCLC: non-small-cell lung carcinoma

According to the National Comprehensive Cancer Network (NCCN) guidelines for treatment of metastatic breast cancer, in the second line metastatic breast cancer (mBC) setting, for patients who are HER2 negative, ixabepilone in combination with capecitabine is a therapeutic option, along with other microtubule inhibitors, such as eribulin, cyclophosphamide, docetaxel, and epirubicin. The choice of a particular microtubule therapeutic is made by the treating oncologist, and the current lack of suitable companion diagnostics to guide therapy selection has hampered the introduction of personalized medicine to this patient group. Our current clinical program for ixabepilone in metastatic breast cancer is focused on a third-line monotherapy in patients selected with the IXEMPRA®-DRP® companion diagnostic.

Despite the success of microtubule inhibitors as a class in the treatment of cancer, the expanded use of these drugs has been limited by certain toxicities, that include neutropenia and neurotoxicity, and the development of tumor resistance to the drugs after long-term use. For example, among taxaIive patients, primary resistance to taxanes is a critical factor for disease progression. More than one-third of patients with metastatic breast cancer do not respond to first-line anthracyclines or taxanes. Taxane resistance rates of up to 55% in anthracycline-pre-treated patients and up to one-third in anthraIne-naive patients have been reported. Second-line, the same spectrum of outcomes can be expected.

Drug resistance is attributed to heterogeneity of tumors. Each patient has his/her own tumor with different characteristics and therefore different therapy outcomes. The variabilities include but are not limited to different genetic, epigenetic, transcriptomic and proteomic properties. The genotypic changes include mutations, gene amplifications, deletions, chromosomal rearrangements, transpositions of the genetic elements, translocations and microRNA alterations. Genomic instability generates a great level of intercellular genetic heterogeneity in cancer.

We believe that our microtubule inhibitor, IXEMPRA®, together with its DRP® companion diagnostic, can overcome many of the limitations of current microtubule inhibitors and has the potential to be a leading drug in its class that can succeed and compete in the marketplace for the treatment of mBC, and potentially other indications. The use of the IXEMPRA®-DRP® companion diagnostic to select and treat only those mBC patients most likely to respond to the drug (while excluding treatment of likely non-responders) can mitigate toxicity events in non-responder patients, while increasing therapeutic benefit in the identified responder patient population. The success of our IXEMPRA® program will establish the ability of our DRP® platform to expand oncology markets for approved cancer therapeutics through a personalized medicine approach using DRP® companion diagnostics.

Secondary Therapeutic Programs

Overview of our DRP® companion diagnostic for LiPlaCis® (targeted, liposomal cisplatin)

Mechanisms of Action

Cisplatin (or cisplatinum or *cis*-diamminedichloroplatinum (II)) is a chemotherapeutic drug that has been used, since the 1970s, in the treatment of various types of human cancers such as ovarian, lung, head and neck, testicular and bladder. Cisplatin has demonstrated anti-cancer activity against various types of cancers such as germ cell tumors, sarcomas, carcinomas as well as lymphomas. The mechanism of action of cisplatin has been associated with ability to crosslink with the urine bases on the DNA to form DNA adducts, preventing repair of the DNA leading to DNA damage and subsequently induces apoptosis (programmed cell death) within cancer cells. However, the drug exhibits certain level of resistance including increased repair of the damaged DNA, reduction in the accumulation of the drug intracellular and cytosolic inactivation of cisplatin.

The drug is also characterized by various toxic side effects including nausea, nephrotoxicity, cardiotoxicity, hepatotoxicity and neurotoxicity. Due to various side effects as well as drug resistance, other anti-cancer drugs that contain platinum such as carboplatin and oxaliplatin, among others, have been used in combination with cisplatin in chemotherapeutic treatment of cancer. In addition to the cytotoxic effects, cisplatin has immunosuppressive and radio-sensitizing properties. As used in this section of this report describing our therapeutic candidate LiPlaCis®, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate LiPlaCis® may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate LiPlaCis® or our putative Cisplatin-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

LiPlaCis® is a novel, targeted liposomal formulation of the anti-cancer drug cisplatin. Liposomes are closed spherical vesicles, having an interior aqueous space entrapped by a bilayer lipid membrane. LiPlaCis® liposomes have cisplatin encapsulated in the interior aqueous space of the liposomes and the bilayer membrane is constituted by 3 phospholipids. The use of liposomes as drug carriers has been limited due to the rapid clearance of these carriers from the blood stream by the reticuloendothelial system. The addition of polyethylenglycol (PEG) polymers to the surface of the liposomes leads to reduced clearance rates. As a result, the use of liposomes is now recognized as a promising strategy for tumor-targeted drug delivery. Due to the leaky tumor vasculature and the incomplete lymphatic drainage system of tumors, long circulatory liposomes may be preferentially trapped and therefore accumulate in cancer tissues. The preferential entrapment and accumulation of the liposomes in the cancer tissue is also known as the enhanced permeability and retention effect (EPR-effect). Because of the trapping of liposomes, significantly more drug substance is present at the site of the tumor compared to administration of plain drug products.

However, it has also been realized that the degradation of liposomes and release of the encapsulated drug(s) after the liposomes accumulate in the tumor are critical elements to the success of liposomal drug delivery. This is the case for hydrophilic drugs such as cisplatin, which do not readily diffuse across the liposomal membrane. Such hydrophilic drugs require that tumor-specific degradation of the liposomal carrier takes place before the drug can be released and exert its cytotoxic action on the cancer cells. In fact, the absence of a trigger mechanism in the tumor tissue was proposed as the explanation for the lack of anti-tumor activity in clinical trials using cisplatin containing Stealth® liposomes (SPI-077) (PEGylated liposomes). In these studies, a high level of cisplatin was found in the tumor tissue inside the liposomes, but it was not bioavailable.

LiPlaCis® includes a tumor-specific targeting mechanism on the surface of its liposomes, which triggers the release of cisplatin specifically in tumor tissue. Secretory sPLA2 is a small secreted and phospholipid-degrading enzyme, which is overexpressed in cancer tissue compared to normal tissue. Until now, 10 catalytically active isoforms of sPLA2 have been identified, of which the Group II sPLA2 isoform seems to be the most predominant form in cancer. In normal tissue, Group II sPLA2 has been found to be expressed in cartilage, digestive tract (stomach, duodenum, jejunum, ileum and colon), and in prostate-, parotid- and lacrimal glands. This enzyme breaks down the LiPlaCis® once it accumulates in the cancer tissue due to the EPR-effect. The lipid composition of the LiPlaCis® is designed to be specifically susceptible to degradation by sPLA2. This leads to tumor-specific release of the encapsulated drug substance in the target tissue. sPLA2 has shown to be overexpressed in a wide range of tumors such as stomach, breast, gastric, liver, lung and pancreatic cancers. It has been shown that sPLA2 expression is increased with advancing stage of cancer disease and that enhanced expression of sPLA2 may be related to tumor progression.

LiPlaCis® enables the targeted transport of high concentrations of encapsulated anti-cancer drugs to cancer tissue. After IV administration, LiPlaCis® will naturally extravasate and accumulate in the extracellular space of the tumor tissue. The secretion of sPLA2 into the extracellular space of the cancer tissue provides further support to the overall concept of achieving a tumor-specific degradation of the LiPlaCis® after extravasation. The targeted delivery of cisplatin to tumors that is achieved by LiPlaCis® has the benefits of transporting this mutagenic and toxic chemotherapeutic to cancer cells while avoiding exposure to healthy cells. The tumor-specific degradation of the liposomal drug carriers by overexpressed sPLA2 offers a novel way to achieve a targeted and triggered release of the encapsulated drugs in the cancer tissue without any prior knowledge of the position and size of the tumor, *e.g.* undetected metastases.

DRP® Companion Diagnostic for LiPlaCis®

LiPlaCis® is being clinically developed by Chosa ApS together with our prospectively validated DRP® companion diagnostic for cisplatin, which enables Chosa to select the patients most likely to respond to the drug in their clinical trials. In August 2019, the FDA approved our IDE application for use of our Cisplatin-DRP® companion diagnostic in a planned pivotal Phase 3 clinical trial of LiPlaCis® in mBC. In June 2019, we announced that the FDA had provided feedback on our pending IND application and proposed pivotal Phase 3 clinical trial in mBC using the Cisplatin-DRP®. The Cisplatin-DRP®, which comprises 205 expressed genes, was initially developed using gene expression data from the National Cancer Institute NCI60 panel of cancer cell lines. We have out-licensed our putative Cisplatin-DRP® companion diagnostic to Chosa as described above.

Our putative Cisplatin-DRP® companion diagnostic was retrospectively validated in two non-small cell lung cancer (NSCLC) cohorts. Molecular prediction of adjuvant cisplatin anti-cancer activity in NSCLC showed a significant prediction at 3-year survival from surgery in univariate (HR = 0.138 (95% CI:0.035 – 0.537), p = 0.004) and multivariate analysis (HR = 0.14 (95% CI:0.030 – 0.6), p = 0.0081).

In sum, we believe our retrospectively and prospectively validated putative LiPlaCis®-DRP® companion diagnostic accurately and reliably identifies responder patients to LiPlaCis®, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance LiPlaCis®, including the planned, expanded Phase 2 clinical trial for mBC being advanced by our licensee, Chosa ApS.

Overview of 2X-111 (targeted, liposomal doxorubicin)

Mechanisms of Action

2X-111 is an advanced, targeted liposomal formulation of doxorubicin, one of the world's most widely used chemotherapies. The specific 2X-111 formulation, which exploits a unique, glutathione enhanced PEG-liposomal delivery system, allows the drug to cross the blood-brain barrier (BBB), thereby enabling the treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and secondary brain tumors that originated from cancers outside the brain, such as metastatic breast cancer.

Doxorubicin is a type of chemotherapy drug called an anthracycline. It slows or stops the growth of cancer cells by blocking an enzyme called topo isomerase 2, which is necessary for DNA replication. Topo isomerase 2 is an enzyme that cuts both strands of the DNA helix simultaneously in order to manage DNA tangles and supercoils. Cancer cells need this enzyme to divide and grow. Doxorubicin is approved and in use for a number of cancer types, including breast cancer, bladder cancer, Kaposi's sarcoma, lymphoma, and acute lymphocytic leukemia. It is often used together with other chemotherapy agents.

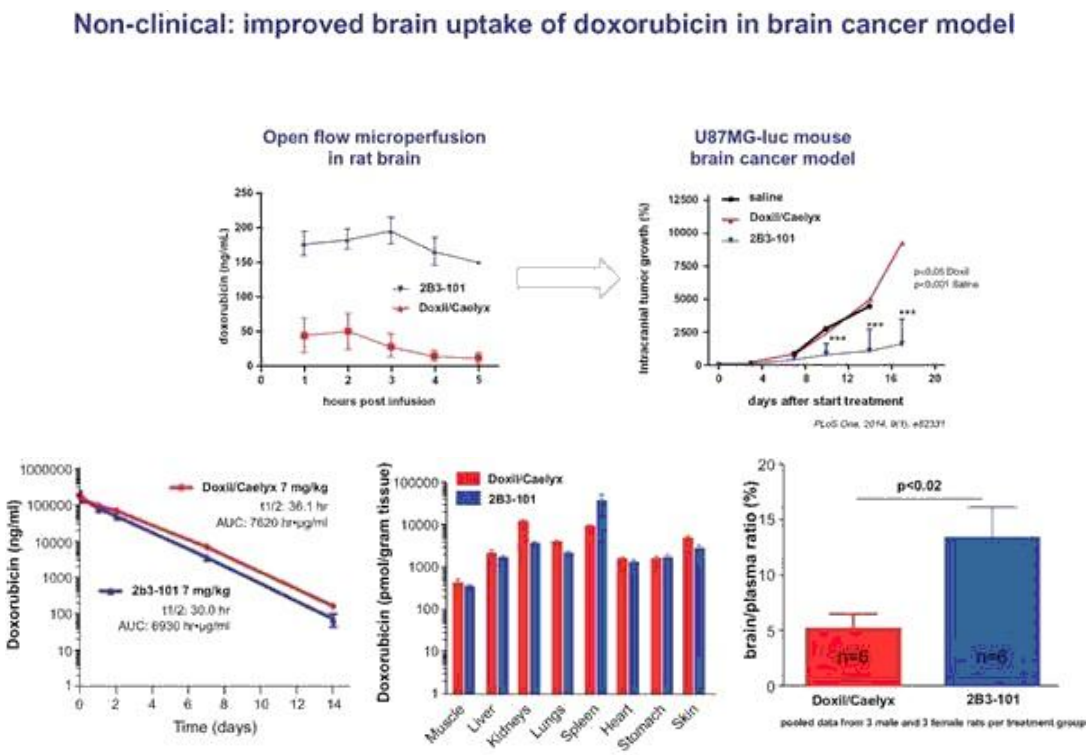
Liposomes are closed spherical vesicles, having an interior aqueous space entrapped by a bilayer lipid membrane. 2X-111 liposomes have doxorubicin encapsulated in the interior aqueous space of the liposomes and the bilayer membrane is constituted by 3 phospholipids. The use of liposomes as drug carriers has been limited due to the rapid clearance of these carriers from the blood stream by the reticuloendothelial system. The addition of polyethylenglycol (PEG) polymers to the surface of the liposomes leads to reduced clearance rates. As a result, the use of liposomes is now recognized as a promising strategy for tumor-targeted drug delivery. Due to the leaky tumor vasculature and the incomplete lymphatic drainage system of tumors, long circulatory liposomes may be preferentially trapped and therefore accumulate in cancer tissues. The preferential entrapment and accumulation of the liposomes in the cIncer tissue is also known as the enhanced permeability and retention effect (EPR-effect). As a consequence of the trapping of liposomes, significantly more drug substance is present at the site of the tumor compared to administration of plain drug products.

Most PEG-liposomal cancer drugs cannot pass the BBB and therefore cannot be used for treatment of primary or secondary brain tumors. The delicate metabolic homeostasis of the central nervous system is largely maintained by the BBB, which plays a key role in excluding potentially neurotoxic and exogenous compounds from the brain, while still allowing the penetration and uptake of essential nutrients. Many potentially highly efficacious anticancer drugs are currently not available to treat brain tumors because they do not adequately cross the BBB, and therefore do not reach the brain.

Glutathione is an endogenous tri-peptide with antioxidant-like properties in the brain and its active (sodium-dependent) transport receptor is highly expressed on the BBB. The unique 2X-111 glutathione-modified PEG-liposome enables transport of encapsulated drugs, such as doxorubicin past the BBB, enhancing the delivery of such drugs to the brain. As used in this section of this report describing our therapeutic candidate 2X-111, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate 2X-111 may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate 2X-111® or our putative Doxorubicin-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Pre-Clinical Studies

Preclinical studies have been performed in order to determine the anti-cancer activity and toleration of 2X-111 both systemically and in the CNS prior to the start of the human clinical trials. 2X-111 showed significantly better tumor growth inhibition and survival benefit in rodents with brain tumors as compared to normal PEGylated liposomal doxorubicin (Caelyx®/Doxil®). In a systemic breast cancer animal model, the tumor suppression was equal between 2X-111 and Caelyx®/Doxil®. Moreover, compared to Caelyx®/Doxil®, enhanced doxorubicin delivery by 2X-111 across the BBB was observed, with a favorable pharmacokinetic and safety profile in animal models. The following graphs represent some of the preclinical observations:



Prior Clinical Trials

2X-111 (formerly 2B3-101) was previously evaluated in Phase I/IIa, multi-center, open-label, dose-escalation clinical trial sponsored by 2-BBB Medicines, B.V. (NCT01818713; NCT01386580). Dieta Brandsma, MD, PhD, Division of Neuro-Oncology, Netherlands Cancer Institute in Amsterdam was the Coordinating Investigator. There were numerous trial sites in the Netherlands, Belgium, and France.

The purpose of this study was the determination of safety, tolerability, and PK of 2X-111 both as single agent and in combination with trastuzumab. Furthermore, the study aimed to explore the preliminary anti-tumor activity of 2X-111 as single agent in patients with solid tumors and brain metastases or recurrent malignant glioma, as well as in patients with various forms of breast cancer in combination with trastuzumab in Her2+ breast cancer patients with brain metastases. The study was performed in two phases: a dose escalation phase following a standard "3+3" design to determine dose-limiting toxicities (DLT) and a safe dose (MTD) of 2X-111, followed by four expanded study arms where patients were treated at the MTD to confirm the Recommended Phase II Dose (RP2D).

84 patients were enrolled in this study, including 37 in the dose escalation phase and an additional 47 patients in the expansion safety cohorts. Only patients who meet all the inclusion and exclusion criteria were enrolled. Two populations were used to analyze the study data including:

- Safety (SAF): Patients who received at least one dose of 2X-111 were evaluable for safety analysis.
- Intention to Treat (ITT): All patients in the SAF who have received at least one dose of trial medication were evaluable for ITT analysis.

To be eligible to participate in this study, candidates must have met the following eligibility criteria:

1. Patients with pathologically confirmed diagnosis of advanced, recurrent solid tumors and unequivocal evidence of brain metastases that were refractory to standard therapy or for whom no standard therapy existed or with unequivocal evidence of newly diagnosed un- treated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision did not require immediate radiotherapy, surgery, or standard systemic chemotherapy. Brain metastases may have been stable, progressive, symptomatic or asymptomatic brain metastasis/es. Stable or decreasing doses of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI or non-enzyme inducing antiepileptic drugs were allowed.

2. Patients with pathology confirmed diagnosis of advanced, recurrent primary malignant (grade III and IV) glioma that were refractory to standard therapy or for whom no standard therapy existed. Stable or decreasing doses of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI or non-enzyme inducing antiepileptic drugs were allowed.

2X-111 in combination with trastuzumab dose-escalation phase:

3. Patients with histologically-confirmed Her2+ (IHC 3+ or fluorescence in situ hybridization [FISH] amplified; by clinical assay on either primary or metastatic tumor) adenocarcinoma of the breast with unequivocal evidence of brain metastases that were refractory to standard therapy or for whom no standard therapy exist or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision did not require immediate radiotherapy, surgery, or standard systemic chemotherapy could be included to this escalation phase as well.

Breast cancer brain metastases study arm of the expansion phase:

4. Patients with pathologically confirmed diagnosis of advanced, recurrent breast cancer with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexamethasone) for 7 days prior to baseline MRI and/or non-enzyme inducing antiepileptic drugs were allowed.

5. Patients with pathologically confirmed diagnosis of advanced breast cancer with newly diagnosed, untreated, brain metastases and controlled extracranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

6. Once the MTD of 2B3-101 with trastuzumab has been determined, patients with histologically-confirmed Her2+ (IHC 3+ or fluorescence in situ hybridization [FISH] amplified; by clinical assay on either primary or metastatic tumor) adenocarcinoma of the breast with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for which no standard therapy exist or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy, could be included to this expansion phase as well.

SCLC brain metastases study arm of the expansion phase:

7. Patients with pathologically confirmed diagnosis of advanced, recurrent SCLC with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexmethasone) for 7 days prior to baseline MRI and/or use of non-enzyme inducing antiepileptic drugs were allowed.

8. Patients with pathologically confirmed diagnosis of advanced SCLC with newly diagnosed, untreated, brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

Melanoma brain metastases study arm of the expansion phase:

9. Patients with pathologically confirmed diagnosis of advanced, recurrent melanoma with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexamethasone) for 7 days prior to baseline MRI and/or use of non-enzyme inducing antiepileptic drugs were allowed.

10. Patients with pathologically confirmed diagnosis of advanced melanoma with newly diagnosed, untreated, brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

Recurrent malignant glioma study arm of the expansion phase:

11. Patients with histologically proven glioma grade IV, which were progressive following first line treatment with surgery or biopsy followed by fractionated radiotherapy with concurrent temozolomide as chemotherapy.

12. Patients with recurrent histologically confirmed malignant (WHO grade III and IV) glioma or histologically confirmed low-grade (WHO grade II) glioma with radiographic evidence of malignant transformation by MRI, that were refractory to standard therapy, or for whom no standard therapy exists or did not require immediate standard therapy per the multi- disciplinary team decision.

13. Patients in both groups should have stable and decreasing dosage of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI. Non-enzyme inducing antiepileptic drugs are allowed.

In the single agent dose-escalation phase, patients eligible for the study were assigned to a dose level cohort. The starting dose was 5 mg/m^2, which was equal to 1/10 of the human equivalent dose of the LD10 of 2X-111 in rats. Dose levels for subsequent cohorts were 10, 20, 30 mg/m^2 and steps of 10 mg/m^2 thereafter. Patients received a single IV dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2B3-101 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the combination with trastuzumab dose-escalation phase, patients were assigned to a 2X-111 dose level cohort. The starting dose of 2X-111 was 40 mg/m^2 every 3 weeks. This dose has been selected based upon safety information from patients treated with 2X-111 at this dose level, as well as upon previous treatment with PEGylated liposomal doxorubicin in combinations trastuzumab.

In both cases, dose-escalation was conducted in steps of 10 mg/m^2 up to the MTD level determined for 2X-111 as single agent. The trastuzumab dose remained fixed to a loading dose of 8 mg/kg at day 1 and 6 mg/kg every 3 weeks at the subsequent cycles throughout the determination of the MTD. All patients received a single IV dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If 2X-111 was well tolerated, the remaining 95% of the infusion thereafter were administered over the next 60 min, resulting in a total infusion time of 90 minutes. The infusion of trastuzumab followed 30 minutes after the completion of the 2B3-101 infusion.

In the breast cancer brain metastases study arm of the expansion phase, each treatment cycle equally also consisted of 21 days. On day 1 of each cycle patients received a single IV 50 mg/m^2 dose of 2X-111 as single agent, or a dose of 2X-111 at the MTD of 2B3-101 in combination with trastuzumab (if different). To minimize the risk of infusion reactions 5% of the total dose (in mg) was infused slowly over the first 30 minutes. If 2X-111 was well tolerated, the remaining 95% of the infusion was thereafter administered over the next 60 minutes, resulting in a total infusion time of 90 minutes. A trastuzumab infusion followed 30 minutes after the completion of the 2X-111 infusion, if applicable. Each treatment cycle consisted of 21 days.

In the SCLC brain metastases study arm of the expansion phase, each treatment cycle also consisted of 21 days. Patients received a single IV 50 mg/m^2 dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was then completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the melanoma brain metastases study arm of the expansion phase, each treatment cycle also consisted of 21 days. Patients received a single IV 50 mg/m^2 dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the recurrent malignant glioma study arm of the expansion phase, each treatment cycle consists of 28 days. Patients received a single IV 60 mg/m^2 dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 28 days.

Infusion or hypersensitivity reactions were expected with the first or subsequent dose of 2X-111 and/or trastuzumab. In case of an infusion reaction, it was recommended to follow the below infusion scheme not only for the continued infusion but also for all future infusions with 2X-111 in the patients that experience such a reaction:

- (Re)-start the 2X-111 infusion with 10 mL/hour for the first 15 minutes and increase the infusion rate every 15 to 30 minutes as follows: 20 mL/hour, 50 mL/hour, 100 mL/hour and finally 200 mL/hour.

- In addition, (pre) medication such as hydrocortisone, ranitidine, cimetidine, antiemetics, and diphenhydramine in line with existing local institutional guidelines all were allowed.

Patients who received 2X-111 in combination with trastuzumab participated in an intensified cardiac program including ECG, LVEF, cTnT and NT-proBNP measurements before start of every treatment cycle.

The following table summarizes the demographic characteristics of patients enrolled in each of the DEP and EPP stages:

Characteristic	Statistic	DEP	EPP
Age (years)	Mean (s.d.)	52.2 (10.6)	51.6 (11.5)
	Median (min, max)	52 (31, 73)	53 (25, 81)
Weight (kg)	Mean (s.d.)	75.1 (13.6)	81.7 (18.2)
	Median (min, max)	71 (41, 103)	82.0 (51, 126)
Height (cm)	Mean (s.d.)	172.1 (11.1)	172.4 (9.4)
	Median (min, max)	172 (153, 197)	170 (147, 191)
Body Surface Area (kg/m^2)	Mean (s.d.)	1.889 (0.211)	2.001 (0.242)
	Median (min, max)	1.873 (1.34, 2.29)	2.038 (1.60, 2.59)
Gender (N)	Female (%)	25 (67.6)	31 (66)
	Male (%)	12 (32.4)	16 (34)
Ethnicity (N)	Black (%)	1 (2.7)	1 (2.1)
	Caucasian/white (%)	34 (91.9)	44 (93.6)
	Oriental (%)	0 (0.0)	2 (4.3)
	Other (%)	2 (5.4)	0 (0)
Tumour Type (N)	BC (%)	13 (35.1)	15 (31.9)
	Mal. Glioma (%)	13 (35.1)	20 (42.6)
	Melanoma (%)	1 (2.7)	5 (10.6)
	Other (%)	7 (18.9)	0 (0)
	SCLC (%)	3 (8.1)	7 (14.9)
Her2/Neu on BC (N)	Negative (%)	1 (2.7)	7 (14.9)
	Positive (%)	12 (32.4)	8 (17.0)
Progesterone receptor on BC (N)	Negative (%)	9 (24.3)	11 (23.4)
	Positive (%)	4 (10.8)	4 (8.5)
Estrogen receptor on BC (N)	Negative (%)	6 (16.2)	7 (14.9)
	Positive (%)	7 (18.9)	8 (17.0)

Preliminary anti-cancer activity for solid tumors was assessed according to RECIST 1.1 criteria. The preliminary anti-cancer activity for recurrent malignant gliomas was assessed according to the RANO criteria. In order to evaluate the anti-cancer activity of the treatment, appropriate imaging procedures were performed to accurately assess the tumor size at baseline, at the last day (day 21 or in case of patients with recurrent malignant glioma enrolled in the dose expansion phase day 28) of every even cycle (e.g. cycle 2, 4, 6 etc.), and at withdrawal from study treatment. Unless not done within 14 days before start of treatment the MRI of the brain was performed to assess brain lesion sizes. Unless not done within 28 days before baseline, a CT/MRI-scan of chest/abdomen/pelvis was performed to assess solid tumor sizes. If corticosteroid treatment (e.g. dexamethasone or methylprednisolone) or increase in corticosteroid treatment was required between screening and the first cycle of 2X-111, the baseline MRI was re-performed after a minimum of 7 days of stable or decreasing doses of the corticosteroids. The first cycle of drug was not initiated until baseline MRI has been performed.

CT/MRI-scans of the chest/abdomen/pelvis were only obtained from patients with solid tumors and brain metastases. These assessments were not required for patients with recurrent malignant glioma. Identified lesions were consistently followed using the unique lesion number assigned at baseline. All tumor measurements were obtained using the same diagnostic procedure used at baseline. For each course in which a tumor assessment was made, standard tumor response criteria were applied and the response for that course documented in the patient file. All identified lesions at screening/baseline were followed using the same imaging procedure. A bone scan was only obtained if clinically indicated during the study if the patient developed symptoms or signs of bone metastases. If bone metastases were known to be present at screening, bone scintigraphy was performed in addition to and at the same time as the CT/MRI-scans throughout the study. All lesions were followed during treatment (i.e. target lesions as well as non-target lesions). All CT/MRI Images from patients enrolled in the dose expansion arms of the study were sent electronically to a central repository system.

Safety was assessed by means of physical examination, neurological examination (and a brain MRI if a neurological deficit was leading to WHO> 2), weight, vital signs, ECOG performance status, MMSE, HDS, laboratory evaluations (hematology, biochemistry and urinalysis and N-terminal Pro-Brain Natriuretic Peptide (NT-ProBNP) and cardiac Troponin T (cTnT)), electrocardiograms (ECG), LVEF (MUGA/ECHO)), and recording of concurrent illness/therapy and adverse events.

Clinical anti-cancer activity was assessed by best overall response (OR) by both, investigator, and computer-based methods. Overall, both methodologies reported similar results with the majority of best overall survival (OS) reported being stable diseases (SDs) while some partial responses (PRs) also being observed.

In the Dose Escalation Phase (DEP) group and in the glioma only patients, SD was the best OR recorded for 26.5% and 23.5% of the patients, as reported by the computer and investigator, respectively. At the same time, in the DEP group and for other solid tumors and across all single and combination arms, one PR (2.9%) was reported by the computer in the 2X-111 50 mg/m^2 + trastuzumab group. However, this response was deemed as SD by the investigator. The rate of SDs reported for this other (non-glioma) solid tumor group, was 23.3% and 20.6% for the computer and investigator, respectively.

In the Expansion Phase (EPP) group and for the glioma patients, both the computer and the investigator methods recorded the best OR as an SD rate of 17.8%. In the solid tumors group, the same SD rate of 26.7% was reported by both methods of assessment also. In addition, PR was also reported, 2.2% by the investigator and 4.4% by the computer.

The following tables summarize best overall responses by dose group and by cohort:

	Dose groups in mg/m^2										
	5	**10**	**20**	**30**	**40**	**50**	**60**	**70**	**40+T**	**50+T**	**Total**
						N (%)					
RANO: Malignant Glioma											
PD											
Computer				1 (33.3)		1 (33.3)					**2 (5.9)**
Investigator				2 (66.7)		1 (33.3)					**3 (8.8)**
SD											
Computer				1 (33.3)	2 (66.7)	1 (33.3)	3 (42.9)	2 (100)			**9 (26.5)**
Investigator					2 (66.7)	1 (33.3)	3 (42.9)	2 (100)			**8 (23.5)**
RECIST: Solid tumour											
PD											
Computer	3 (100)	2 (66.7)	2 (100)	1 (33.3)	1 (33.3)		4 (57.1)	1 (50)	1 (33.3)	1 (20)	**16 (47.1)**
Investigator	3 (100)	2 (66.7)	2 (100)	1 (33.3)	1 (33.3)		4 (57.1)	1 (50)	1 (33.3)	1 (20)	**16 (47.1)**
PR											
Computer										1 (20)	**1 (2.9)**
SD											
Computer		1 (33.3)				1 (33.3)			2 (66.7)	3 (60)	**7 (20.6)**
Investigator		1 (33.3)				1 (33.3)			2 (66.7)	4 (80)	**8 (23.5)**
Total [N; %]	**3 (100)**	**3 (100)**	**2 (100)**	**3 (100)**	**3 (100)**	**3 (100)**	**7 (100)**	**2 (100)**	**3 (100)**	**5 (100)**	**34 (100)**

	Dose groups in mg/m^2						
	60 prog. Glioma	60 Glioma	50 Breast new	50 Breast rec.	50 SCLC	50 Melanoma	Total
	N (%)						
RANO: Malignant Glioma							
PD							
Computer	5 (62.5)	5 (50)					**10 (22.2)**
Investigator	5 (62.5)	5 (50)					**10 (22.2)**
SD							
Computer	3 (37.5)	5 (50)					**8 (17.8)**
Investigator	3 (37.5)	5 (50)					**8 (17.8)**
RECIST: Solid tumour							
PD							
Computer			4 (50)	3 (42.9)	3 (42.9)	3 (60)	**13 (28.9)**
Investigator			4 (50)	1 (14.3)	5 (71.4)	4 (80)	**14 (31.1)**
PR							
Computer				1 (14.3)		1 (20)	**2 (4.4)**
Investigator				1 (14.3)			**1 (2.2)**
SD							
Computer			4 (50)	3 (42.9)	4 (57.1)	1 (20)	**12 (26.7)**
Investigator			4 (50)	5 (71.4)	2 (28.6)	1 (20)	**12 (26.7)**
Total [N; %]	**8 (100)**	**10 (100)**	**8 (100)**	**7 (100)**	**7 (100)**	**5 (100)**	**45 (100)**

Finally, analysis of the three exploratory populations revealed that SDs are the predominant best OR. In the glioma patient group receiving 2X-111 greater or equal to 40 mg/m^2, 16 out of the 27 patients experienced PD. In the breast-patient-group receiving 2X-111 greater or equal to 40 mg/m^2, 2 out of 24 patients experienced PR according to the computer or investigator method of assessment, respectively and at the same time, 12 or 15 out of 24 experienced an SD. In the Her2+ breast patient group receiving 2X-111 greater or equal to 40 mg/m^2 in combination with trastuzumab, 2 or 1 out of 16 patients experienced PR according to the computer or investigator method of assessment, respectively and at the same time, 10 or 12 out of 24 experienced an SD. The following table summarizes those results:

	Dose groups in mg/m^2 > = 40 mg		
	Glioma	Breast	Her2+
		N (%)	
RANO: Malignant Glioma			
PD			
Computer	11 (40.7)		
Investigator	11 (40.7)		
SD			
Computer	16 (59.3)		
Investigator	16 (59.3)		
RECIST: Solid tumour			
PD			
Computer	1 (3.7)[38]	10 (41.7)	4 (25)
Investigator	1 (3.7)[38]	8 (33.3)	3 (18.8)
PR			
Computer		2 (8.3)	2 (12.5)
Investigator		1 (4.2)	1 (6.3)
SD			
Computer		12 (50)	10 (62.5)
Investigator		15 (62.5)	12 (75)
Total	**27 (100)**	**24 (100)**	**16 (100)**

All patients have reported at least one treatment emergent adverse event (grade I to IV) but all of them were manageable and none of them have been considered unexpected based on the previous experience from treatment with liposomal doxorubicin (Doxil/Caelyx) and/or non-clinical safety information with Allarity.

The number of infusions administered as single agent or in combination with trastuzumab to the individual patients ranged from 1 to 10. Long-term toxicity data (> 2 infusions of 2X-111) were available from 34 patients, all but one of these patients were treated with doses more or equal to 40 mg/m^2. One patient has received 10 infusions. The maximum total dose of 2X-111 delivered to date is 240 mg/m^2. Following treatment with 2X-111 infusion related reactions were reported in 27% of the patients in the Dose Escalation and 34% in the EPP. All infusion related reactions (dyspnea, chest pain, back pain, fatigue, headache, flushing, chills, tachycardia) that were observed in this study with 2X-111 were in between grade 1 to 3, but no grade 4 reactions. After modification of the initial infusion rate (5% given over the first 30 min and the remaining 95% over 60 min) at a dose of 30 mg/m^2, infusion reaction grade 1-2 has been reduced and reported in 16 out of 68 treated patients (23%), the majority still without any premedication. In all patients experiencing an infusion reaction the infusions were continued after a shorter treatment interruption. Only one case was reported as SAE (grade 2 bronchospasm). With respect to hematological toxicity, neutropenia was observed in 40.5%, leukocytopenia in 24.3% and thrombocytopenia in 18.9% of patients in the DEP. In EPP neutropenia occurred in 31.9%, leukocytopenia in 8.5% and thrombocytopenia in 4.3% of patients. In all patients with hematologic side effects the subsequent dose has been withheld for 1-2 weeks, per protocol and in 1 case also a dose reduction by 10 mg/m^2.

Palmar plantar erythrodysthesia (PPE) was reported in 45.9% of patients in DEP and 55.3% in EPP. However, no hand-foot syndrome grade 4 or 5 was reported. Grade 3 hand-foot syndrome was present in approximately 21.6% in DEP and 23.4% in EPP. While hand-foot syndrome caused by 2X-111 was reversible within one or two weeks, it caused dose delays and dose reductions in several patients. However, a favorable safety profile was observed and 2X-111 was relatively well tolerated in both patients with BCBM from solid tumors and patients with recurrent malignant gliomas.

Overview of Glioblastoma Multiforme (GBM)

Malignant brain tumors account for approximately 190,000 new cases and 40,000 deaths per year globally. In the U.S., gliomas account for 81% of all malignant brain tumors where glioblastoma (GBM) (WHO grade IV) is the most aggressive form and represents the most prevalent (54%) form of all gliomas and 46% of all primary malignant brain tumors. The majority of GBM (95%) has histologically been classified as primary GBM mostly in elderly without any clinical history of lower grade gliomas. Secondary GBM develops from lower grade gliomas in younger patients (age <45 years) in the course of many months to years of disease. Today the distinction is based on isocitrate dehydrogenase (IDH) mutations.

The prognosis of newly diagnosed GBM is poor with overall survival (OS) rates in the U.S. at 1-year, 2-year, and 5-year survival of 37.2%, 8.8%, and 5.1%, respectively. The current standard of care is tumor resection followed by radiotherapy combined with chemotherapy with temozolomide (TMZ) and then continuing with TMZ maintenance, and results in median OS of 14.6 months, which does not seem to have been relevantly improved over the past several decades. Thus, the therapeutic results are still not satisfactory, and new and more efficacious therapies are needed. Only a subgroup of GBM patients (approximately 32%), who have a methylated MGMT (O6-methylguanine-DNA methyltransferase) promotor, may benefit from TMZ treatment. The MGMT gene is involved in DNA repair, and epigenetic silencing by promotor methylation has previously been shown to be associated with longer survival in patients receiving alkylating agents. It has been shown that TMZ treatment improves OS from 15.3 to 21.7 months in patients with MGMT silencing, while patients with unmethylated MGMT promotors had no significant benefit from TMZ.

In most GBM patients the disease will progress sooner or later, however there is no clear recommendations for second line treatment. Depending on the clinical picture of each individual patient the treatment of recurrent GBM includes a second surgical procedure with or without implantation of carmustine wafers, nitrosoureas, TMZ treatment, the VEGF-blocking antibody bevacizumab (Avastin®) alone or in combination with the topoisomerase 1 inhibitor irinotecan, and, in some countries, systemic chemotherapy (e.g. carmustine plus irinotecan). In a Danish study of bevacizumab in combination with irinotecan an overall response rate (ORR) of 30%, median PFS of 5 months, and median OS of 7.5 months was observed. However, the treatment options for recurrent GBM are limited and the prognosis is poor. Patients should therefore be encouraged to participate in clinical trials.

Rationale for Liposomal Doxorubicin in GBM

Several studies on established glioma cell lines have shown promising levels of therapeutic activity of doxorubicin. In the last decade, treatment of GBM with pegylated liposomal doxorubicin (Doxil®/Caelyx®) has been assessed in three small studies. The treatment has been shown to result in a modest positive effect (1.5 months) on survival. However, this effect has not been considered sufficient to justify the use of Doxil®/Caelyx® as a standard treatment option in patients with brain tumors according to treating clinicians and regulatory agencies.

Existing PEG-liposomal formulations of doxorubicin, such as Doxil®/Caelyx®, do not readily pass the BBB and therefore do not deliver sufficient levels of the drug to brain tumors in order to provide meaningful therapeutic benefit. Likewise, doxorubicin itself does not pass the BBB.

The FDA granted orphan drug designation for 2X-111 for the treatment of glioma on August 16, 2010 (FDA/103119). Additionally, on September 21, 2010, the orphan drug designation of 2X-111 for the treatment of glioma was approved by the EMA (EMA/OD/031/10).

2X-111 is a novel PEG-liposomal formulation of doxorubicin, which, by virtue of the glutathione modification on the liposomal surface, can pass the BBB and deliver therapeutically sufficient levels of doxorubicin to brain tumors. Accordingly, 2X-111 has the potential to be a new and beneficial therapeutic option for the treatment of GBM.

Rationale for Liposomal Doxorubicin in Breast Cancer (Brain Metastases)

Brain metastases are diagnosed in approximately 15% of unselected patients with advanced breast cancer. Over time, it has become increasingly clear that the biology of the primary tumor influences the pattern of metastatic spread, including the likelihood of relapse in the central nervous system (CNS). As many as half of patients with HER2-positive advanced breast cancer will develop brain metastases at some point in the course of their disease.

Within the HER2-positive subset, hormone receptor status appears to further define the risk of CNS relapse, with patients having hormone receptor-negative/HER2-positive tumors experiencing increased risk developing metastases in the CNS as the first site of relapses, compared with patients with hormone receptor-positive/HER2-positive tumors. Furthermore, patients with metastatic, triple-negative (ER, PR and HER2 negative) breast cancer are equally at high risk, with 25 – 46% of patients developing brain metastases at some point in the course of their disease. The timing of the CNS relapse also appears to vary by tumor subtype. Patients with non-luminal tumors (e.g. triple-negative cancers) appear to experience a shorter time to relapses in the CNS compared to patients with luminal tumors.

In a historical series of unselected patients with breast cancer brain metastases treated with whole-brain radiotherapy (WBRT), the median survival has been reported to be approximately five to six months. More recent analyses have identified performance status of the patient and the biologic tumor subtype as major drivers of prognosis. For example, in a multi-institutional retrospective database of over 400 patients with breast cancer brain metastases, a prognostic model (the Diagnosis-Specific Graded Prognostic Assessment, DSGPA) using these factors (plus age) was able to distinguish between patients experiencing a two-year median survival versus those with 3.4 months median survival.

Across multiple retrospective studies, the most striking differences consistently noted have been between patients with HER2-positive breast cancer (who carry the most favorable prognosis) and patients with triple-negative breast cancer. Based on several lines of evidence, it is likely that improved systemic tumor control is a major contributing factor to this difference. First, although one must interpret retrospective data cautiously because of issues with patient selection, it has been observed by multiple investigators that patients with HER2-positive tumors who continue anti-HER2 therapy following the diagnosis of brain metastases do far better than those who receive either no therapy, or chemotherapy without HER2-directed therapy. Second, as many as half of the patients with HER2-positive brain metastases die primarily from CNS progression of their disease (as opposed to systemic progression). Accordingly, the need for a brain-targeted therapy for the treatment of brain metastases is warranted in this patient population. This is distinguished from patients with triple-negative brain metastases, where patients most commonly die of uncontrolled systemic disease.

Existing PEG-liposomal formulations of doxorubicin, such as Doxil®/Caelyx®, do not readily pass the BBB and therefore do not deliver sufficient levels of the drug to brain tumors in order to provide meaningful therapeutic benefit. Likewise, doxorubicin itself does not pass the BBB.

2X-111 is a novel PEG-liposomal formulation of doxorubicin, which, by virtue of the glutathione modification on the liposomal surface, can pass the BBB and deliver therapeutically sufficient levels of doxorubicin to brain tumors. Accordingly, 2X-111 has the potential to a new and beneficial therapeutic option for the treatment of brain metastases of breast cancer.

Future Opportunities & Development Plans for 2X-111

In June of 2020, we out-licensed our 2X-111 program to Smerud Medical Research International, our long-time CRO partner in Europe, which was subsequently terminated on March 28, 2022. Allarity, SMERUD, and original drug owner 2BBB Medicines, B.V. are currently negotiating a revised agreement under which SMERUD will secure grant funding to advance this program, with DRP® companion diagnostic support from Allarity.

DRP® Companion Diagnostic for 2X-111

We anticipate that 2X-111 will be developed together with our retrospectively validated DRP® companion diagnostic for doxorubicin, which enables us to select the patients most likely to respond to the drug in our clinical trials. The FDA has previously approved our IDE applications for use of our DRP® companion diagnostics in clinical trials of two of our priority programs: Stenoparib and LiPlaCis®. Accordingly, we are confident the FDA will approve an eventual IDE for our Doxorubicin-DRP® companion diagnostic for U.S. clinical trials of 2X-111. The Doxorubicin-DRP®, which comprises 299 expressed genes, was initially developed using gene expression data from the National Cancer Institute NCI60 cancer cell lines panel.

The putative Doxorubicin-DRP®, developed through our DRP® platform using gene expression data from cancer cell line testing data, was retrospectively validated using biopsy materials from the screening of breast cancer patients for our LiPlaCis® trial (clinicaltrial.gov number NCT01861496). A total of 140 patients received epirubicin and were included in the analysis. The study population was diagnosed with primary BC between 1986 and 2015 and received epirubicin in the locally advanced or metastatic setting between May 1997 and November 2016. The hazard ratio for DRP scores differing by 50 percentage points was 0.55 (95% CI –0.93, one-sided). The results were published in Breast Cancer Res Treat. 2018 Aug 11.

In sum, our retrospectively validated Doxorubicin-DRP® companion diagnostic correctly identifies responder patients to 2X-111 and we expect this DRP® companion diagnostic will be used for all clinical programs to advance 2X-111.

Existing Liposomal Doxorubicin Drugs & Our Opportunity

There has not been a therapeutically meaningful new drug for the treatment of GBM since bevacizumab (Avastin®) was approved, by the FDA, in 2009 as a monotherapy for patients who have progressed on prior therapy. Prior to introduction of bevacizumab in the GBM treatment landscape, TMZ was approved, by the FDA in 2005, for the treatment of adult patients with newly diagnosed GBM concomitantly with radiotherapy and then as maintenance treatment. Nearly 20 years later, TMZ remains the only front-line therapy for GBM, and its effectiveness is limited. Similarly, the effectiveness of benefit of second-line therapeutic bevacizumab remains limited. Accordingly, there is pressing need for new and innovative therapies for the treatment of this aggressive and incurable cancer.

There is no currently approved, available therapy for the treatment of brain metastases of breast cancer, and these metastases remain fatal to breast cancer patients. Accordingly, there is pressing need for new and innovative therapies for the treatment of this aggressive and incurable metastatic cancer.

Worldwide annual sales TMZ exceeded $1 billion annually in 2009. The global GBM drugs market to projected to reach nearly $1.8 billion by 2027, expanding at a CAGR of 12.8% during the forecast period, driven by rising geriatric population, growing incidence cases and clinical pipeline of new products. The global breast cancer therapeutics market has been valued at over $19 billion in 2018 and is expected to reach over $40 billion by the year 2026, at a CAGR of 10.6%. Since an estimated 10-15% of breast cancer patients will develop brain metastases, which are fatal, the estimated annual market for new therapeutics to treat such brain metastases will exceed $4 billion by 2026.

While there are several approved PEG-liposomal doxorubicin formulations (e.g. Doxil®/Caelyx®) currently marketed for the treatment of numerous cancer, including breast cancer, these drugs do not pass the BBB. There are currently no approved, targeted liposomal formulations of doxorubicin on the market that are capable of passing the BBB and therefore treating both primary and secondary brain tumors. Accordingly, 2X-111 has the potential to be a novel, beneficial product with the potential, together with its DRP® companion diagnostic, to gain substantial market share not only in GBM and breast cancer (brain metastases) but as a new therapy for the numerous other primary and second brain tumors.

Overview of Our Prior Therapeutic Candidate Irofulven (DNA damaging agent) and Our Out-licensed Putative DRP® Companion Diagnostic

Mechanisms of Action

Irofulven (6-hydroxymethylacylfulvene) is a unique DNA damaging agent that is a semi-synthetic sesquiterpene derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (*Omphalotus illudens*). Irofulven has two primary anti-tumor mechanisms of action: first, it produces bulky single strand DNA adducts that are only repairable by the transcription coupled nucleotide excision repair (TC-NER) pathway; and second, it stalls RNA polymerase II leading to transcription and cell cycle arrest and apoptosis.

Irofulven is a prodrug. The active metabolite is created by the reduction of the unsaturated α−β ketone by the NADPH-dependent Prostaglandin Reductase 1 (PTGR1). This metabolite is unstable and highly reactive, binding to either protein or DNA. The DNA binding is primarily to the 3-N of deoxyadenosine (98%) with the remainder binding to 7-N deoxyguanine. The resulting bulky single strand adducts can cause single strand DNA breaks and S-phase double strand DNA breaks. The GG-NER, BER and MMR pathways do not detect or remove Irofulven-DNA adducts, which either persist into, or are created during, S-phase of cancer cell duplication and create double strand DNA breaks which may be repaired by Homologous Recombination.

Irofulven is more active *in vitro* against tumor cells of epithelial origin and is more resistant than other alkylating agents to deactivation by p53 loss and MDR15. Irofulven showed impressive anticancer results in xenograft models, shows synergy with topoisomerase I inhibitors, and has demonstrated activity against cell lines that are resistant to other therapies. Irofulven has significant scope for combination with other therapies, including PARP inhibitors, checkpoint inhibitors (e.g. PD-1 inhibitors) and standard chemotherapeutic regimes, and is synergistic with other therapies targeting the TC-NER pathway and other DNA damage pathways.

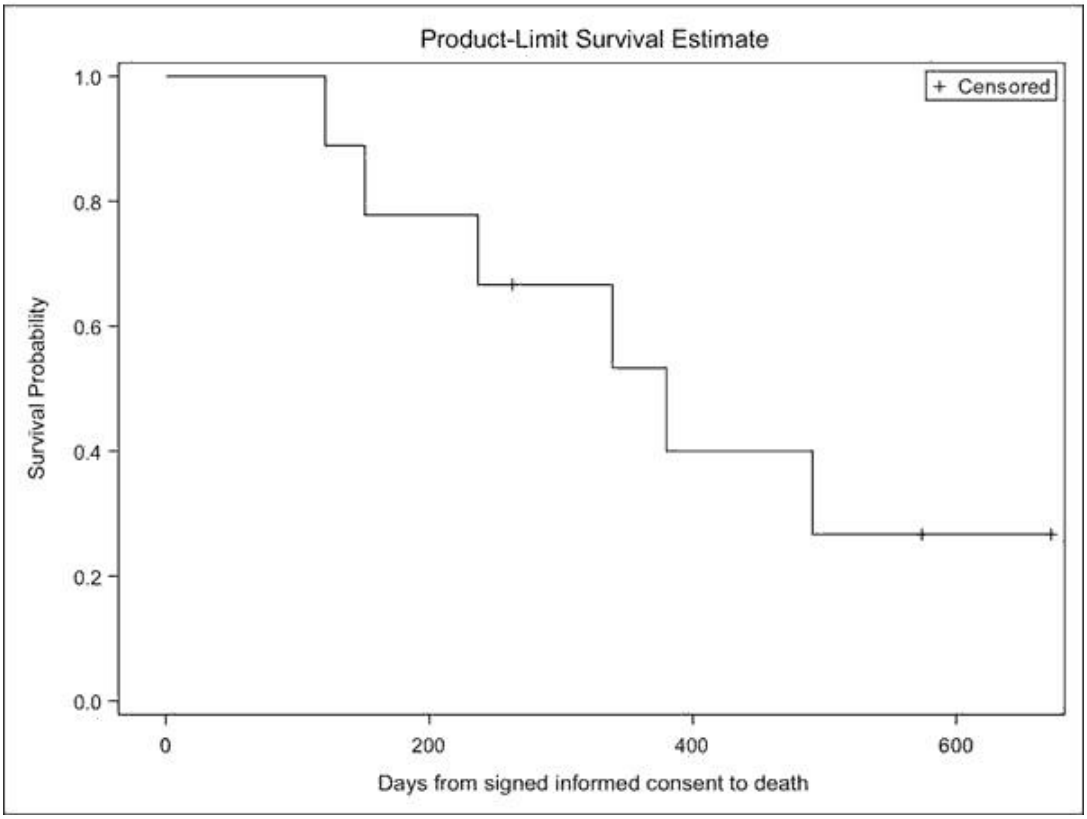
Irofulven causes apoptosis in sensitive tumor cell lines. Activation of caspases 3, 7, 8, and 9 has been well documented in Irofulven-treated tumor cell lines. Irofulven also causes upregulation of ATM/Chk2 and ATR-dependent FANCD2 mono-ubiquitination. In all cases, however, the functional linkage(s) between irofulven adducts (both DNA and protein) and subsequent pathway activation steps are, at present, not fully understood.

DRP®-Guided Phase 2 Clinical Trial

Prior to July 23, 2021, and our sale of Irofulven to Lantern Pharma, Inc., we commenced a DRP®-guided Phase 2 clinical trial of Irofulven in androgen receptor (AR)-targeted and Docetaxel-Pre-treated Metastatic Castration-Resistant Prostate Cancer (mCRPC) patients using our putative Irofulven-DRP® companion diagnostic to select and treat patients most likely to respond to the drug (study SMR-365). This trial was not completed and was an open-label, non-randomized, multi-center study in patients with docetaxel and AR-targeted therapy pre-treated mCRPC. Up to 27 mCRPC patients with predicted high probability of response to Irofulven (as determined by the Irofulven-DRP® companion diagnostic) were included. A high likelihood of Irofulven response was defined as a patient having an Irofulven-DRP® score of >80%. This study was suspended in 2019 when we internally deprioritized Irofulven. We had previously developed and patented a putative DRP® companion diagnostic specific for Irofulven, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate although we have not yet filed a PMA with the FDA for this companion diagnostic. To devote more of our development resources to our priority therapeutic candidates, on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of Irofulven active pharmaceutical ingredients, ("API"), our clinical data and records ("Data"), and our know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to use our putative DRP® companion diagnostic specific for Irofulven. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

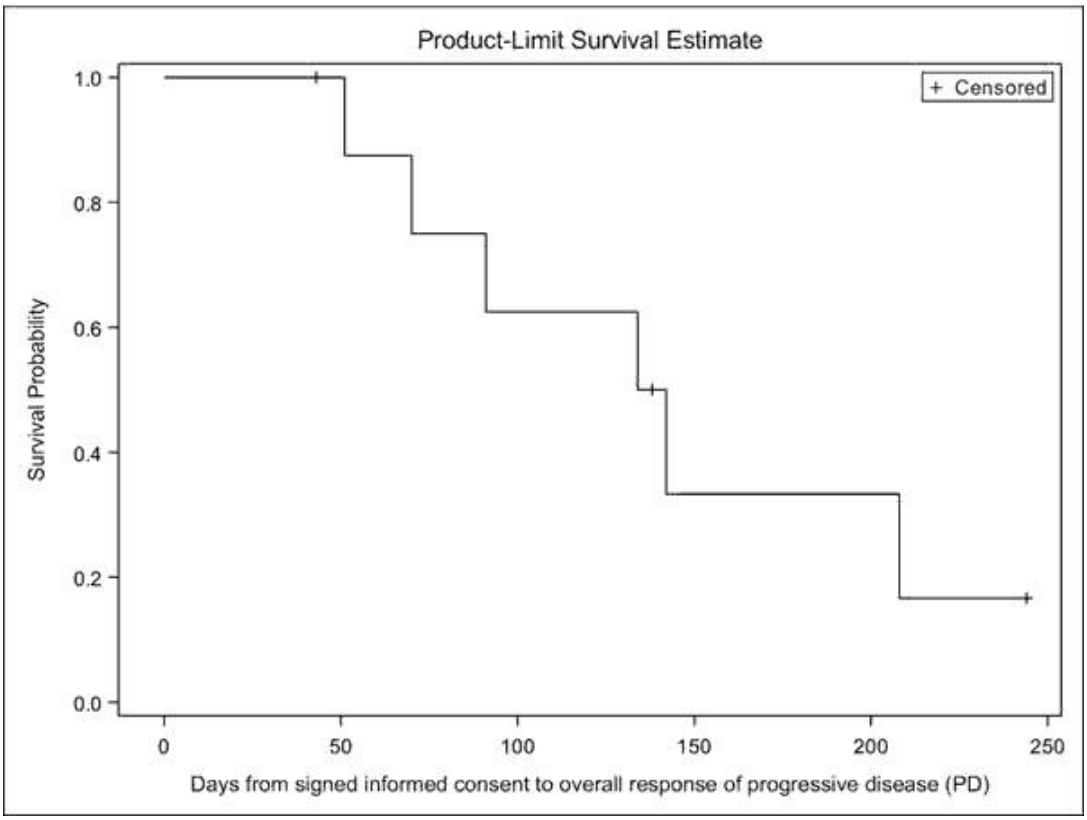
Study SMR-3165. Time (days) from enrolment to death of any cause.

The LIFETEST Procedure



Study SMR-3165. Time (days) from enrolment to overall response of progressive disease (PD).

The LIFETEST Procedure



Overview of Our PRP® (Patient Response Predictor)

Collections of drug specific putative DRP® companion diagnostics can be grouped together to form a panel of putative DRP® companion diagnostics that we believe can help guide therapeutic decision making for a given patient, in a true personalized medicine approach. For example, putative DRP® companion diagnostics for a number of cancer drugs with a similar mechanism-of-action, for example chemotherapeutics such as cisplatin, doxorubicin, and irofulven can be grouped together, by drug type (e.g. DNA damaging agents) in a panel to help identify which of these chemotherapeutics is most likely to benefit a particular patient. Similarly, putative DRP® companion diagnostics for a number of cancer drugs with differing mechanism-of-action, such as fulvestrant, cisplatin, and dovitinib, can be grouped together, by cancer type (e.g. drugs that treat metastatic breast cancer) in a panel to help identify which of these drugs is most likely to benefit a particular patient. We call such panels of putative DRP® companion diagnostics Patient Response Predictors (PRP®s).

We believe PRP®s, once approved, have the potential to achieve the true promise of personalized cancer care, specifically to pre-screen a given cancer patient for their likelihood of responding to a range of therapeutic options, then selecting the drug(s) most likely to benefit that patient, while avoiding the prescription of therapeutics that are not likely to benefit that patient. In practice, the treating oncologist and/or cancer center would provide us with a tumor biopsy from a given patient (or gene expression data from such biopsy) and we would then run a PRP® analysis, as requested by the oncologist, resulting in a PRP® report, provided to the oncologist and the patient, identifying the therapy options most likely to benefit the patient. This report would be somewhat analogous to currently marketed predictive diagnostic panels and reports, such as FoundationOne® (Foundation Medicine, Inc.), but with a different underlying technology base and therapeutic response predictive power.

An example of such a PRP® product for multiple myeloma was published in 2018 where the sensitivity of 67 patients to 14 drugs was predicted. A.J. Vangsted *et al.*, Gene 644 80-86)

We continue to explore the strategic and market potential of such PRP® panels. Market introduction and penetration of such personalized medicine diagnostic tests and reports is challenging and subject to close scrutiny of regulatory agencies such as the FDA, and also are very capital intensive to develop, bring to market, and expand sales. Accordingly, development of a potential PRP® product and business is not currently part of our priority strategy.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other major oncology markets and countries for our investigational products and our DRP® companion diagnostics, to operate without being subject to the enforcement of third-party patents and proprietary rights, and to prevent others from infringing on our proprietary or intellectual property rights. We seek to protect our proprietary position by (1) filing, in the U.S. and certain other regions/countries (include the EU), patent applications intended to cover our DRP® companion diagnostics and their use with a particular therapeutic to guide patient therapy decision making, and maintaining any DRP® pending patent applications and issued patents in our major markets; (2) maintaining and advancing, and where possible expanding, existing patents and patent applications covering the composition-of-matter of our investigational products, their methods of use and related discoveries, their formulations and methods of manufacture, and related technologies, inventions and improvements that may be commercially important to our business; and (3) filing, in the U.S. and certain other regions/countries, new patent applications on novel therapeutic uses of our investigational products, alone or together with their DRP® companion diagnostics. We may also rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, and which are difficult to reverse engineer. We also intend to take advantage of regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

We have investigational products, and putative DRP® companion diagnostics, for a number of therapeutic targets, although none of our companion diagnostics have yet received FDA or other regulatory agency approval. As of the date of this report, our Company-owned patent portfolio consists of:

- 17 DRP® companion diagnostics patents granted covering 70 different cancer drugs, including 8 issued patents in the U.S. and 4 issued patents in the EU. Our issued patents cover, among others, DRP® companion diagnostics for Dovitinib, LiPlaCis®, 2X-111, and Irofulven. Our issued patent portfolio includes patents granted in the U.S., EU, China, Japan, Canada, and Australia.

- 27 DRP® companion diagnostics patent applications pending covering 2 additional drugs, including pending applications in the U.S., EU, China, Japan, Canada, India, Brazil and Australia. Our pending patent applications cover, among others, DRP® companion diagnostics for IXEMPRA® and for Stenoparib.

- Over 50 granted patents and pending patent applications, for composition-of-matter, methods of use, formulation, and methods of manufacturing, for many of our pipeline assets, including Dovitinib, Stenoparib, and 2X-111. These granted patents and applications generally cover the U.S. and EU, as well as numerous additional major world cancer therapeutics markets; although existing and remaining patent/application coverage varies from drug program to drug program. In some instances, we own and control such pre-existing patent/application portfolios (such as for Dovitinib) and in some instances the original drug owner/licensor owns and controls such pre-existing patent/application portfolios (such as for Stenoparib).

- 1 U.S. patent application pending covering novel anti-viral uses of Stenoparib as a therapeutic for treatment of COVID-19 infection.

- The term of any patents that issue from our company-owned (or in-licensed) U.S. and foreign patent applications will vary in accordance with the laws of each jurisdiction and available patent term extension but is typically 20 years from the earliest priority application filing date. Expiration dates for certain patents covering our portfolio assets ranges between 2028 and 2032. Expiration dates for the DRP® companion diagnostic patents that cover our current pipeline programs will typically expire between 2030 and 2040. Any patents that may issue in the future from our company-owned (or in-licensed) pending patent applications are projected to expire between 2031 and 2041, unless extended or otherwise adjusted. Generally, the older and more developed the drug program the earlier the patent portfolio on the product will expire. For example, remaining patent portfolio term for dovitinib is less than remaining patent term for stenoparib. Such product patent portfolio expiration is independent from continuing patent coverage provided by DRP® companion diagnostics for each product.

- In countries or regions, such as the U.S. and EU, where regulatory approval of a companion diagnostic together with its drug, on the label, is available, approved DRP® companion diagnostics will substantially extend patent protection well after the core product patents (e.g. composition-of-matter) have expired.

We have obtained or are pursuing patent protection for our proprietary drug response predictor (DRP®) technology, a unique diagnostic platform, with a particular focus on the application of the DRP® technology to treat renal cell carcinoma, ovarian cancer, and metastatic breast cancer. Specifically, the DRP® technology is being applied to select patients to be treated with dovitinib, stenoparib, or ixabepilone. Our patent portfolio also includes patents and applications in-licensed from Novartis International AG ("Novartis") that protect dovitinib compositions and methods of its use for treatment, as well as patents and applications in-licensed from Eisai Co., Ltd. ("Eisai") that protect stenoparib compositions and methods of its use for treatment. Our in-licensed patent on the composition of matter for dovitinib expired on September 11, 2021.

DOVITINIB

Our dovitinib patent portfolio, which includes U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the dovitinib patent portfolio, which includes in-licensed patent families, as well as patent families owned by us.

In-licensed patents:

- Patents granted in the United States (US 9,545,402), Australia (AU 2011273519), Canada (CA 2,801,826), China (CN 106943355), Europe (EP 2588086), and Japan (JP 2013-517282) from national stage applications of Patent Cooperation Treaty Application No. PCT/EP2011/060949, protect pharmaceutical dovitinib compositions and methods for producing pharmaceutical compositions containing dovitinib. The patents are scheduled to expire beginning in 2031.

- Patents granted in the United States (US 8,741,903), Europe (EP 2558095), and Australia (AU 2011239999) from national stage applications of Patent Cooperation Treaty Application No. PCT/EP2011/055906, protect methods of treating hepatocellular carcinoma or liver cancer with dovitinib. The patents are scheduled to expire beginning in 2031.

Owned patents:

- We have patent rights covering the use of the DRP® technology in conjunction with dovitinib in the United States (US 10,835,531). Patent rights outside the U.S. are being pursued in key foreign jurisdictions, including Australia, Canada, China, Europe, India, and Japan as national stage applications of Patent Cooperation Treaty Application No. PCT/EP2020/066724 filed in November 2021. This portfolio is scheduled to expire in 2040.

STENOPARIB

Our stenoparib patent portfolio, which includes U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the stenoparib patent portfolio, which includes patent families in-licensed from Eisai, as well as patent applications owned by Allarity.

In-licensed patents:

- Patents granted from national stage applications of Patent Cooperation Treaty Application No. PCT/US2008/078606 that are in-licensed from Eisai include composition of matter claims directed to genera and species encompassing stenoparib. Patents have issued in the United States (US 8,236,802 and US 8,894,989) and in key foreign jurisdictions including, e.g., Europe (EP 2209375), Canada (CA 2,700,903), China (CN 102083314B), Japan (JP 5439380), and South Korea (KR 10-1596526). The patents are scheduled to expire in 2028.

Owned patents:

- We are pursuing patent protection for the use of our DRP® technology in conjunction with stenoparib via national stage applications of Patent Cooperation Treaty Application No. PCT/EP2019/062508 filed in the United States, Australia, Canada, China, Europe, India, and Japan. This portfolio is scheduled to expire in 2039.

IXABEPILONE

Our ixabepilone patent portfolio, which is owned by us, is based on protecting our DRP® technology in the United States and in key foreign jurisdictions. We have filed national stage applications of Patent Cooperation Treaty Application No. PCT/EP2021/052132, which seeks to cover the use of the DRP® technology in conjunction with ixabepilone, in the United States and in key foreign jurisdictions, including Australia, Canada, China, Europe, India, and Japan starting in July 2022. This portfolio is scheduled to expire in 2041. We do not own or control any patents relating to ixabepilone itself in the EU market, where such patents have previously expired.

2X-111

Our 2X-111 patent portfolio, which includes U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the 2X-111 patent portfolio, which includes patent families in-licensed from 2BBB Medicines, B.V., as well as patent and patent applications owned by Allarity.

In-licensed patents:

Our 2X-111 patent portfolio includes the following patent families in-licensed from 2BBB Medicines, B.V.: (1) drug conjugates, which patents are issued and in force until March 2028; (2) liposomal delivery system, which patents are issued and in force until December 2025; and modified drug delivery system, which patents are issued and in force until February 2030. Generally, the issued patents of each patent family cover most of the European Union countries, including, among others, Germany, Spain, United Kingdom, Italy, France, and Turkey. Patents within family (3) have also been granted in Australia, Canada, China, Japan and New Zealand.

Owned patents:

We own exclusive, global rights to the use of our DRP® technology in conjunction with doxorubicin, which is the active therapeutic ingredient of 2X-111. A patent to this technology has issued in the United States (US 10,900,089) and Europe (EP18172585.4). Patent applications are also pending in Australia, Canada, China, Hong Kong, and India. This portfolio is scheduled to expire in 2038.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our investigational products and/or DRP® companion diagnostics and enforce the patent rights that we own or to which we have exclusive rights, and could affect the value of such intellectual property and the business. See section entitled “Risk Factors - Risks Related to Our Intellectual Property” for list of risks related to our intellectual property.

License Agreement with Novartis Pharma for Dovitinib

On April 6, 2018, Allarity Therapeutics Europe ApS ("Allarity Europe"), our wholly owned subsidiary, in-licensed the exclusive worldwide rights to all therapeutic and/or diagnostic uses related to cancer in humans for dovitinib from Novartis Pharma AG ("Novartis") pursuant to a license agreement. Upon execution of the agreement, Allarity Europe paid Novartis a one-time, non-refundable, non-creditable upfront payment of $1 million. Pursuant to the agreement, we are solely responsible for the development of dovitinib during the term of the agreement. The agreement also contemplated that a convertible promissory note in the amount of $1 million would also be issued to Novartis by one of our subsidiaries but was unenforceable due to the operation of the liability limitation provisions of the license agreement. As part of current discussions with Novartis over the possible restructuring of the milestone payments described below, the parties entered into an amendment to the license agreement on April 12, 2022, to be effective as of March 30, 2022, to exclude the convertible promissory note from the liability limitation provisions of the license agreement and, subject to the parties execution of the amendment to the license agreement, our subsidiary executed an enforceable convertible promissory note in the principal amount of $1 million with a maturity date of April 6, 2025 (the "Novartis Promissory Note"). The Novartis Promissory Note will bear interest at the rate of 5% per annum commencing on April 6, 2018, which shall be paid, together with the principal amount, on the maturity date. The Novartis Promissory Note was issued by Allarity Therapeutics Denmark ApS ("Allarity Denmark"), a wholly owned special purpose vehicle of our subsidiary Allarity Europe, the licensee under the license agreement. In the event that there is a change of control, as defined under the Novartis Promissory Note, of Allarity Europe, Novartis would be entitled to a payment equal to 5% of the first $30 million we receive in connection with the change of control and up to 3% of any amounts we receive in excess of $30 million in connection with the change of control. In addition, in the event Allarity Denmark undertakes an initial public offering ("IPO") resulting in its shares being listed on an internationally recognized securities exchange, then Novartis would have a one-time right to convert all amounts owed under the Novartis Promissory Note into 3% of Allarity Denmark outstanding equity securities immediately before the IPO.

Development Milestone Payments

Pursuant to the agreement, as amended on September 27, 2022, Allarity Europe has agreed to make milestone payments to Novartis in connection with the development of dovitinib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the dovitinib development program from us corresponding to: (i) upon enrollment of half of the patients required in a Phase 2 clinical trials in certain countries in accordance with agreed upon protocols; (ii) upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of a first application or submission for approval to market a pharmaceutical product ("MAA") to the EMA or any other Regulatory Authority in certain countries; (v) upon receipt of the first authorization by the FDA to market and sell a licensed product; and (vi) upon receipt of a first MAA (including a respective pricing and reimbursement approval) for a licensed product in one or more specified European countries. If all milestones have been achieved, we may be obligated to pay Novartis up to a maximum of $26.5 million. As of December 31, 2021, prior to the September 27, 2022, amendment, we accrued a $5 million royalty payment due to Novartis as a current liability relating to the submission of our NDA to the FDA for the treatment of mRCC. The September 27, 2022, amendment restructured the payment terms of this milestone payment into an installment plan with the final installment due in 2023, allowing us more time to make the milestone payment in exchange for a $500,000 increase in the amount of the milestone payment. In the event that we complete a Financing Transaction, as defined in the amendment, the installment payments would be accelerated.

Royalty Payments

In addition to the milestone payments described above, Allarity Europe has agreed to pay Novartis royalties based on annual incremental sales of product derived from dovitinib in an amount between 5% and 10% of annual sales of between $0 and $250 million, between 6% and 13% of annual sales between $250 million and $500 million, between 7% and 13% of annual sales between $500 million and $750 million, and between 13% and 15% of annual sales in excess of $750 million.

Allarity Europe is are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the 10 year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by Allarity Europe upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Novartis that is not cured within 30 days. Novartis also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 30 days or if we file for bankruptcy.

License Agreement with Eisai for Stenoparib

On July 6, 2017, we in-licensed the exclusive worldwide rights to all preventative, therapeutic and/or diagnostic uses related to cancer in humans and by amendment to the agreement on December 11, 2020, viral infections in humans (including, but not limited to, coronavirus vaccines and other treatments) for stenoparib from Eisai Inc. ("Eisai") pursuant to a license agreement. Upon the execution of the agreement in 2017, we paid Eisai a one-time, non-refundable, and non-creditable payment of $1 million. Pursuant to the license agreement, we are solely responsible for the development of stenoparib during the term of the agreement. The agreement also provides for a joint development committee consisting of six members, three appointed by us and three appointed by Eisai. One of our members of the joint development committee is designated chair of the committee and has the power to break any deadlock in decisions by the committee that must be made by a majority vote with each representative having one vote. The purpose of the committee is to implement and oversee development activities for stenoparib pursuant to the clinical development plan and serve as a forum for exchanging data, information, and development strategy.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Eisai in connection with the development of stenoparib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the stenoparib development program from us corresponding to: (i) successful completion of a Phase 2 clinical trial; (ii) dosing of the first patient in the first Phase 3 clinical trial; (iii) submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA; (v) submission of an NDA to the Ministry of Health Labor and Welfare of Japan, or the Pharmaceuticals and Medical Devices Agency of Japan, or any successor thereto (the "MHLW"); (vi) receipt of authorization by the FDA to market and sell a licensed product; (vii) receipt of approval of an MAA by the EMA for a licensed pro)uct; and (viii) receipt of approval by the MHLW in Japan for a licensed product. If all milestones have been achieved, we may be obligated to pay Eisai up to a maximum of $94 million. In addition, we have agreed to pay Eisai a one-time sales milestone payment in the amount of $50 million the first time our annual sales of licensed product are $1 billion or more.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of product derived from stenoparib in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 10% of annual sales between $100 million and $250 million, between 7% and 11% of annual sales between $250 million and $500 million, and between 11% and 15% of annual sales in excess of $500 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the 15 year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Eisai that is not cured within 90 days (30 days for a payment default). Eisai also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. By an amendment effective as of August 3, 2021, and executed by Eisai on August 23, 2021, Eisai also had the right to terminate the agreement if we did not complete a Phase 2 clinical trial before December 31, 2022, unless we elected to pay a $1 million extension payment ("Extension Payment"). Notwithstanding the foregoing, in the event we failed to enroll and dose at least 30 patients with the first dose of cancer drug in the ongoing Phase 2 Ovarian Cancer Clinical Trial by July 1, 2022, then the Extension Payment would have become due and payable in full on July 30, 2022. By a further amendment effective July 12, 2022, and executed by Eisai on August 17, 2022, in exchange for a payment of $100,000 on or before August 27, 2022, and a further $900,000 payment on or before April 1, 2023, which will constitute the payment of the Extension Payment, we will have until April 1, 2024, to complete a Phase 1b or Phase 2 Clinical Trial. We have paid the initial $100,000 of the Extension Payment and have until April 1, 2023, to pay the remaining $900,000. Consequently, if we fail to pay the remaining $900,000 of the Extension Payment on or before April 1, 2023, or if we fail to achieve successful completion of a Phase 1b or Phase 2 Clinical Trial prior to April 1, 2024, then Eisai may terminate the agreement in its sole discretion pursuant to the terms of the amendment.

Option to Reacquire Rights to Stenoparib

For the period of time commencing with enrollment of the first five patients in a Phase 2 clinical trial pursuant to the clinical development plan and ending 90 days following successful completion of such Phase 2 clinical trial, Eisai has the option to reacquire our licensed rights to develop stenoparib for a purchase price equal to the fair market value of our rights, giving effect to the stage of development of stenoparib that we have completed under the agreement. We commenced a Phase 2 clinical trial in April 2019 and as of the date of this report, Eisai has not indicated an intention to exercise its repurchase option.

Sub-License Agreements with OncoHeroes Biosciences for Dovitinib & Stenoparib

On January 2, 2022, we sub-licensed the exclusive worldwide rights to any and all pediatric cancer development and commercialization of dovitinib and stenoparib to OncoHeroes Biosciences, Inc. Upon the execution of the agreements, OncoHeroes paid us a one-time, non-refundable, and non-creditable payment of $350,000. Pursuant to the license agreements, OncoHeroes is solely responsible for the pediatric cancer development of stenoparib and dovitinib, together with their respective DRP® companion diagnostics, during the term of the agreements. The agreements also provide for a joint development committee consisting of five members, three appointed by OncoHeroes and two appointed by us. The purpose of the committee is to implement and oversee pediatric cancer development activities for stenoparib and dovitinib pursuant to the clinical development plan and serve as a forum for exchanging data, information, and development strategy. Under the agreements, Allarity will provide, at its own cost, DRP® companion diagnostic support for any pediatric clinical trials that OncoHeroes conducts in Europe; for any U.S. pediatric clinical trials, Allarity will facilitate DRP® companion diagnostic support through its U.S. CLIA lab partner, Almac, at OncoHeroes' cost. Further, under the Agreements, Allarity shall supply finished stenoparib and dovitinib to OncoHeroes at our cost of goods (to manufacture or have manufactured the drugs). In certain events where Allarity is unwilling or unable to supply sufficient amounts of the drugs, OncoHeroes can obtain manufacturing rights from Allarity.

Development Milestone Payments

Pursuant to the agreements, OncoHeroes will make milestone payments to us in connection with its development of stenoparib and dovitinib, or by a third-party (a "Program Acquirer") that assumes control of the development programs from OncoHeroes, corresponding to, for each drug: (i) upon receipt of authorization by the FDA to market and sell a licensed product; and (ii) upon receipt of approval of an MAA by the EMA for a licensed product.

Royalty Payments

In addition to the milestone payments described above, OncoHeroes has agreed to pay us royalties based on annual incremental sales of any product derived from stenoparib and/or dovitinib in an amount between 5% and 8% of annual sales of between $0 and $100 million, between 9% and 11% of annual sales between $100 million and $200 million, and between 11% and 14% of annual sales above $200 million.

OncoHeroes is obligated to pay us royalties under the agreements on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the 10 year anniversary of the date of first commercial sale of dovitinib in such country and the 15 year anniversary of the date of first commercial sale of stenoparib in such country. However, the agreements may be sooner terminated upon written notice of Allarity of a material breach of the agreements by OncoHeroes that is not cured within 60 days. After the first anniversary of each agreement, OncoHeroes also has the right to terminate the agreements, at will, upon written notice to Allarity (i) 90 days in advance if prior to first commercial sale of license product or (ii) 180 days in advance if after first commercial sale of licensed product.

Option to Reacquire Rights

Under the terms of the agreements, Allarity has a first buy back option for licensed pediatric cancer field rights for each of stenoparib and dovitinib triggered by the first to occur of (i) written notice from Allarity to OncoHeroes that it has received an offer from a pharmaceutical company with at least $250 million of net sales (based upon its most recently-completed calendar year financial performance) that wishes to acquire global commercialization rights to the product in the licensed field (pediatric cancers) and retained field (all other cancers); or (ii) completion of the receipt of the first MAA (including an NDA) approval for a product in any country in the licensed territory (worldwide) in the licensed field; and (b) ending 120 days after the occurrence of the matters set forth in clause (i) and (ii) above, as applicable. Allarity may exercise its buy back option by submitting a written offer prior to the expiration of the option period outlined above. Upon the timely exercise by Allarity of its option: (i) any development milestone payments due from OncoHeroes to Allarity shall be cancelled, and (ii) the parties shall enter into exclusive good faith negotiations regarding a fair market value ("FMV") payment to OncoHeroes which will take into account the value generated by OncoHeroes to the product, and may include a one-off payment to OncoHeroes and royalties on future net sales for the product, or a one-time upfront payment, or such other FMV as the parties shall negotiate in good faith.

Development, Option and License Agreement with R-Pharm for IXEMPRA®

On March 1, 2019, we entered into an option to in-license the rights to any and all therapeutic and/or diagnostic uses in humans for IXEMPRA® in the European Union (including Great Britain but excluding Switzerland and Lichtenstein) (the "Territory") from R-Pharm U.S. Operating, LLC ("R-Pharm"), pursuant to a Development, Option and License Agreement (the "Option"). Upon the execution of the agreement, we paid R-Pharm a non-refundable, non-creditable option payment of $100,000 and agreed to an anniversary payment of $250,000 on or before March 1, 2020, which we have paid. Upon exercise of the option by us, we have agreed to pay R-Pharm an exercise payment of $250,000. By an amendment to the agreement effective August 4, 2022, the term of the option will expire on September 1, 2023, if not exercised by us before then. As a condition to the exercise of the Option, we are required to offer R-Pharm a right to re-acquire the licensed rights from us on terms to be mutually agreed upon, including the payment to us of the fair market value of the licensed rights. Pursuant to the Option, we are solely responsible for the development of IXEMPRA® during the term of the Option within the Territory. The agreement also provides for a joint development committee consisting of four members, two appointed by us and two appointed by R-Pharm. Decisions by the committee that must be made by a unanimous consent of the parties, with us having the tie breaking vote on matters involving our DRP Biomarker, patient selection in the mBC clinical trial and the commercialization plan and R-Pharm having the tie breaking vote on all other matters. The purpose of the committee is to implement and oversee development activities for IXEMPRA® pursuant to the clinical development plan, serves as a forum for exchanging data, information, and development strategy.

Development Milestone Payments

Pursuant to the agreement, once we have exercised the Option, we have agreed to make milestone payments to R-Pharm in connection with the development of IXEMPRA® by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the IXEMPRA® development program from us corresponding to: (i) upon receipt of regulatory approval for the Product for the treatment of the first indication in the first country in the Territory; and (ii) upon receipt of regulatory approval for the Product for the treatment of each additional indication in the first country in the Territory for each such additional indication. If all milestones have been achieved, and assuming only one additional indication in the second milestone is achieved, we may be obligated to pay R-Pharm up to a maximum of $12.5 million.

Royalty Payments

In addition to the milestone payments described above, once we have exercised the Option, we have agreed to pay R-Pharm royalties based on annual incremental sales of product derived from IXEMPRA® in an amount between 5% and 8% of annual sales of between $0 and $30 million, and between 8% and 12% of annual sales over $30 million.

After the Option is exercised, we would be obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the seven year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 90 days prior written notice, or upon written notice of a material breach of the agreement by R-Pharm that is not cured within 90 days (30 days for a payment default). R-Pharm also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy.

Drug License and Development Agreement for Irofulven

From May 2015 until July 23, 2021, we in-licensed various rights to Irofulven from Lantern Pharma, Inc. pursuant to a drug license and development agreement.

Pursuant to the agreement, we were responsible for the development of Irofulven pursuant to a defined clinical development plan. The agreement also provides for a joint development committee, including representatives from Lantern Pharma and us, to regularly discuss, plan and inform the development of products under the agreement. In 2018, we commenced a DRP®-guided Phase 2 clinical trial of Irofulven in androgen receptor (AR)-targeted and Docetaxel-Pre-treated Metastatic Castration-Resistant Prostate Cancer (mCRPC) patients using our putative Irofulven-DRP® companion diagnostic to select and treat patients most likely to respond to the drug (study SMR-365). This trial was not completed and was an open-label, non-randomized, multi-center study in patients with docetaxel and AR-targeted therapy pre-treated mCRPC. Up to 27 mCRPC patients with predicted high probability of response to Irofulven (as determined by the Irofulven-DRP® companion diagnostic) were included. A high likelihood of Irofulven response was defined as a patient having an Irofulven-DRP® score of >80%. This study was suspended in 2019, when we deprioritized Irofulven as a therapeutic candidate in order to devote more of our development resources to our priority therapeutic candidates, and on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of API, our clinical data and records, and our manufacturing know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to Lantern Pharma to use our putative DRP® companion diagnostic specific for Irofulven. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

Asset Purchase Agreement between Allarity Therapeutics A/S and Lantern Pharma, Inc. for Irofulven

On July 23, 2021, we entered into an Asset Purchase Agreement with Lantern Pharma, Inc. relating to our inventory of Irofulven active pharmaceutical ingredients ("API"), our clinical research data relating to Irofulven developed by us during the drug development program under the May 2015 Drug License and Development Agreement for Irofulven (the "Data") and terminated our obligation to further advance the development of Irofulven under the May 2015 agreement. Under the Asset Purchase Agreement, Lantern Pharma agreed to pay us $1 million on closing of the transaction, and additional amounts (i) when the inventory of Irofulven API is recertified with a longer shelf life; (ii) upon the initiation of treatment of the first patient in an investigator-led "compassionate use" ERCC2/3 mutation subgroup study using Irofulven in certain agreed upon investigators; (iii) upon the first to occur of (x) initiation of treatment of the first patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma for regulatory purposes, and (y) initiation of treatment of the 26th patient in any human clinical trial of Irofulven after the closing of the transaction initiated by Lantern Pharma or under the investigator-led study; and (iv) upon the initiation of treatment of the second patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma. In addition to the sale of our inventory of Irofulven API and Data to Lantern Pharma, we also granted Lantern Pharma a non-exclusive, worldwide license to use our putative Irofulven DRP® companion diagnostic to advance the development and commercialization of Irofulven and other Illudins (sesquiterpenes with anti-tumor properties produced by some mushrooms). We have also agreed not to engage in any drug development program for Illudins or any of its analogues or any use thereof for a period of five years.

Milestone Payments

Under the Asset Purchase Agreement, we would also be entitled to receive certain milestone payments relating to our out-licensed putative Irofulven DRP® companion diagnostic upon the occurrence of the following events: (i) upon the first use of our putative Irofulven DRP® companion diagnostic in a clinical trial for Irofulven; and (ii) upon the first regulatory approval of our putative Irofulven DRP® companion diagnostic as a companion diagnostic for use with an approved drug. In addition to the milestone payments relating to our putative Irofulven DRP® companion diagnostic, we would also be entitled to receive certain milestone payments relating to the development and commercialization of Irofulven upon the occurrence of the following events: (i) upon the first filing for regulatory approval for commercialization of Irofulven in the United Kingdom, Germany, France and Italy, or upon the first and second filings for regulatory approval for commercialization of Irofulven in countries located in the European Union that are not Germany, France or Italy; (ii) upon the first filing for regulatory approval for commercialization of Irofulven in the United States; (iii) upon receiving the first regulatory approval for commercialization of Irofulven in the United Kingdom, Germany, France and Italy, or upon the first and second receipts for regulatory approval for commercialization of Irofulven in countries located in the European Union that are not Germany, France or Italy, (iv) upon receiving the first regulatory approval for commercialization of Irofulven in the United States. If all milestones have been achieved, then we would be entitled to receive up to $16 million in milestone payments under the Asset Purchase Agreement.

Royalty Payments

In addition to the milestone payments described above, Lantern Pharma has agreed to pay us royalties based on annual incremental net sales of product derived from Irofulven, on a country by country basis, in an amount between 2%) and 7% of annual sales of between $0 and $50 million, between 3% and 8% of annual sales between $50 million and $150 million, between 4% and 9% of annual sales between $150 million and $300 million, and between 5% and 10% of annual sales in excess of $300 million.

The royalty amounts we are entitled to receive may be subject to reduction in the event of generic competition, patent expiry, or if products are (i) sold in the form of a combination product containing one or more active pharmaceutical ingredients which are not Irofulven or (ii) sold under a bundled or capitated arrangement with one or more products which are not Irofulven or (iii) sold under an arrangement whereby the sale of the product is only available with or conditioned upon the purchase of other products.

License Agreement with 2-BBB Medicines B.V. for 2X-111

On March 27, 2017, we in-licensed the exclusive worldwide rights to the central nervous system ("CNS") and/or cerebrocardiovascular drug application, including the (preventive) treatment of peripheral effects of agents causing CNS disease or symptoms, including cancer, for 2X-111 from 2-BBB Medicines B.V. ("2-BBB") pursuant to a license agreement. Upon execution of the agreement, we paid 2-BBB a one-time, non-refundable, non-creditable payment of $500,000. Pursuant to the agreement, we are solely responsible for the development of 2X-111 during the term of the agreement.

Development and Sales Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to 2-BBB in connection with the development of 2X-111 by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the 2X-111 development program from us corresponding to: (i) enrollment of the first ten patients required in a Phase 2 clinical trial; (ii) the successful completion of a Phase 2 clinical trial; (iii) dosing of the first patient in the first Phase 3 clinical trial; (iv) submission of the first NDA with the FDA; (v) submission of an MAA to the EMA in the European Union; (vi) submission of an NDA in the first of either China or India; (vii) receipt of the first authorization by the FDA to market and sell a licensed product; (viii) receipt of a MAA for a licensed product in the European Union; and (ix) receipt of regulatory approval in the first of either China or India. If all development milestones have been achieved, we may be obligated to pay 2-BBB up to a maximum of $27.75 million which could increase to $55.5 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans. In addition to the development milestones described above, we have agreed to make a mid-level seven figure one-time payment upon our sales of a licensed product reaching $500 million annually and a low eight figure payment upon the first and second time our sales of a licensed product reaches $1 billion annually. If all sales milestones have been achieved, we would be obligated to pay 2-BBB up to a maximum of $22.5 million which could increase to $45 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay 2-BBB royalties based on annual incremental sales of product derived from 2X-111 in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 13% of annual sales between $100 million and $250 million, and between 7% and 13% of annual sales in excess of $250 million. We are obligated to pay royalties under the agreement on a product-by-product and country-by-country basis, from the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) the 2-BBB intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual property arose from activities under the clinical development plan), or (b) the 10^{th} anniversary of the date of first commercial sale of such product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by 2-BBB that is not cured within 90 days. 2-BBB also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. 2-BBB also has the right to terminate the agreement in the event we challenge a 2-BBB patent and we have the right to terminate the agreement upon 30 days' notice for specified safety reason.

Out-License Agreement with SMERUD

In June of 2020, we out-licensed our secondary LiPlaCis® and 2X-111 programs to Smerud Medical Research International, our long-time CRO partner in Europe, for further Phase 2 clinical development of each program together with its DRP® companion diagnostic. On March 28, 2022, we restructured our LiPlaCis® license agreements with Smerud and original drug owner LiPlasome Pharma ApS, in a way that will enable Smerud to step into the shoes of Allarity and assume full control of this program for further development in a Smerud affiliated subsidiary, Chosa ApS, and to secure additional investment funding and collaborative development of the program through the affiliate. Pursuant to the terms of the Support Agreement (as described below in the section titled "LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome") and in connection with the termination of our exclusive licensee rights to LiPlaCis® under the Amended License Agreement (as described below in the section titled "Amended and Restated License Agreement with LiPlasome Pharma ApS for LiPlaCis®"), we agreed to terminate our out-license agreement with SMERUD. However, notwithstanding the termination of the out-license agreement, we are currently engaged in discussions with Smerud in connection with the further development of 2X-111.

Amended and Restated License Agreement with LiPlasome Pharma ApS for LiPlaCis®

In January 2021, we entered into an Amended and Restated License Agreement with LiPlasome Pharma ApS ("LiPlasome") for the perpetual, exclusive, world-wide rights to develop, use and market LiPlaCis® for any indication which superseded all prior license and development agreements between us and LiPlasome (the "Original License Agreement"). On March 28, 2022, we entered into an amended and restated license agreement which assigned, amended and restated the Original License Agreement, pursuant to which the parties agreed to replace Allarity Europe with Chosa, an affiliate of Smerud, as exclusive licensee to further advance clinical development and commercialization of LiPlaCis® (the "Amended License Agreement"). Under the Amended License Agreement, Chosa replaced Allarity Europe as the exclusive licensee to the LiPlaCis® technology. In addition, Allarity Europe also granted Chosa an exclusive, royalty-free, transferable and sublicensable license for (i) its DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® for the research and development of LiPlaCis® products, and (ii) the use of any and all know-how and intellectual property rights owned by Allarity Europe for Chosa's use of our DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® for the development and commercialization of LiPlaCis® products, as contemplated in the Amended License Agreement.

Development Milestone Payments

Pursuant to the Amended License Agreement, Allarity Europe is entitled to receive certain milestone payments from Chosa relating to the development and commercialization of LiPlaCis® upon the occurrence of the following events, which milestone payments are to be shared with LiPlasome: (i) receipt of first regulatory approval of a product in the United States, (ii) receipt of first regulatory approval of a product in any country in Europe, including on a centralized filing basis by the EMA, (iii) the first achievement on a cumulative basis of net sales of a product in the United States, and (iv) the first achievement on a cumulative basis of net sales of a product in any country in Europe. Each milestone payment is payable one time only, regardless of the number of times the corresponding milestone event is achieved by a product and regardless of the number of products to achieve such milestone event. If all milestones are achieved, then we would be entitled to receive up to $3.5 million in milestone payments under the Amended License Agreement.

As a result of the Amended License Agreement, we no longer have any rights to use or commercialize LiPlaCis® and are only entitled to receive the milestone payments upon the achievement of the respective milestones.

LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome

On March 28, 2022, and concurrent with the entry into the Amended License Agreement, we entered into the LiPlaCis Support Agreement with Allarity Europe, Smerud, Chosa and LiPlasome (the "Support Agreement"). Pursuant to the terms of the Support Agreement, we agreed (i) to pay to LiPlasome a certain percentage of the Commercialization Proceeds (as defined under the Original License Agreement) we received from Smerud by way of debt cancellation relating to prior work on LiPlaCis® by Smerud, which obligation was to be satisfied by the payment of 2,273,020 Danish Kroner to LiPlasome upon execution of the Support Agreement, (ii) to equally share the milestone payments under the terms of the Amended License Agreement, pursuant to which it was contemplated that upon the achievement of all the milestones, our pro rata share of the milestone payments would be up to $3.5 million, (iii) to amend and restate the Original License Agreement, and (iv) to terminate the Out-License Agreement with SMERUD as contemplated by the parties pursuant to the terms of the Support Agreement.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our investigational products for preclinical and clinical testing, as well as for commercial manufacture if any of our investigational products obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational products, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our investigational products.

To date, we have obtained APIs and drug product for our investigational products from either the original drug owner/licensee or from single-source third-party clinical manufacturing organizations (CMOs). We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs, and which agreements will provide us with intellectual property rights necessary to conduct the business. We may use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant. Overall, as we advance our investigational products through development, we will start by seeking multiple sources for raw materials and address other potential points in concern over time.

Commercialization

We intend to retain significant development and commercial rights to our investigational products and, if marketing approval is obtained, to commercialize our investigational products on our own, or potentially with a partner, in the U.S. and other regions, either globally or on a region-by-region basis. We do not intend to build the necessary infrastructure and sales, marketing and commercial product distribution capabilities for the U.S., and potentially other regions, following further advancement of our investigational products. We instead prefer to build appropriate partnerships with marketing, sales, and distribution partners to effect launch and market penetration for each of our therapeutic programs. However, as we near approval and commercial launch of each program, we will assess the suitability of marketing and sales partners and reserve the right to potentially develop and implement our own infrastructure to support the commercial success of our programs. Clinical data, the size of the addressable patient population and the size of the commercial infrastructure and manufacturing needs and economics related to the foregoing may all influence or alter our commercialization plans.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer therapies. Any investigational products that we successfully develop and commercialize will compete with new therapies that may become available in the future. Similarly, our core DRP® platform technology, and any drug-specific DRP® companion diagnostics that we develop and commercialize, will compete with new companion diagnostic technologies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop small molecules and drug conjugates, together with companion diagnostics, as treatments for cancer patients. There are many other companies that have commercialized and/or are developing such treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca plc, Bristol-Myers Squibb Company (“BMS”), Merck, Pfizer in partnership with Merck KGaA, Regeneron Pharmaceuticals, Inc. in partnership with Sanofi Genzyme (“Sanofi”) and Roche. There are also many other companies that are developing, have developed, and/or have commercialized patient-selective, companion diagnostic technologies/approaches for cancer patients, such as Foundation Medicine, Inc., Kura Oncology, Inc., and Lantern Pharma, Inc.

For our Dovitinib program, we are aware of a number of companies that are currently marketing approved pan-TKIs and/or developing pan-TKIs that are or may be competitive to our drug, such as Big Pharma companies Eisai, Bayer, Pfizer, Novartis, and smaller pharmaceutical players Exelixis, Mirati Therapeutics, and Aveo Oncology. To our knowledge, there is currently no approved or in development pan-TKI, for the treatment of RCC or other indications, that has an identical therapeutic profile to dovitinib, with or without its Dovitinib-DRP® companion diagnostic.

For our Stenoparib program, we are aware of a number of companies that are currently marketing approved PARP inhibitors and/or developing PARP inhibitors that are or may be competitive to our drug, such as Big Pharma companies AstraZeneca, BMS, Novartis, and GlaxoSmithKline (GSK), and smaller pharmaceutical players BeiGene and Clovis Oncology. To our knowledge, there is currently no approved or in development PARP inhibitor, for the treatment of ovarian cancer or other indications, that has an identical therapeutic profile to stenoparib, with or without its Stenoparib-DRP® companion diagnostic.

For our IXEMPRA® program, we are aware of a number of companies that are currently marketing approved microtubule inhibitors and/or developing microtubule inhibitors that are or may be competitive to our drug, such as Big Pharma companies Eisai and Sanofi, and smaller pharmaceutical players like Celgene and Veru Pharma. To our knowledge, there is currently no approved or in development microtubule inhibitor, for the treatment of metastatic breast cancer (mBC) or other indications, that has an identical therapeutic profile to IXEMPRA®, with or without its IXEMPRA®-DRP® companion diagnostic.

For our LiPlaCis® program, we are aware of a number of companies that are currently or have been developing liposomal formulations of cisplatin that are or may be competitive to our drug, such as Regulon, Inc. To our knowledge, there is currently no approved liposomal formulation of cisplatin. Furthermore, to our knowledge, there is no in development liposomal formulation of cisplatin, for the treatment of mBC or other indications, that has an identical therapeutic profile to LiPlaCis®, with or without its Cisplatin-DRP® companion diagnostic.

For our 2X-111 program, we are aware of a number of companies that are currently marketing approved liposomal formulations of doxorubicin and/or developing liposomal formulations of doxorubicin that are or may be competitive to our drug, such as Janssen Pharmaceuticals, Baxter, and Teva, and Zydus Cadilla. To our knowledge, there is currently no approved or in development Glutathione-modified liposomal formulation of doxorubicin, for the treatment of GBM or other indications, that has an identical therapeutic profile to 2X-111, with or without its Doxorubicin-DRP® companion diagnostic.

For our Irofulven-DRP® companion diagnostic that we have out-licensed to Lantern Pharma, we are aware of a number of companies that are currently marketing approved DNA damaging chemotherapeutics and/or developing DNA damaging chemotherapeutics that are or may be competitive to Irofulven. Many approved chemotherapeutics are now generic and sold by companies such as Teva Pharmaceuticals and Baxter. Some smaller pharmaceutical companies, such as Alkido Pharma and Lantern Pharma, are attempting to develop novel chemotherapeutics. Lantern Pharma, for example, is pre-clinically attempting to develop novel analogues of Irofulven. To our knowledge, there is currently no approved or in development DNA damaging agent, for the treatment of mCRPC or other indications, that has an identical therapeutic profile to Irofulven, with or without its Irofulven-DRP® companion diagnostic.

For our core DRP® platform technology (and its resulting drug specific DRP® companion diagnostics), we are aware of a number of companies that are currently marketing approved companion diagnostic platforms, or are attempting to develop such platforms, that are or may be competitive to (although distinct from) our DRP® platform, such as Foundation Medicine and Lantern Pharma. To our knowledge, there is currently no approved or developmental diagnostic technology or platform — for the development of drug-specific companion diagnostics to guide selection and treatment of cancer patients most likely to respond to a given drug — that is as broadly applicable, robust, and highly validated as our DRP® platform.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize therapeutic products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Similarly, it is possible that our commercial opportunity may be reduced by the development and commercialization of competing companion diagnostic products that are superior to our DRP® companion diagnostics. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all our investigational products, if approved, are likely to be their degree of anti-cancer activity, tolerability profile, convenience and price, the effectiveness of companion diagnostics (if required), the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. All these factors will be impacted by the value and superiority of our DRP® companion diagnostics over any competing companion diagnostic approaches that currently exist or evolve in the oncology market.

Government Regulation

Government authorities in the U.S. at the federal, state, and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. Similar regulations and approvals exist in the EU and other major oncology therapeutic markets.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Food, Drug, and Cosmetic Act ("FDCA"). Similarly, in the European Union (EU), the European Medicines Agency (EMA) regulates the clinical trial, approval, and marketing of drugs. Drugs also are subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. or EU requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's or EMA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our therapeutic candidates are considered small molecule drugs and must be approved by the FDA through the new drug application ("NDA"), and similarly by the EMA under an equivalent process, before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP;
- submission to the FDA of an Investigational New Drug (IND) application, which must become approved and effective before human clinical trials may begin;
- submission to the FDA of an Investigational Device Exemption (IDE) application, which must become approved and effective before a drug-specific DRP® companion diagnostic can be used in human clinical trials;
- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related protocols and regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a New Drug Application (NDA) after completion of all pivotal trials;
- submission to the FDA of a Pre-Market Approval (PMA) application to allow use of a DRP® companion diagnostic on the market together with its approved drug;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the pre-clinical study and/or clinical trial sites that generated the data in support of the NDA filing;

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.; and

- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: pre-clinical and clinical. The pre-clinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for any current and future therapeutic candidates will be granted on a timely basis, or at all, whether in the U.S, EU, or other region/country.

Pre-Clinical Studies and IND/IDE

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, retrospective data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Similarly, and IDE is a request for authorization from the FDA to use a diagnostic — in our case a DRP® companion diagnostic — to screen, select, and treat specific patients in a human clinical trial.

Pre-clinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, retrospective data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Similarly, an IDE sponsor must submit information about the prior development and validation of the diagnostic, including results of the pre-clinical tests, together with manufacturing information, retrospective data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IDE. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Similarly, submission of an IDE for a DRP® companion diagnostic may not result in the FDA allowing use of such DRP® in an approved clinical trial.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Clinical development in other major oncology markets, such as the EU, is subject to similar requirements and regulations.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well conducted foreign clinical trial not conducted under an IND if the clinical trial is conducted in compliance with GCP and. the FDA is able to validate the data through an onsite inspection, if deemed necessary. An NDA based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies have been performed by clinical investigators of recognized competence and (3) the FDA is able to validate the data through an onsite inspection or other appropriate means, if deemed necessary.

Clinical trials in the U.S. generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the therapeutic candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability, and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Clinical development in other major oncology markets, such as the EU, is subject to similar requirements and regulations.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies may complete additional animal safety studies and must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our therapeutic candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our therapeutic candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the U.S. for one or more specified indications and must contain proof of safety and efficacy for a drug. Concomitantly, a PMA is submitted to the FDA as part of NDA approval that is conditioned on use of a companion diagnostic. In short, the PMA is a request for approval to market the companion diagnostic in the U.S., together with and required for prescription of the drug, for one or more specified indications and must contain clinical evidence of safety and efficacy and sufficient validation of the companion diagnostic used to select patients for treatment with the drug.

The NDA application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the U.S. Similarly, FDA approval of a PMA must be obtained before a DRP® companion diagnostic may be legally marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must decide on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification. Similarly, the FDA must decide on accepting a PMA for review within 45 days of receipt. After acceptance, the FDA will begin substantive review of the PMA. During the review process, FDA will notify the PMA applicant via major/minor deficiency letters of any information needed by FDA to complete the review of the application. FDA may refer the PMA to an outside panel of experts (advisory committee). In general, all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel for review and recommendation.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Similarly, an IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor via email prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. In cases of disapproval, a sponsor can respond to the deficiencies

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a therapeutic candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our therapeutic candidates designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union (EU) has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast-track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast-track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Marketing and promotion of approved drugs in other major oncology markets, such as the EU, are subject to similar requirements and regulations.

Other U.S. Regulatory Matters

Pharmaceutical manufacturers are subject to various healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state, and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal false claims, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or *qui tam* actions, and civil monetary penalties law prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.
- HIPAA, as amended by HITECH, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain healthcare providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; additionally, the Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act, under the provision titled "Fighting the Opioid Epidemic with Sunshine," in part, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made, or ownership and investment interests held, in 2021.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the PPACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion, and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Marketing, promotion, and sale of approved drugs in other major oncology markets, such as the EU, are subject to similar requirements and regulations. For example, in the EU, safeguarding the privacy, security and transmission of individually identifiable health information is subject to the General Data Protection Regulation (GDPR) and laws, which are widely considered to be the most stringent in the world.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of FDA approval of any future therapeutic candidates, some of our U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for the lost opportunity to market the drug during the patent term while the drug was under the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from regulatory approval. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA"), and one or more Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In the European Economic Area ("EEA"), which comprises the 28 Member States of the European Union and three European Free Trade Association States (Norway, Iceland, and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). There are two types of MAs.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SOPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SOPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above-described procedures, before granting the MA, EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Like the U.S. patent term-restoration, Supplementary Protection Certificates ("SPCs") serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of the ability to market a drug during the patent term due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and Reimbursement

Sales of our therapeutic products and DRP® companion diagnostics, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical therapeutic candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific therapeutic candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

In addition, where a drug product requires a companion diagnostic (in our case, a DRP® companion diagnostic), then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. In general, insurance payors will cover and reimburse a companion diagnostic where sufficient clinical proof is provided to support that use of the companion diagnostic improves healthcare outcomes and/or reduces healthcare expenses associated with a given drug.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the PPACA substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. The PPACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

There remain judicial and Congressional challenges to certain aspects of the PPACA, as well as efforts by the previous administration to repeal or replace certain aspects of the PPACA. Since January 2017, there have been several executive orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have passed. In 2017, the Tax Act repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In April 2020, the U.S. Supreme Court reversed a federal circuit decision that previously upheld Congress' denial of $12.0 billion in "risk corridor" funding. In December 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, in December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. On June 17, 2021, the U.S. Supreme Court reversed the decision of the Fifth Circuit holding that the state plaintiffs lacked standing to challenge the individual mandate under Article III, Section 2 of the U.S. Constitution. It is unclear how future litigation and other efforts to repeal and replace the PPACA will impact the PPACA and our business. We will continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business. Complying with any new legislation, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. The CARES Act, which was signed into law in March 2020, and designed to provide financial support and resources to individuals and businesses affected by COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, to offset the added expense of the 2020 suspension. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the way drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, at the federal level, the administration's budget proposals for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Although a number of these and other measures may require additional authorization to become effective, Congress and the administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on July 24, 2020, the administration announced four executive orders to lower drug prices, including allowing importation of certain drugs, changing how drug rebates are negotiated by middlemen, like pharmacy benefit managers, and directing such rebates to be passed to patients as point-of-sale discounts, and requiring Medicare to pay certain Part B drugs at the lowest price available in economically comparable countries (the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs). The president has delayed the effective date of the international drug pricing order, pending discussion with major drug companies. How these executive orders will be implemented and their impact on the industry remain uncertain. Additionally, the FDA recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition, and results of operations.

Facilities

Our principal executive office is in Boston, MA USA, where we lease at-will, month-to-month share space where we are not bound by any lease. This office is sufficient to support our U.S.-based executive team members, most of whom are based on the East Coast of the U.S., including our CEO, CMO, and SVP of Corporate Development. Our principal laboratory and R&D facility is in Hoersholm, Denmark (just north of Copenhagen), where we have a modest space in a technology park, with an open-ended facility lease, which terminates upon 12-month notice. We believe that these existing facilities will be adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

Human Capital

As of March 1, 2023, we had 9 employees, all of whom were full-time and most of which were engaged in research and development activities. Of our employees, the majority are in Hoersholm, Denmark. Among our executive management team members, one is located near Boston, MA, one is located near New York City, NY, and one is in Vancouver, British Columbia, Canada. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We recognize that attracting, motivating, and retaining talent at all levels is vital to our continued success. Our employees are a significant asset, and we aim to create an environment that is equitable, inclusive, and representative in which our employees can grow and advance their careers, with the overall goal of developing, expanding, and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical-stage platform, business, and operations, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage, and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value agility, passion, and teamwork, and are building a diverse environment where our employees can thrive and one that inspires exceptional contributions and professional and personal development to achieve our mission to significantly change the practice of oncology. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees.

We plan to continue to develop our efforts related to attracting, retaining, and motivating our workforce as we grow and develop and hire more employees.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Financial Position and Need for Capital

We have a limited operating history and have never generated any revenues other than from research grants and a limited number of DRP® biomarker development agreements, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We were incorporated as a Delaware corporation in April 2021 for the purposes of undertaking our Recapitalization Share Exchange. In December 2021, Allarity Therapeutics A/S, became our predecessor upon consummation of the Recapitalization Share Exchange, and was deemed to be the accounting acquirer in the Recapitalization Share Exchange. Our predecessor, Allarity Therapeutics A/S, was organized under the laws of Denmark on September 9, 2004, and was largely focused on organizing and staffing our company, raising capital, developing our proprietary DRP® companion diagnostics platform and acquiring the rights to, advancing the development of, our therapeutic candidates, including conducting clinical trials on our therapeutic candidates, and completing our Recapitalization Share Exchange. As such, we have a limited operating history and have not generated any revenues.

In addition, we have not yet demonstrated an ability to successfully obtain marketing approvals, manufacture drugs on a commercial scale, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drugs.

We are dependent on a short-term bridge loan to finance our current operations. Our continued operations are dependent on us raising capital.

We currently do not have sufficient working capital to fund our continued operations. In November 2022, we entered into a short-term bridge loan arrangement with 3i, LP, the sole holder of our Series A Preferred Stock, pursuant to which 3i, LP agreed to provide us with a loan for up to $1,000,000 in cash subject to achievements of certain milestones. In November 2022, $350,000 was advanced to us and the second advance of $650,000 was advanced in December 2022. In connection with the $1 million bridge loan, the Company also issued a secured promissory note to 3i, LP in the principal amount of $1,666,640, which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Certificate of Designations for the Series A Preferred Stock, that began to accrue on July 14, 2022. The Company received no proceeds from the issuance of the $1,666,640 promissory note. In February 2023, pursuant to a private placement of our Series C Preferred Stock, we issued 50,000 shares of our Series C Preferred Stock at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million.

We will need to raise additional capital after this offering to support our operations and execute on our business plan. We may be required to pursue sources of additional capital through various means, including debt or equity financings. Any new securities that we may issue in the future may be sold on terms more favorable for our new investors than the terms of this offering. Newly issued securities may include preferences, superior voting rights, and the issuance of warrants or other convertible securities that will have additional dilutive effects. We cannot assure that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial condition and results of operations. Our ability to obtain needed financing may be impaired by such factors as the weakness of capital markets, and the fact that we have not been profitable, which could impact the availability and cost of future financings. If the amount of capital we are able to raise from financing activities is not sufficient to satisfy our capital needs, we may have to reduce our operations accordingly.

In the event of default of the Secured Promissory Notes to 3i, LP, such default could adversely affect our business, financial condition, results of operations or liquidity.

The indebtedness evidenced by the secured promissory notes issued and to be issued to 3i, LP in connection with the bridge loan and obligation to pay an Alternative Conversion Floor Amount ("3i Promissory Notes") is secured by all of our assets pursuant to certain security agreement between the Company and 3i, LP ("Security Agreement"). Each of the secured 3i Promissory Notes matures on January 1, 2024 and carries an interest rate of at 5% per annum. 3i, LP may exchange 3i Promissory Notes for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of such promissory note. In addition, each 3i Promissory Note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing. As a secured party, upon an event of default, 3i, LP will have a right to the collateral granted to them under the Security Agreement, and we may lose our ownership interest in the assets. A loss of our collateral will have a material adverse effect on our operations, our business and financial condition.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability. We need to raise additional capital to continue our operations, initiate clinical trials and to implement our business plan.

Since our inception of our predecessor, Allarity Therapeutics A/S, we have incurred losses and have an accumulated deficit of $82.6 million as of December 31, 2022. Our net losses were $16.1 million and $26.6 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, our cash deposits of $2.0 million were determined to be insufficient to fund our current operating plan and planned capital expenditures for the next twelve months. These conditions give rise to a substantial doubt over our ability to continue as a going concern. We expect to incur substantial operating losses for the foreseeable future and may never achieve profitability. None of our current therapeutic candidates have been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized drug that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue the development of our therapeutic candidates, including, but not limited to, the re-submission of an application for New Drug Approval ("NDA") for dovitinib, our most advanced therapeutic candidate, to the FDA and advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer and our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at trial sites in Europe;

- initiate preclinical studies and clinical trials for any additional indications for our current therapeutic candidates and any future therapeutic candidates that we may pursue;

- continue to build our portfolio of therapeutic candidates through the acquisition or in-license of additional therapeutic candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- continue to develop, maintain, and expand our proprietary DRP® companion diagnostics platform;
- pursue regulatory approvals for our current and future therapeutic candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing, distribution and other commercial infrastructure to commercialize any therapeutic candidate for which we may obtain marketing approval, or partner with third parties to affect the same;
- hire additional clinical, regulatory, scientific and accounting personnel; and
- incur additional legal, accounting and other expenses in operating as a U.S. listed public company.

To become and remain profitable, we must develop and eventually commercialize one or more therapeutic candidates with significant market potential or license one or more of our therapeutic candidates to an industry partner. This will require us to be successful in a range of challenging activities, including completing clinical trials of our therapeutic candidates, publishing our data and findings on our therapeutic candidates with peer reviewed publications, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future therapeutic candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We submitted an NDA to the U.S. FDA on our therapeutic candidate Dovitinib in December 2021 and on February 15, 2022, we received RTF letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA determined that our NDA was not sufficiently complete to permit a substantive review and therefore our NDA was not accepted for filing. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP® Dovitinib companion diagnostic. We anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP can be obtained. While we have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success, we continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. If we are successful in raising the necessary funds, we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 Clinical Trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. However, despite our efforts, we may never succeed in any or all these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our therapeutic candidates. If we are required by the FDA, or other regulatory authorities such as the European Medicines Agency, or EMA, to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future therapeutic candidates, our expenses could increase, and profitability could be further delayed.

A decline in the value of our company also could cause you to lose all or part of your investment.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this report. Our audited financial statements at December 31, 2022, and for the year then ended, were prepared assuming that we will continue as a going concern.

The report from our independent registered public accounting firm for the year ended December 31, 2022, includes an explanatory paragraph stating that our recurring losses from operations since inception and our accumulated deficit raise substantial doubt about our ability to continue as a going concern. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations. Our ability to continue as a going concern is contingent upon, among other factors, the sale of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our drug development programs or commercialization efforts.

We anticipate that our expenses will increase substantially as we continue our efforts relating to the re-submission of an NDA to the U.S. FDA for our therapeutic candidate dovitinib and as we advance our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at trial sites in Europe, and advance development of our other therapeutic candidates; seek to identify and develop additional therapeutic candidates; acquire or in-license other therapeutic candidates or technologies; seek regulatory and marketing approvals for our therapeutic candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various drugs for which we may obtain marketing approval, if any; require the manufacture of larger quantities of therapeutic candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; develop, maintain, and expand our proprietary DRP® companion diagnostics platform; hire and retain additional personnel, such as clinical, quality control and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our drug development and help us comply with our obligations as a public company; and add equipment and physical infrastructure to support our research and development programs.

Subject to availability of funding, we intend to use such funds for our ongoing clinical development efforts for our three priority pipeline projects, including commencing a stenoparib in combination with dovitinib Phase 1b/2 clinical trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. We will be required to expend significant funds in order to prepare and re-submit an NDA with the U.S. FDA for our therapeutic candidate dovitinib and to advance the development of stenoparib, IXEMPRA®. In addition, while we may seek one or more collaborators for future development of our current therapeutic candidates or any future therapeutic candidates that we may develop for one or more indications, we may not be able to enter into a partnership or out-license for any of our therapeutic candidates for such indications on suitable terms, on a timely basis or at all. In any event, our existing cash and cash equivalents will not be sufficient to fund all the efforts that we plan to undertake or to fund the completion of development of our therapeutic candidates or our other preclinical studies. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Further financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We will need to seek additional funding, which future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at trial sites in Europe, and our preclinical studies and clinical trials of our other therapeutic candidates;

- the costs associated with maintaining, expanding and updating our proprietary DRP® companion diagnostics platform;

- the costs, timing and outcome of seeking regulatory approvals;

- the costs of our licensing or commercialization activities for any of our therapeutic candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing drug sales, marketing, distribution and manufacturing capabilities;

- our headcount growth and associated costs as we expand our research and development activities as well as potentially establish a commercial infrastructure;

- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;

- revenue received from commercial sales, if any, of our current and future therapeutic candidates;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending against intellectual property related claims;

- the number of future therapeutic candidates that we pursue and their development requirements;

- changes in regulatory policies or laws that may affect our operations;

- changes in physician acceptance or medical society recommendations that may affect commercial efforts;

- the costs of acquiring potential new therapeutic candidates or technology;

- the costs associated with maintaining and expanding our cybersecurity systems; and

- the costs of operating as a public company.

We have identified material weaknesses in our internal controls over financial reporting and as of December 31, 2022, our disclosure controls and procedures and internal control over financial reporting were not effective. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, and disclosure controls and procedures, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price.

In connection with the audits of our financial statements for the years ended December 31, 2022 and 2021, we identified material weaknesses in our internal controls over financial reporting because we did not have a formal process for period end financial closing and reporting, we historically had insufficient resources to conduct an effective monitoring and oversight function independent from our operations and we lack accounting resources and personnel to properly account for accounting transactions such as the issuance of warrants with a derivative liability component. In particular, the material weaknesses identified were:

- a lack of accounting resources required to fulfill US GAAP and SEC reporting requirements;

- a lack of comprehensive US GAAP accounting policies and financial reporting procedures and personnel;

- a lack of adequate procedures and controls to appropriately account for accounting transactions including liability and the valuation allowance on the deferred tax asset relating to the net operating losses; and

- a lack of segregation of duties given the size of our finance and accounting team.

We have implemented and are continuing to implement various measures to address the material weaknesses identified; these measures include:

- as of June 30, 2022, upon separation with our former Chief Financial Officer, our Director of Financial Reporting, a CPA (Illinois) in 2021 who is experienced with public company reporting and is conversant in US GAAP and SEC accounting issues, was promoted to Interim Chief Financial Officer. Effective January 1, 2023, our Interim Chief Financial Officer was promoted to our full time Chief Financial Officer. With this hire we are continuing to address our ongoing development of our comprehensive US GAAP accounting policies, financial reporting procedures and internal controls over financial reporting;

- retaining consulting services to assist with the accounting treatment of complex financial instruments and tax; and

- engaged an independent US GAAP consulting firm as well as an independent tax consulting firm.

A significant deficiency is a control deficiency, or a combination of control deficiencies, that adversely affects our ability to initiate, authorize, record, process, or report external financial data reliably in accordance with US GAAP such that there is more than a remote likelihood that a misstatement of our annual or interim financial statements that is more than inconsequential will not be prevented or detected by our employees. A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of our annual or interim financial statement will not be prevented or detected by our employees on a timely basis. In response, we have begun the process of evaluating our internal control over financial reporting. We have also taken several remedial actions set forth above to address these material weaknesses.

Furthermore, it is possible that, had our independent registered public accounting firm conducted an audit of our internal control over financial reporting such firm might have identified additional material weaknesses and deficiencies. We are a public company in the United States subject to the Sarbanes-Oxley Act of 2002. Once we cease to be an "emerging growth company" as such term is defined in the JOBS Act and a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may continue to conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation, testing and any required remediation.

While documenting and testing our internal control procedures to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented, or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we fail to achieve and maintain an effective internal control environment, we could experience material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of our common stock. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the Nasdaq Stock market, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements for prior periods.

In addition, based on an evaluation of our disclosure controls and procedures and internal control over financial reporting as of December 31, 2022, we have concluded that, as of such date, because (i) of the material weaknesses identified in our internal controls over financial reporting; and (ii) we were late in filing our reports on Form 10-Q for the quarterly periods ended March 31, 2022 and June 30, 2022, our disclosure controls and procedures, and internal control over financial reporting were not effective.

We are committed to remediating our material weakness as promptly as possible. Although we believe we are making process towards remediating the material weaknesses there can be no assurance as to when this material weakness will be remediated or that additional material weaknesses will not arise in the future. If we are unable to maintain effective internal control over financial reporting, our ability to record, process and report financial information timely and accurately could be adversely affected, which could subject us to litigation or investigations, require management resources, increase our expenses, negatively affect our business and investor confidence in our financial statements and adversely impact the price of our common stock.

We received a request for documents from the SEC in the investigation known as "In the Matter of Allarity Therapeutics, Inc.," the consequences of which are unknown.

In January 2023, we received a request to produce documents from the SEC that stated that the staff of the SEC is conducting an investigation known as "In the Matter of Allarity Therapeutics, Inc." to determine if violations of the federal securities laws have occurred. The documents requested appear to focus on submissions, communications and meetings with the FDA regarding our NDA for Dovitinib or Dovitinib-DRP. The SEC letter also stated that investigation is a fact-finding inquiry and does not mean that that the SEC has concluded that the Company or anyone else has violated the laws.

We do not know when the SEC's investigation will be concluded or what action, if any, might be taken in the future by the SEC or its staff as a result of the matters that are the subject to its investigation or what impact, if any, the cost of continuing to respond to inquiries might have on our financial position or results of operations. We have not established any provision for losses in respect of this matter. In addition, complying with any such future requests by the SEC for documents or testimony would distract the time and attention of our officers and directors or divert our resources away from ongoing business matters. This investigation may result in significant legal expenses, the diversion of management's attention from our business, could cause damage to our business and reputation, and could subject us to a wide range of remedies, including enforcement actions by the SEC. There can be no assurance that any final resolution of this or any similar matters will not have a material adverse effect on our financial condition or results of operations.

Risks Related to the Discovery and Development of Our Therapeutic Candidates

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for most of our therapeutic candidates is substantial. It is impossible to predict when or if any of our therapeutic candidates will prove effective or safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our therapeutic candidates, we must demonstrate through extensive preclinical studies and clinical trials that our therapeutic candidates are safe and effective in humans for use in each target indication. Preclinical investigation and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical investigation or clinical trial process, or during the regulatory approval process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies and clinical trials for our therapeutic candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results.

Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. Several companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our therapeutic candidates, the development timeline and regulatory approval and commercialization prospects for our therapeutic candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our therapeutic candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the therapeutic candidate for its intended indications. Preclinical studies and clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of preclinical or clinical development include:

- delays in conducting experiments or preclinical studies or unsatisfactory results from such experiments or studies;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, other pandemics or other events outside our control;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of therapeutic candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the therapeutic candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, committee and staff shortages causing delays at processing the trials at the investigator sites resulting in delayed and slow patient enrollment, which may delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. In addition, current inflation levels could lead to further increases in the costs for clinical supply both in the U.S. and Europe, which could lead to further increases in our development costs and materially affect our results of operations.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our therapeutic candidates, we may need to conduct additional testing to bridge our modified therapeutic candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our therapeutic candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our therapeutic candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an institutional review board ("IRB") may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, ("GCP"), regulations, that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug ("IND") Applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our therapeutic candidates could be negatively impacted, and our ability to generate revenues from our therapeutic candidates may be delayed or eliminated entirely.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including committee and staff shortages causing delays at processing the trials at the investigator sites resulting in delayed and slow patient enrollment. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll enough patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the therapeutic candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- sufficient number of patients willing to consent to a recent biopsy; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as our therapeutic candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our therapeutic candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our current or planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our therapeutic candidates.

If we fail to comply with our obligations in the agreements under which we have licensed the intellectual property rights from third parties for our therapeutic candidates dovitinib and stenoparib or otherwise experience disruptions to our business relationships with our licensors, we could lose rights to advance the development of dovitinib and stenoparib which would have a material adverse effect on our business.

We have entered into intellectual property license agreements with third party licensors for our two most advanced therapeutic candidates, dovitinib and stenoparib that are important to our business. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with any obligations under any of these agreements with our licensors, we may be subject to termination of the license agreements in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize the therapeutic candidate covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property rights subject to the license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the therapeutic candidate covered by the license agreement which would have a material adverse effect on our business.

We may expend our limited resources to pursue a particular therapeutic candidate or indication and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications using our proprietary DRP® companion diagnostics platform. As a result, we may forego or delay pursuit of opportunities with other therapeutic candidates or for other indications, even those that we have begun investigating and that may have shown promise, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and therapeutic candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

We have limited experience in drug discovery and drug development and may not receive regulatory approval to market our therapeutic candidates.

Prior to the acquisition of our therapeutic candidates, we were not involved in and had no control over their preclinical and clinical development. In addition, we rely upon the parties from whom we have acquired our therapeutic candidates from to have conducted such research and development in accordance with the applicable protocol, legal, regulatory, and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable therapeutic candidate, and having correctly collected the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these therapeutic candidates.

We are dependent on our ability to advance the development of our therapeutic candidates. If we are unable to submit an NDA to the FDA for our therapeutic candidate dovitinib, or initiate or complete the clinical development of, obtain marketing approval for or successfully commercialize our other therapeutic candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

Although we submitted an NDA to the FDA for our therapeutic candidate dovitinib in December 2021, we currently do not have any drugs that have received regulatory approval and may never be able to develop marketable therapeutic candidates. In addition, if we do not obtain the regulatory approval for and successfully commercialize our therapeutic candidates or experience significant delays in doing so, we may never generate any revenue or become profitable. We are investing a significant portion of our efforts and financial resources in the advancement of dovitinib, stenoparib, IXEMPRA®, and our other therapeutic candidates and in the development of our proprietary DRP® companion diagnostics platform. Our prospects are substantially dependent on our ability, or those of any future collaborator, to develop, obtain marketing approval for and successfully commercialize therapeutic candidates in one or more disease indications.

The success of dovitinib, stenoparib, IXEMPRA®**,** and our other therapeutic candidates will depend on several factors, including the following:

- our ability to successfully complete clinical trials to obtain regulatory approval for our therapeutics candidates without significant delay. On February 15, 2022, we receive RTF letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA determined that our NDA was not sufficiently complete to permit a substantive review and therefore or NDA was not accepted for filing. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP® Dovitinib companion diagnostic. We anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP can be obtained. While we have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success, we continue to evaluate other potential Phase 1b/2 clinical trials for dovitinib combined with other approved drugs in the mRCC space and in other indications. If we are successful in raising the necessary funds, we anticipate commencing a stenoparib in combination with dovitinib Phase 1b/2 Clinical Trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. The FDA has asserted that neither our NDA or PMA meets the regulatory requirements to warrant a complete agency review. The primary grounds of rejection asserted by the FDA relates to Allarity's use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP®-Dovitinib companion diagnostic. While we are currently evaluating other potential Phase 1b/2 Clinical Trials for dovitinib combined with other approved drugs in the mRCC space, if we raise the necessary funds, we intend to commence a stenoparib in combination with dovitinib Phase 1b/2 Clinical Trial for second-line or later treatment of metastatic ovarian cancer and/or other solid tumors. However, despite our efforts, we may never succeed in any or all these activities and, even if we do, we may never generate sufficient revenue to achieve profitability;

- advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, and our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at trial sites in Europe;
- initiation, progress, timing, costs and results of clinical trials of our other therapeutic candidates and potential therapeutic candidates;
- establishment of a safety, tolerability and efficacy profile that is satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and relevant global markets;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including the results of clinical trials, the time required for the FDA or any comparable foreign regulatory authorities to review any regulatory submissions we may make, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize dovitinib and our other therapeutic candidates, on our own or with any future collaborator or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our therapeutic candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but can take many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later-stage clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biotechnology and pharmaceutical industries to suffer significant setbacks in advanced clinical trials due to nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our future clinical trial results may not be successful, and notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. The historical failure rate for therapeutic candidates in our industry is high. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a therapeutic candidate's clinical development and may vary among jurisdictions. We have not obtained final regulatory approval for any therapeutic candidate and it is possible that none of our existing therapeutic candidates or any therapeutic candidates we may seek to develop in the future will ever obtain regulatory approval.

Our therapeutic candidates could fail to receive regulatory clearance or marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including, but not limited to, the use of genomic or biomarker signatures to identify patients that may respond to drug efficacy;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a therapeutic candidate is safe and effective for its proposed indication;
- we may be unable to identify and recruit a sufficient number of patients with relevant genomic or biomarker signatures in order to conduct clinical trials on our therapeutic candidates or the FDA or comparable foreign regulatory authorities may not approve a DRP® companion diagnostic that is required to select patients responsive to one of our therapeutic candidates;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our therapeutic candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have not previously completed all clinical trials for any of our therapeutic candidates and we have relied on the clinical trial results of others to advance dovitinib to the submission of an unsuccessful NDA filing with the FDA. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate in a way that leads to our obtaining marketing approval for our therapeutic candidates in a timely manner, or at all. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our therapeutic candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our therapeutic candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, may approve a therapeutic candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that therapeutic candidate or may restrict its distribution. Any of the foregoing restrictions or requirements could materially harm the commercial prospects for our therapeutic candidates.

We have not successfully filed an NDA to the FDA or similar drug approval filings to comparable foreign authorities, for any therapeutic candidate, and we cannot be certain that any of our therapeutic candidates will be successful in clinical trials or receive regulatory approval. Further, our therapeutic candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our therapeutic candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our therapeutic candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our therapeutic candidates are not as significant as we estimate, or if the price we charge for our therapeutic candidate is too high, we may not generate significant revenues from sales of such drugs, if approved.

We plan to seek regulatory approval to commercialize our therapeutic candidates both in the United States and the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and possible limitations placed upon commercial sales, pricing and distribution of our therapeutic candidates, and we cannot predict success in these jurisdictions.

Our business strategy of using our proprietary DRP® companion diagnostics platform to advance therapeutic candidates that have previously failed therapeutic clinical trial endpoints in Phase 2 or later clinical trials conducted by others and that we believe may be successfully developed with a DRP® companion diagnostic may not be successful, and important issues relating to safety and efficacy remain to be resolved for most of our therapeutic candidates. Our strategy also involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical trials.

Our therapeutic candidate portfolio includes small molecules that others have tried, but failed, to develop into an approved commercialized drug. Our strategy to use our proprietary DRP® companion diagnostics platform to identify and subsequently clinically advance therapeutic candidates that have previously failed clinical trial endpoints but that we believe have potential to succeed with a DRP® companion diagnostic may not be successful.

Our business strategy includes a focus on leveraging our proprietary DRP® companion diagnostics platform to streamline the drug development process and to identify patients that will benefit from therapeutic candidates that other biotechnology or pharmaceutical companies have abandoned or shelved after initiating clinical trials under an IND application filed with the FDA, including candidates that have failed to achieve statistical significance on the original endpoints established in the clinical trials. We use our proprietary DRP® companion diagnostics platform to advance therapeutic candidates by targeting and evaluating patient sub-populations having gene signatures, determined by our DRP® companion diagnostics platform, that will potentially correlate with drug efficacy and patient response to treatment. While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. These risks and uncertainties include, but are not limited to, the following:

- The remaining term of the initial patents filed with respect to a therapeutic candidate may be significantly less than the patent term for a newly discovered therapeutic candidate;

- Potential out-licensees, alliance partners and collaborators may view a therapeutic candidate identified with our proprietary DRP® companion diagnostics platform with more skepticism because of its history of failed clinical trials, thereby requiring a higher level of additional data and further explanations of mechanisms of action in order to overcome this skepticism and obtain commercially reasonable terms for future development or collaboration;

- Key personnel and institutional knowledge relating to a therapeutic candidate that we couple with a DRP® companion diagnostic may no longer be available for us;

- The current standard of care in the targeted therapeutic indication for the DRP® companion diagnostic-selected patient population may be different than the standard of care that existed during the candidate's last clinical trial, which will require more time and resources from us to reassess and redesign the regulatory development path for the DRP® -coupled therapeutic candidate; and

- The DRP®-coupled therapeutic candidate may be perceived to be in an "older" therapeutic drug type or focus area of oncology, thereby generating less enthusiasm and support compared to therapeutic focus areas of oncology that may be perceived as more recent.

We rely on Smerud Medical Research International and Chosa ApS for the development of our LiPlaCis® DRP® companion diagnostic.

We have out-licensed our LiPlaCis® DRP® companion diagnostic to Chosa ApS, an affiliate of our long-time CRO partner Smerud Medical Research International, in our efforts to advance the clinical development of this asset. Chosa ApS intends to conduct expanded enrollment of a DRP®-guided Phase 2 clinical trial in Europe for LiPlaCis®, with the intent of establishing sufficient clinical results to garner the interest of a larger pharmaceutical acquirer or partner to advance the program through Phase 3 clinical trials and, if approved, to market. Although Chosa ApS and SMERUD will be solely responsible for the development of LiPlaCis®, we intend to support these clinical trials with our proprietary DRP® companion diagnostics and our clinical trial and regulatory expertise, as requested. Under the agreements, we are entitled to receive certain specified milestone payments from Chosa ApS and SMERUD. As a result of these agreements, we rely on Chosa ApS and SMERUD for the further development of LiPlaCis®.

We may depend on enrollment of patients with specific genomic or biomarker signatures, identified through DRP® companion diagnostics, in our clinical trials in order for us to continue development of our therapeutic candidates. If we are unable to enroll patients with specific genomic or biomarker signatures in our clinical trials, our research, development and commercialization efforts could be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients with genomic or biomarker signatures we have identified by our DRP® companion diagnostics platform, and who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Patient enrollment is affected by many factors including the size and nature of the patient population with the specific genomic or biomarker signature we have identified, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the size of the patient population required for analysis of the trial's primary endpoints, the proximity of patients to study sites, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, the risk that patients enrolled in clinical trials will drop out of the trials before completion, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We will compete with other pharmaceutical companies for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in oncology clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. The delay or inability to meet planned patient enrollment may result in increased costs and delay or termination of our trials, which could have a harmful effect on our ability to develop drugs.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we intend to advance our ongoing DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, and our ongoing DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at trial sites in Europe, we are planning for certain clinical trials relating to our other therapeutic candidates, or for other indications of all of our therapeutic candidates, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory clearance to commence a trial or obtaining regulatory approval to utilize a DRP® companion diagnostic in a trial to select and treat patients;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in our CRO's schedules relating to testing patients involved in our clinical trials;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- identifying clinical sites with adequate infrastructure (including data collection) to conduct the trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities and quality of a therapeutic candidate for use in clinical trials.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our therapeutic candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- we may not have the ability to test patients for our clinical trials that require a specific genomic or biomarker signature in order to qualify for enrollment;
- clinical trials of our therapeutic candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our therapeutic candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- the cost of clinical trials of our therapeutic candidates may be greater than we anticipate;

- the supply or quality of our therapeutic candidates or other materials necessary to conduct clinical trials of our therapeutic candidates may be insufficient or inadequate;

- regulators may revise the requirements for approving our therapeutic candidates, or such requirements may not be as we anticipate; and

- any future collaborators that conduct clinical trials may face any of the above issues and may conduct clinical trials in ways they view as advantageous to themselves but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our therapeutic candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our therapeutic candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;

- be delayed in obtaining marketing approval for our therapeutic candidates or not obtain marketing approval at all;

- obtain marketing approval in some countries and not in others;

- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;

- be subject to additional post-marketing testing requirements; or

- have the drug removed from the market after obtaining marketing approval.

Furthermore, we intend to rely on CROs, cancer research centers and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities. They may not perform as required or we may face competition from other clinical trials being conducted by other pharmaceutical companies.

We could encounter delays if a clinical trial is suspended or terminated by us, by the Institutional Review Board or IRB of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our current and future therapeutic candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of our therapeutic candidates, the commercial prospects of our therapeutic candidates will be harmed, and our ability to generate revenues from any of these therapeutic candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our therapeutic candidate development and approval process and jeopardize our ability to commence drug sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our therapeutic candidates.

Our therapeutic candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The clinical evaluation of some of our therapeutic candidates in patients is still in the early stages and it is possible that there may be side effects associated with their use. In such an event, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our therapeutic candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our therapeutic candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our therapeutic candidates. Inadequate training in recognizing or managing the potential side effects of our therapeutic candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our therapeutic candidates receives marketing approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such drugs;
- we may be required to recall a drug or change the way such a drug is administered to patients;
- additional restrictions may be imposed on the marketing or distribution of the particular drug or the manufacturing processes for the drug or any component thereof;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- we may be required to implement Risk Evaluation and Mitigation Strategies, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- our drug may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular therapeutic candidate or for particular indications of a therapeutic candidate, if approved, and could significantly harm our business, results of operations and prospects.

We are leveraging our proprietary DRP® companion diagnostics platform in an attempt to create a pipeline of therapeutic candidates using biomarker identification and patient stratification for the development of oncology drugs in a personalized medicine approach. While we believe that applying our proprietary DRP® companion diagnostics platform to drugs that have failed, been abandoned or otherwise failed to meet clinical endpoints and then developing a precision oncology approach that identifies the mechanism of action, potential combination drug usage and potentially responsive patient population is a strategy, our approach has not been approved by the FDA or any equivalent foreign regulatory authority. While we have retrospectively validated our proprietary DRP® companion diagnostics platform in 35 clinical trials conducted by other companies, we have not yet received approval from the FDA or other regulatory agency to market a companion diagnostic. Because our approach is both innovative and in the early stages of development, the cost and time needed to develop our therapeutic candidates is difficult to predict, and our efforts may not result in the successful discovery and development of commercially viable medicines. We may also be incorrect about the effects of our therapeutic candidates on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected.

Our proprietary DRP® companion diagnostics platform may fail to help us select and treat likely responder patients for our therapeutic candidates or help us identify additional potential therapeutic candidates.

Any drug development that we are conducting using our proprietary DRP® companion diagnostics platform may not be successful or have commercial value or therapeutic utility. Our proprietary DRP® companion diagnostics platform may initially show promise in identifying potential therapeutic candidates, yet fail to yield viable therapeutic candidates for clinical development or commercialization for a number of reasons, including:

- research programs to identify new therapeutic candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new therapeutic candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop therapeutic candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;

- compounds identified through our proprietary DRP® companion diagnostics platform may not demonstrate efficacy, safety or tolerability at levels acceptable to regulatory authorities;

- our DRP® companion diagnostics platform may fail to successfully identify likely responder patients and therefore not yield greater therapeutic benefit than observed in un-selected patients.

- potential therapeutic candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;

- competitors may develop alternative therapies that render our potential therapeutic candidates non-competitive or less attractive; or

- a potential therapeutic candidate may not be capable of being produced at an acceptable cost.

Any failure by us to comply with existing regulations could harm our reputation and operating results.

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell our therapeutic candidates if and after they are approved. For example, we will have to adhere to all regulatory requirements including the FDA's current GCPs, Good Laboratory Practice, or GLP, and GMP requirements. If we fail to comply with applicable regulations, including FDA pre-or post- approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We will need to expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our therapeutic candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may be subject to extensive regulations outside the United States and may not obtain marketing approvals for drugs in Europe and other jurisdictions.

In addition to regulations in the United States, should we or our collaborators pursue marketing approvals for our therapeutic candidates internationally, we and our collaborators will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our drugs. Whether or not we, or our collaborators, obtain applicable FDA regulatory clearance and marketing approval for a drug, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug in those countries. The requirements and process governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country.

We expect to pursue marketing approvals for IXEMPRA® and our other therapeutic candidates in Europe and other jurisdictions outside the United States with collaborative partners. The time and process required to obtain regulatory approvals and reimbursement in Europe and other jurisdictions may be different from those in the United States regulatory and approval in one jurisdiction does not ensure approvals in any other jurisdiction; however, negative regulatory decisions in any jurisdiction may have a negative impact on the regulatory process in other jurisdictions.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any therapeutic products on the market, our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we may market, sell and distribute our therapeutic products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the PPACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Our inability to obtain or retain sufficient clinical trial liability insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit our ability to conduct clinical trials for therapeutic candidates we develop.

Although we currently have clinical trial liability insurance, in the future we may need to secure additional coverage before commencing patient enrollment for our clinical trials in the United States or other jurisdictions. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our existing insurance or that is more than the limits of our insurance coverage. We expect we will supplement our clinical trial coverage with product liability coverage in connection with the commercial launch of dovitinib or other therapeutic candidates we develop in the future; however, we may be unable to obtain such increased coverage on acceptable terms or at all. If we are found liable in a clinical trial lawsuit or a product liability lawsuit in the future, we will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to the Approval and Commercialization of Our Therapeutic Candidates

Even if we are successful in completing all preclinical studies and clinical trials, we may not be successful in commercializing one or more of our therapeutic candidates.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our therapeutic candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our therapeutic candidates, and our ability to generate revenue will be materially impaired.

Our therapeutic candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency (the "EMA") and similar regulatory authorities outside of the United States. Failure to obtain marketing approval for a therapeutic candidate will prevent us from commercializing the therapeutic candidate. We have not submitted an application for or received marketing approval for any of our therapeutic candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the therapeutic candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our therapeutic candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our therapeutic candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the therapeutic candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent marketing approval of a therapeutic candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If our drugs do not gain market acceptance, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our drugs or any other products we develop or acquire, including, among others:

- the price of our drugs relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our drugs for their indicated applications and treatments, or the value of our DRP® companion diagnostics in improving patient benefit;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

If our drugs do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new therapeutic candidates and expanding our sales and marketing efforts for our approved drugs, which would cause our business to suffer.

We may in the future develop therapeutic candidates in combination with other therapies and that may expose us to additional risks.

We may develop future therapeutic candidates for use in combination with one or more currently approved cancer therapies. Even if any therapeutic candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our therapeutic candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our therapeutic candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our therapeutic candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our therapeutic candidates we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our therapeutic candidates, we may be unable to obtain approval of or market our therapeutic candidates.

We may rely on orphan drug status to commercialize some of our therapeutic candidates, and even if orphan drug status is approved, such approval may not confer marketing exclusivity or other commercial advantages or expected commercial benefits.

We may rely on orphan drug exclusivity for our therapeutic candidates. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a drug that has orphan drug designation subsequently receives the first FDA marketing approval for the disease for which it has such designation, the drug is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, and except in limited circumstances the applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we, or any future collaborators, obtain orphan drug designation for a therapeutic candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that therapeutic candidate. We may not be the first to obtain marketing approval of any therapeutic candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products, and it is possible that another company also holding orphan drug designation for the same therapeutic candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure enough of the drug to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the drug with orphan exclusivity is unable to maintain sufficient drug quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same therapeutic candidate as ours for indications other than those in which we have been granted orphan drug designation.

On August 3, 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Breakthrough Therapy designation by the FDA for our therapeutic candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our therapeutic candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our therapeutic candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our therapeutic candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation for a therapeutic candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our therapeutic candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track designation for some of our therapeutic candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular therapeutic candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Failure to obtain marketing approval in foreign jurisdictions would prevent our therapeutic candidates from being marketed abroad.

To market and sell our drugs in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA marketing approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market.

If we are required by the FDA to obtain approval of a DRP® companion diagnostic in connection with approval of a therapeutic candidate, and we do not obtain or face delays in obtaining FDA approval of a DRP® diagnostic device, we will not be able to commercialize the therapeutic candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic drug or indication, the FDA generally will not approve the therapeutic drug or new therapeutic drug indication if the companion diagnostic is not also approved or cleared for that indication. Under the Federal Food, Drug, and Cosmetic Act, or FDCA, companion diagnostics are regulated as medical devices, and the FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain Premarket Approval, or a PMA, for the diagnostic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. As a result, if we are required by the FDA to obtain approval of a companion diagnostic for a therapeutic candidate, and we do not obtain or there are delays in obtaining FDA approval of a diagnostic device, we may not be able to commercialize the therapeutic candidate on a timely basis or at all and our ability to generate revenue will be materially impaired.

Our business strategy involving drug development includes the development of a companion diagnostic using our proprietary DRP® companion diagnostics platform for each of our therapeutic candidates. On April 2, 2021, we filed a PMA with the FDA for a companion diagnostic for dovitinib, which is currently under review by the FDA, and we intend to file a PMA for each of our therapeutic candidates if, and when, we decide to pursue the submission of an NDA for each therapeutic candidate.

Any therapeutic candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements, improperly promoted off-market label uses of our drugs or therapeutic candidates or if we experience unanticipated problems with our drugs, when and if any of them are approved.

Any therapeutic candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a therapeutic candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our therapeutic candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our drugs;
- drug seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our drugs.

We operate in a highly competitive and rapidly changing industry.

Biotechnological and pharmaceutical drug development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop, and obtain regulatory approval for new and innovative drugs on a cost-effective basis and to market them successfully, as well as maintaining the competitive advantages of our DRP® companion diagnostics platform. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the European Union, and other jurisdictions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase because of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any therapeutic candidate that we may develop.

Established pharmaceutical and biotechnology companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our therapeutic candidates less competitive. Similarly, such companies may invest heavily to accelerate discovery and development of novel companion diagnostic approaches that make our DRP® companion diagnostics platform less competitive. In addition, any new drug that competes with an approved drug must demonstrate compelling advantages in efficacy, convenience, tolerability and safety to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' drugs, or competitive companion diagnostics, could limit the demand and the price we are able to charge for any therapeutic candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing our therapeutic candidate.

We have no experience in marketing and selling drug products. We have not yet entered into arrangements for the sale and marketing of dovitinib, stenoparib, IXEMPRA® or any other therapeutic candidate, although we are exploring several such arrangements. Typically, pharmaceutical companies would employ groups of sales representatives and associated sales and marketing staff numbering in the hundreds to thousands of individuals to call on this large number of physicians and hospitals. We may seek to collaborate with a third-party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third-party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us. If we seek to market and sell our drugs directly, we will need to hire additional personnel skilled in marketing and sales. We cannot be sure that we will be able to acquire, or establish third-party relationships to provide, any or all these marketing and sales capabilities. The establishment of a direct sales force or a contract sales force or a combination direct and contract sales force to market our drugs will be expensive and time-consuming and could delay any drug launch. Further, we can give no assurances that we may be able to maintain a direct and/or contract sales force for any period or that our sales efforts will be sufficient to generate or to grow our revenues or that our sales efforts will ever lead to profits.

Even if we obtain regulatory approvals to commercialize dovitinib, stenoparib, IXEMPRA® or our other therapeutic candidates, our therapeutic candidates may not be accepted by physicians or the medical community in general.

There can be no assurance that dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates or any other therapeutic candidate successfully developed by us, independently or with partners, will be accepted by physicians, hospitals and other health care facilities. Dovitinib, stenoparib, IXEMPRA® and our other and any future therapeutic candidates we develop will compete with several drugs manufactured and marketed by major pharmaceutical and biotech companies. The degree of market acceptance of any drugs we develop depends on several factors, including:

- our demonstration of the clinical efficacy and safety of dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates;
- timing of market approval and commercial launch of dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates;
- the clinical indication(s) for which dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates are approved;
- drug label and package insert requirements;

- advantages and disadvantages of our therapeutic candidates compared to existing therapies, particularly in combination with our DRP® companion diagnostics;
- continued interest in and growth of the market for anticancer tyrosine kinase inhibitory, PARP inhibitory, and microtubule inhibitory drugs;
- strength of sales, marketing, and distribution support;
- drug pricing in absolute terms and relative to alternative treatments;
- future changes in health care laws, regulations, and medical policies; and
- availability of reimbursement codes and coverage in select jurisdictions, and future changes to reimbursement policies of government and third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of any therapeutic candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations.

Healthcare reform measures could hinder or prevent our therapeutic candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare drugs and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our drugs which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been several legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our drugs profitably.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed drugs. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed drugs may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed drugs on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the therapeutic candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during drug development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved drugs.

Governmental efforts to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

Prior presidential administrations have taken several executive actions, including the issuance of several executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, requiring that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order included a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order required agencies to identify regulations to offset any incremental cost of a new regulation. While the current Biden administration has revoked this executive order, no assurances can be given that a future presidential administration will not issue a similar executive order. If a future presidential administration were to issue a similar executive order, it would be difficult to predict how those requirements would be implemented, and the extent to which they would impact the FDA's ability to exercise its regulatory authority. If future executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our therapeutic candidates and affect the prices we may charge for such therapeutic candidates.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our therapeutic candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The PPACA includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There remain judicial, executive and congressional challenges to certain aspects of the PPACA. Since 2017, there have been executive orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. In addition, while Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, effective January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In 2018, a U.S. District Court ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was effectively repealed by Congress as part of the Tax Act. Additionally, in 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court heard oral argument on the case on November 10, 2020, and issued its decision on June 17, 2021, holding that the state plaintiff's in the case challenging the constitutionality of minimum essential health care coverage provisions of the PPACA lacked standing to bring an action under Article III, Section 2 of the U.S. Constitution. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the PPACA. Although the U.S. Supreme Court had not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. Notwithstanding the Supreme Court recent ruling on standing to challenge the constitutionality of the PPACA, it is unclear how additional litigation and the healthcare reform measures of the Biden administration will impact the PPACA and our business. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2021. Recently, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020, the administration announced several executive orders to lower drug prices that attempt to implement several of the administration's proposals. Additionally, the FDA recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved therapeutic product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our therapeutic candidates.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our therapeutic candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or any third-party manufacturers or contractors we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business.

We and third-party manufacturers we engage now are, and any third-party manufacturers we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, including work conducted through third-party manufacturers or contractors, involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers or other contractors, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our drugs, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our therapeutic candidates or drugs. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions because of their non-compliance with environmental, health and safety laws and regulations.

We may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for our proprietary DRP® companion diagnostics platform.

Our proprietary DRP® companion diagnostics platform and other aspects of our business strategy requires sophisticated computer systems and software for data collection, data processing, cloud-based platforms, analytics, statistical projections and forecasting, and other applications and technologies. We seek to address our technology risks by increasing reliance on the use of innovations by cross-industry technology leaders and adapt these innovations for their biopharmaceutical and diagnostic use in our proprietary DRP® companion diagnostics platform. Some of the technologies supporting these industries are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There can be no guarantee that we will be able to develop, acquire or integrate new technologies, that these new technologies will meet our needs or achieve our expected goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render our proprietary DRP® companion diagnostics platform obsolete. Our continued success will depend on our ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance, features and reliability of our services in response to changing client and industry demands. We may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of our proprietary DRP® companion diagnostics platform, limiting our ability to identify new therapeutic candidates. New services, or enhancements to existing services, using our proprietary DRP® companion diagnostics platform may not adequately meet our requirements. Any of these failures could have a material adverse effect on our operating results and financial condition.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our therapeutic candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all our drugs in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our therapeutic candidates. As a result, our results of operations and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are substantially dependent on third parties for the manufacture of our clinical supplies of our therapeutic candidates and Clinical Laboratory Improvements Act ("CLIA") diagnostic laboratories to test patient biopsies in support of our clinical trials, and we intend to rely on third parties to produce commercial supplies of any approved therapeutic candidate. Therefore, our development of our drugs could be stopped or delayed, and our commercialization of any future drug could be stopped or delayed or made less profitable if third-party diagnostic laboratories lose their CLIA credentials or manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us timely test results or with drug products in sufficient quantities or at acceptable prices.

The manufacture of pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We do not currently have nor do we plan to acquire the infrastructure or capability internally in accordance with cGMP prescribed by the FDA or to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of our drugs. Drug manufacturing facilities are subject to inspection before the FDA will issue an approval to market a new drug product, and all the manufacturers that we intend to use must adhere to the cGMP regulations prescribed by the FDA.

We expect therefore to rely on third-party manufacturers for clinical supplies of our therapeutic candidates that we may develop. These third-party manufacturers will be required to comply with current good manufacturing practices, or cGMPs, and other applicable laws and regulations. We will have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our other therapeutic candidates or any drugs that we may successfully develop, or if it withdraws any such approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our therapeutic candidates and adversely affect our business.

We and/or our third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our drugs. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, pandemics, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If we or our third-party manufacturers were to encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any drug for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for drugs that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

We also rely on third-party diagnostic laboratories certified under CLIA for testing of patient biopsies in our clinical trials. Under the CLIA, diagnostic laboratories are subject to inspection and certification by the CMS and if a diagnostic laboratory we use to test patient biopsies fail their CMS inspection or lose their CMS certification for the type of tests we need, our clinical trials could be delayed or the results from our clinical trials may not be acceptable to the FDA or an equivalent foreign regulatory authority.

We, or third-party manufacturers on whom we rely, may be unable to successfully scale-up manufacturing of our therapeutic candidates in sufficient quality and quantity, which would delay or prevent us from developing our therapeutic candidates and commercializing approved drugs, if any.

In order to conduct clinical trials of our therapeutic candidates and commercialize any approved therapeutic candidates, we, or our manufacturers, will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our therapeutic candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our therapeutic candidates in sufficient quality and quantity, the development, testing, and clinical trials of that therapeutic candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our therapeutic candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our therapeutic candidates successfully.

Our failure to find third-party collaborators to assist or share in the costs of drug development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary therapeutic candidates may include the formation of collaborative arrangements with third parties. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future therapeutic candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake drug development and commercialization at our own expense. Such an undertaking may limit the number of therapeutic candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration, and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our therapeutic candidates. To the extent we agree to work exclusively with one collaborator in each area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of therapeutic candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or successfully commercialize any therapeutic candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Risks Related to Our Business and Industry

Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have from time-to-time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our clinical development plans could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on clinical trials.

The effect of Covid-19 could cause potential on going delay in clinical trials due to backup at ethical committee and staff shortage causing delay a s processing the trials at the investigator site resulting in delay or slow patient enrollment which we have no control over.

In addition, our ongoing clinical trials in the U.S. and Europe may be affected by the COVID-19 pandemic. In the future, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing growth.

As of March 1, 2023, we employed a total of 9 full-time employees. Our current internal departments include research and development, finance, and administration. We intend to expand our management team to include an operation ramp up of additional scientific development and technical staff required to achieve our business objectives. We will need to expand our managerial, operational, technical, and scientific, financial, and other resources in order to manage our operations and clinical trials, establish independent manufacturing, continue our research and development activities, and commercialize our therapeutic candidates. Our management and scientific personnel, systems, and facilities currently in place may not be adequate to support our future growth.

Our need to effectively manage our operations, growth and various projects requires that we:

- manage our ongoing and future clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of vendors and research partners or collaborators to perform tasks including preclinical studies and clinical trial management, statistics and analysis, regulatory affairs, medical advisory, market research, formulation development, chemistry, manufacturing and control activities, other drug development functions, legal, auditing, financial advisory, and investor relations. Our growth strategy may also entail expanding our group of contractors or consultants to implement these and other tasks going forward. Because we rely on numerous consultants to outsource many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our therapeutic candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our therapeutic candidate and, accordingly, may not achieve our research, development and commercialization goals.

We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our business depends largely upon the continued services of our founder and Chief Scientific Officer, Dr. Steen Knudsen, Ph.D., and James G. Cullem, our i Chief Executive Officer, Chief Business Officer and Director. We do not maintain "key person" insurance for Messrs. Knudsen and Cullem or any of our other key employees. We also rely on employees in the areas of research and development, regulatory compliance and approvals, and general and administrative functions. From time to time, there may be additional changes in our executive management and employees resulting from the hiring or departure of executives or other key employees which could disrupt our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. We might not be successful in maintaining our unique culture and continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience in bioinformatics, genomics, or experience working with the biopharma market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

In addition, in making employment decisions, particularly in the biotechnology and pharmaceutical industries, job candidates often consider the value of the stock options or other equity instruments they are to receive in connection with their employment. Volatility in the price of our stock might, therefore, adversely affect our ability to attract or retain highly skilled personnel. Furthermore, the requirement to expense stock options and other equity instruments might discourage us from granting the size or type of stock option or equity awards that job candidates require to join our company. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained during clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of therapeutic candidates, which could result in regulatory sanctions and serious harm to our reputation.

Although we adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to follow such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

International operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.

Our business will be subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the U.S. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our therapeutic candidates in patient populations outside the U.S. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves several risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions of clinical trial due to backup at ethical committees and staff shortages causing delays in processing the trials at investigator sites resulting in delayed and slow patient enrollment. ;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our therapeutic candidates and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease;
- certain expenses including, among others, expenses for travel, translation and insurance; and

- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

Our failure to successfully acquire, develop and market additional therapeutic candidates could impair our ability to grow.

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional therapeutic candidates and technologies. We anticipate these investments will constitute a material portion of our business. However, our internal research capabilities are limited, and we may be dependent upon pharmaceutical and biopharmaceutical companies, academic scientists and other researchers to sell or license therapeutic candidates or technologies to us. The success of this strategy depends partly upon our ability to identify, select, and acquire promising pharmaceutical therapeutic candidates for further development together with our proprietary DRP® companion diagnostics platform. The process of proposing, negotiating, and implementing a license or acquisition of a therapeutic candidate is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of therapeutic candidates and technologies. We have limited resources to identify and execute the acquisition or in-licensing of potential therapeutic candidates and technologies and to integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Furthermore, we may not be able to acquire the rights to additional therapeutic candidates on terms that we find acceptable, or at all.

In addition, future acquisitions of intellectual property rights may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's and technical personnel's time and attention to develop acquired therapeutic candidates or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisition costs;
- higher than expected acquisition costs; and
- increased amortization expenses.

Any therapeutic candidate that we acquire may require additional development efforts prior to commercial sale or out-licensing, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All therapeutic candidates are prone to risks of failure typical of pharmaceutical drug development, including the possibility that a therapeutic candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any drugs that we may develop or approved drugs that we may acquire will be manufactured profitably or achieve market acceptance.

We have obtained statistical data, market data and other industry data and forecasts used throughout this report from market research, publicly available information and industry publications which we believe are reliable.

This report contains estimates, projections and other information concerning our industry, our business and the markets for our therapeutic candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this report from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

Risks Related to Our Intellectual Property

If we do not obtain patent term extension for any therapeutic candidates we may develop or obtain a patent on our DRP® companion diagnostic for a therapeutic candidate, our business may be materially harmed.

In the United States, depending upon the timing, duration, and specifics of any FDA marketing approval of a therapeutic candidate, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the lost opportunity to market the drug during the patent term while the drug was under the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the typical statutory expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of regulatory approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, when our therapeutic candidates receive FDA approval, we expect to apply for patent term extensions on patents directed to those therapeutic candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of the relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, or if we are not able to obtain a patent on our DRP® companion diagnostic for our therapeutic candidate, our competitors may obtain approval of competing drugs following the expiration of our patent rights, or use a similar companion diagnostic, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drugs.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes several significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

We or our licensors may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate, or otherwise violate our or our licensors' issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third-party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our therapeutic candidates and use our proprietary. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to pursuing these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our therapeutic candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and therapeutic candidates and their uses. Thus, we do not know with certainty that our technology and therapeutic candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate, or otherwise violate any third-party's intellectual property.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any technology or therapeutic candidate covered by the asserted third-party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing, and marketing our technology and therapeutic candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive; thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or drug. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our collaborators or others. A finding of infringement could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our therapeutic candidates, seek new regulatory approvals, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications directed to our therapeutic candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to license and funding agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance, and other obligations on us. Under our existing licensing and funding agreements, we are obligated to pay certain specified milestone payments and royalties on net drug sales of therapeutic candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any therapeutic candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, these and other license agreements may not provide exclusive rights to use the licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and drugs in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products and technology in fields of use and territories not included in such agreements. In addition, we may not have the right to control or participate in the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are the subject of such licensed rights could be adversely affected.

We may need to obtain additional licenses from others to advance our research or allow commercialization of our therapeutic candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all, or such licenses may be non-exclusive. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

If we are unable to obtain rights to necessary third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and therapeutic candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and therapeutic candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Despite our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize therapeutic candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours upon successful negotiation with the relevant licensor. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and enforcing patents on therapeutic candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license exclusively.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims by third parties asserting that our employees, consultants, contractors or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their trade secret or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants, contractors and advisors were previously employed, or may currently be employed, at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, contractors, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants, contractors and advisors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

In addition to seeking patents for some of our technology and therapeutic candidates, we also rely on trade secrets and confidentiality agreements relating to the development of our proprietary DRP® companion diagnostics platform to protect our unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. Although we may not have done so in the past, we intend to enter into confidentiality and invention or patent assignment agreements with our employees and consultants in the future. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- depending on applicable law, we, or our license partners or current or future collaborators, might not have been the first to invent or file patent applications for or may have derived from a later-filed patent application the inventions covered by the issued patent or pending patent applications that we license or may own in the future;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;

- it is possible that some or all of our owned and in-licensed pending patent applications or those we may own or in-license in the future will not result in issued patents or the claims that issue may be narrow in scope and not provide us with a competitive advantage, including as a result of actions by our competitors;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies or investigational products that are patentable or protectable as a trade secret;

- the patents of others may harm our business, including by preventing us from discovering, developing or commercializing our investigational products; and

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property or may independently develop such trade secret and be free to exploit it.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Owning our Securities

We currently do not satisfy The Nasdaq Global Market continued listing requirements and if we fail to regain compliance our Common Stock will be delisted.

The listing of our common stock on The Nasdaq Global Market is contingent on our compliance with The Nasdaq Global Market's conditions for continued listing. On April 20, 2022, we received notice from the Nasdaq Listing Qualifications stating that because we had not yet filed our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K") by its due date, we were no longer in compliance with the listing requirement which requires listed companies to timely file all required periodic financial reports with the SEC. On May 17, 2022, we filed our Form 10-K with the SEC. Subsequent to the filing of the Form 10-K, we were late in filing our Form 10-Q for the quarterly periods ended March 31, 2022, and June 30, 2022.

On August 23, 2022 we received a letter from Nasdaq Regulation advising that we were not in compliance with the Nasdaq Listing Rules (the "Rules") for failing to file our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022. We were given 60 days to submit a plan to regain compliance and, if our plan is accepted by Nasdaq, we may be granted an exception of up to 180 calendar days, or until February 20, 2023, to regain compliance. On October 7, 2022, we filed the delinquent Form 10-Q and regained compliance.

On October 12, 2022, we received a letter from Nasdaq Listing Qualifications notifying us that the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended June 30, 2022 (the "Form 10-Q"), did not satisfy the continued listing requirement under Nasdaq Listing Rule 5450(b)(1)(A) for The Nasdaq Global Market, which requires that a listed company's stockholders' equity be at least $10.0 million. As reported on the Form 10-Q, the Company's stockholders' equity as of June 30, 2022, was approximately $8.0 million. Pursuant to the letter, we were required to submit a plan to regain compliance with Nasdaq Listing Rule 5450(b)(1)(A) by November 26, 2022. After discussions with the Nasdaq staff, on December 12, 2022, we filed a plan to regain and demonstrate long-term Nasdaq compliance including seeking to phase-down to The Nasdaq Capital Market. On December 21, 2022, the Company received notification from the Nasdaq staff that they have granted the Company an extension of time until April 10, 2023, to regain and evidence compliance with the Rule. If the Nasdaq staff determines to seek the delisting our common stock on the Nasdaq, we intend to appeal such determination before the Nasdaq Hearing Panel.

On November 21, 2022, the Company received another written notice from Nasdaq indicating that the Company is not in compliance with the minimum bid price requirement of $1.00 per share under the Nasdaq Listing Rules. Based on the closing bid price of the Company's listed securities for the last 30 consecutive business days from October 10, 2022 to November 18, 2022, the Company no longer met the minimum bid price requirement set forth in Listing Rule 5550(a)(2). Although the Company is currently evaluating various alternative courses of action to regain compliance, there is no guarantee or assurance that the Company will be able to regain compliance and meet the listing standards. In the event the Company does not regain compliance by the prescribed deadline, the Company may be eligible for additional time to regain compliance or may face delisting. If the Company is unable to regain compliance, the Company may transfer to the Nasdaq Capital Market, subject to the Company's satisfaction of the Nasdaq Capital Market's continued listing requirements, but there is no assurance that we will be able to satisfy the listing requirements for the Nasdaq Capital Market.

On December 20, 2022, the Company received a notification letter from Nasdaq Regulation of non-compliance with the Rules requiring listed securities to maintain a minimum market value of publicly held shares of $5,000,000 and if the Company does not regain compliance with the Rule prior to the expiration of the compliance period on June 19, 2023, it will receive written notification that its securities are subject to delisting.

On February 8, 2023, the Company received a notification letter from Nasdaq notifying the Company that due to the resignation of Soren G. Jensen from the Company's board and audit committee, effective on February 4, 2023, the Company no longer complies with Nasdaq's independent director and audit committee requirements as set forth in Nasdaq Listing Rules 5605(b)(1)(A) and 5605(c)(4) which requires a majority of the board of directors to be comprised of independent directors and an audit committee of at least three independent directors. In accordance with Nasdaq Listing Rules, the Company has a cure period to regain compliance as follows: (i) until the earlier of the Company's next annual shareholders' meeting or February 4, 2024; or (ii) if the next annual shareholders' meeting is held before August 3, 2023, then the Company must evidence compliance no later than August 3, 2023.

If we fail to meet the Nasdaq listing requirements and do not regain compliance, we will be subject to delisting by Nasdaq. In the event our common stock is no longer listed for trading on The Nasdaq Global Market and we are unable to transfer to The Nasdaq Capital Market, our trading volume and share price may decrease and you may have a difficult time selling your shares of common stock. In addition, we may experience difficulties in raising capital which could materially adversely affect our operations and financial results. Further, delisting from Nasdaq markets could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees. Finally, delisting could make it harder for you and the Company to sell the securities and hard for us to raise capital.

Our Series C Preferred Stock has super-voting power.

As of the date of this report, we had 30,000,000 shares of common stock, 10,650 shares of Series A Preferred Stock and 50,000 shares of Series B Preferred Stock issued and outstanding. Each share of common stock is entitled to one vote per share, and each share of Series C Preferred Stock is entitled to six hundred twenty (620) votes. The Series A Preferred Stock do not have any voting rights. Except as otherwise required or limited by law, and our Certificate of Incorporation, as amended ("Certificate of Incorporation") and/or Certificate of Designation for the Series C Preferred Stock ("COD"), the holders of common stock and Series C Preferred Stock are entitled to vote as a single class, only on proposals relating to authorized share increase, and reverse stock split ("Amendment Proposals"). As of the date of this report, based on 50,000 shares of Series C Preferred Stock outstanding, the holder of Series C Preferred Stock had voting power equal to approximate 50.8% of the voting power. Therefore, to the extent the voting rights of Series C Preferred Stock are not otherwise extinguished or redeemed, as the case may be, or limited to vote only the Amendment Proposals, certain matters requiring stockholder approval may be achieved with only the votes of the Series C Preferred Stock, which limits the weight of voting rights of a holder of common stock.

If our business developments and achievements do not meet the expectations of investors or securities analysts or for other reasons the expected benefits do not occur, the market price of our common stock traded on Nasdaq may decline.

If our business developments and achievements do not meet the expectations of investors or securities analysts, the market price of common stock traded on Nasdaq may decline. The trading price of our common stock could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a negative impact on your investment in our securities and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- adverse regulatory decisions;
- any delay in our regulatory filings for our therapeutic candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the impacts of the ongoing COVID-19 pandemic and related restrictions as they may related to our clinical trials;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our therapeutic candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our therapeutic candidates;
- lower than expected market acceptance of our therapeutic candidates following approval for commercialization, if approved;
- changes in financial estimates by us or by any securities analysts who might cover our securities;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

- investors' general perception of our business prospects or management;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the U.S. or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

The price of our common stock has fluctuated substantially.

The price of our common stock has fluctuated substantially. Therefore, some investors who have purchased our common stock at high prices face the risk of losing a significant portion of their original investment if they have to sell at a time when the price of our common stock has declined. In addition, the volatility of our stock price could cause other consequences including causing a short squeeze due to the difference in investment decisions by short sellers of common stock and buy-and-hold decisions of longer investors.

You should consider an investment in our securities to be risky, and you should invest in our securities only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this report, are:

- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our proposed clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new drugs by our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;

- the lack of market acceptance and sales growth for our therapeutic candidates, if any, that receive marketing approval;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our therapeutic candidates or any future clinical trials we may conduct;
- changes in the development status of our therapeutic candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned NDA, PMA and clinical trials;
- any delay in our submission for studies or drug approvals or adverse regulatory decisions, including failure to receive regulatory approval for our therapeutic candidates;
- unanticipated safety concerns related to the use of our therapeutic candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy and future issuances of securities;
- sales of large blocks of common stock by our stockholders, including, but not limited to, sales by 3i, LP as a result of the exercise of the warrant issued in our PIPE Financing ("PIPE Warrant") and conversion of Series A Preferred Stock into common stock and the liquidation of the PIPE Financing, and exchange of outstanding secured promissory notes for common stock;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new drugs;
- reputational issues;
- competition from existing technologies and drugs or new technologies and drugs that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new drugs, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We are subject to penalties if we fail to meet certain conditions of the Certificate of Designations of the Series A Preferred Stock and related registration rights agreement.

We are authorized to issue up to 500,000 shares of preferred stock, 20,000 shares of which have been designated as Series A Preferred Stock and sold in connection with the PIPE Financing, 200,000 shares of Series B Preferred Stock of which all of the 190,786 shares of Series B Preferred Stock issued have been redeemed, and 50,000 shares of which has been designated as Series C Preferred Stock and sold in a private placement. We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our common stock might believe to be in their best interests or in which the holders of our common stock might receive a premium over the market price of the common stock. Additionally, the issuance of preferred stock may adversely affect the rights of holders of our common stock by restricting dividends on our common stock, diluting the voting power of our common stock or subordinating the liquidation rights of our common stock.

If certain defined "triggering events" defined in the Certificate of Designations occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Series A Preferred Stock into common stock when a conversion right is exercised, failure to issue our common stock when the PIPE Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, certain defaults on our debts or contractual obligations, or upon a "bankruptcy triggering event" (as defined in the Certificate of Designations), then we may be required to pay a dividend that is added to the stated value on the Series A Preferred Stock in the amount of 18% per annum, but paid quarterly in cash, so long as the triggering event is continuing, or to redeem the Series A Preferred Stock for cash in an amount of 125% of the stated value of the Series A Preferred Stock and in the event that we experience a "Change of Control" (as defined in the Certificate of Designations) we may also be required to redeem the Shares at a premium of 125% of their stated value. In addition, if thirty days after our common stock commences trading on Nasdaq the average daily dollar volume for the 10 days previous to conversion divided by 10 is less than $2,500,000, then the Series A Preferred Stock shall be entitled to a one-time dividend equal to an 8% increase in the stated value of the Preferred Share, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per Preferred Share. This dividend was paid during the first quarter of 2022.

On May 4, 2022, the Company and the Investor entered into a Forbearance Agreement and Waiver, dated April 27, 2022, wherein the Investor confirmed that no Triggering Event as defined under the COD has occurred prior to April 27, 2022, that a Triggering Event under Section 5(a)(ii) will and has occurred on April 29, 2022, and that in consideration for the Registration Delay Payments the Company is obligated to pay under the RRA, and additional amounts the Company is obligated to pay under the COD and the Investor's legal fees incurred in the preparation of the Forbearance Agreement and Waiver in the aggregate of $538,823.00 paid upon execution of the Forbearance Agreement and Waiver, and so long as the Company pays the Registration Delay Payments that become due and payable under the RRA after the execution of the Forbearance Agreement and Waiver, the Investor has agreed to forbear exercising any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the COD (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022 (such period, the "Forbearance Period"). Provided that the Company is not in breach of its obligations under Forbearance Agreement and Waiver, effective as of the Trading Day immediately following the date the Company cures the Triggering Event under Section 5(a)(ii) of the COD, the Investor agrees to waive any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a) of the COD and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver.

In connection with the private placement of Series C Preferred Stock ("Series C Offering"), we also entered into a registration rights agreement with 3i, LP ("Series C RRA"). Under the Series C RRA and Certificate of Designation for the Series C Preferred Stock we have obligations and are subject to terms similar to provisions of the Registration Rights Agreement and the Certificate of Designation for the Series A Preferred Stock.

In addition, under the Series C Offering and PIPE Financing, we are under an obligation to use our best efforts to call a meeting of stockholders to seek stockholder approval for the Amendment Proposals. Since we do not have authorized shares of common stock reserved to be issued upon the potential conversion of the Series A Preferred Stock and exercise of PIPE Warrant, we are in technical default under the terms of the Certificate of Designation for the Series A Preferred Stock and PIPE Warrant, which we have obtained a waiver from 3i, LP in connection with any default arising in connection with the Series C Preferred Stock.

As a result of these or other factors, the issuance of preferred stock could diminish the rights of holders of our common stock, or delay or prevent a change of control of the Company and could have an adverse impact on the market price of our common stock.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our common stock to decline.

The sale of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that it deems appropriate.

Our Certificate of Incorporation, as amended, authorizes capital stock consisting of 30,000,000 shares of common stock, par value $0.0001 per share, and 500,000 shares of preferred stock, par value $0.0001 per share. We held a meeting on February 3, 2023, to among other things have our stockholders vote for (i) proposals to approve an amendment to our Certificate of Incorporation to increase the number of authorized shares from 30,500,000 to 150,500,000, and to increase the number of our common stock from 30,000,000 to 150,000,000, and (ii) a proposal to approve an amendment to our Certificate of Incorporation to approve a reverse stock split. Such proposals were not approved by our stockholders.

As of March 3, 2023, we have issued all of our authorized shares of common stock. We are scheduled to hold a Special Meeting of Stockholders on March 20, 2023 (the "Special Meeting") to approve the following proposals: (1) to approve an amendment to our Certificate of Incorporation to increase the number of authorized shares from 30,500,000 to 750,500,000, and to increase the number of our common stock from 30,000,000 to 750,000,000 (the "Share Increase Proposal"), and (2) to approve an amendment to our Certificate of Incorporation to effect a reverse stock split with respect to the Company's issued and outstanding common stock, par value $0.0001 per share, at a ratio between 1-for-20 and 1-for-35 (the "Range"), with the ratio within such Range to be determined at the discretion of the Board (the "Reverse Stock Split Proposal") and included in a public announcement (collectively, the "Amendment Proposals"). Such amendments are subject to the approval of our stockholders at our Special Meeting and will only become effective upon receipt of the requisite approval. If the proposals are approved, we will have additional shares of common stock available for issuance from time to time, and the authority to issue additional shares of common stock.

As of the date of this report, we had 30,000,000 authorized shares of Common Stock, $0.0001 par value per share, of which 30,000,000 shares were issued and outstanding; and 500,000 authorized shares of preferred stock, $0.0001 par value, of which 10,650 shares of Series A Preferred Stock and 50,000 shares of Series C Preferred Stock were issued and outstanding. As of the date of this report, we do not have sufficient shares of Common Stock authorized for the following: 2,018,958 shares for the issuance upon the exercise of issued and outstanding PIPE Warrant based on initial exercise price, 676,949 shares for issuance upon the exercise of issued and outstanding equity awards, 1,960,266 shares to be reserved for future issuance under our 2021 Equity Incentive Plan ("2021 Plan"), and additional shares for issuance upon the conversion of remaining outstanding shares of Series A Preferred Stock. However, if the Amendment Proposals are approved we will have to reserve the foregoing and such shares will be available for issuance, which issuances will result in dilution to our stockholders. In addition, we expect to file one or more registration statements on Form S-1 for the shares of common stock issuable upon conversion of Series C Preferred Stock and we have ongoing obligations for the registration of the shares of common stock issuable upon conversion of the remainder Series A Preferred Stock and exercise of the PIPE Warrant. In addition, we expect to file one or more registration statements on Form S-8 under the Securities Act to register shares of our common stock or securities convertible into or exchangeable for shares of our common stock issued pursuant to our 2021 Plan. Any such registration statements on Form S-8 will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

We do not have authorized shares of common stock available for issuance, which limits our ability to satisfy our contractual obligations and limit our ability to seek equity financing which may cause us to be unable to continue operations.

As of the date of this report, we have issued all of our authorized shares of common stock. As mentioned above, we are schedule to hold a Special Meeting to seek the required stockholder approval for the Share Increase Proposal and Reverse Stock Split Approval. If the stockholders do not approve such proposals, we will not have shares of common stock authorized available and reserved, this could trigger a right of redemption under the Certificate of Designations for the Series A Preferred Stock, and other adjustments and rights under existing agreements with 3i, L.P. In addition, this could adversely impact our ability to pursue opportunities in which shares of our common stock could be issued that our Board may determine would otherwise be in the best interest of the Company and our stockholders, including financing and strategic transaction opportunities and employee recruitment and retention purposes. Failure to obtain equity financing through the issuance of our securities, including our common stock, may cause us to be unable to continue our operations.

Because there are no current plans to pay cash dividends on shares of our common stock for the foreseeable future, you may not receive any return on investment unless you sell your shares of common stock for a price greater than that which you paid for it.

We intend to retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our Board of Directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our Board of Directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur or from restrictions imposed by any preferred stock we may issue in the future. As a result, you may not receive any return on an investment in our common stock unless you sell your shares of common stock for a price greater than that which you paid for it.

We may incur substantial penalties if we fail to maintain the effectiveness of our registration statement covering the resale of our common stock issued to 3i, LP upon conversion of our Series A Preferred Stock.

Under the terms of the Registration Rights Agreement entered into in connection with the PIPE Financing, or Series A RRA, with 3i, LP, if we fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods, we will incur certain registration delay payments equal to 2% of 3i, LP's investment that has not yet been converted to common stock and sold pursuant to the registration statement upon our failure to maintain the effectiveness of the registration statement and every 30 days thereafter. As a result of the Company's delay in filing its periodic reports with the SEC, a Triggering Event under Section 5(a)(ii) occurred on or about April 29, 2022, and that in consideration for the Registration Delay Payments that the Company was obligated to pay under the Series A RR, and additional amounts the Company was obligated to pay under the Certificate of Designations together with 3i, LP's legal fees incurred in the preparation of the Forbearance Agreement and Waiver, the Company agreed to pay 3i, LP an aggregate amount of $538,823.00 which was paid pursuant to that certain Forbearance Agreement and Waiver with 3i, LP. Failure to maintain the effectiveness of the registration statement also constitutes a "triggering event" under the Certificate of Designations for the Series A Preferred Stock that would result in the accrual and payment of a dividend and provide 3i, LP the right to have its remaining Series A Preferred Stock redeemed for a premium of 125% of the stated value of the Series A Preferred Stock. If 3i, LP were to exercise its option to redeem its Series A Preferred Stock, our available cash for the development of our therapeutic candidates and for our continued operations would be materially and adversely effected.

There is no assurance that an active and liquid trading market in our common stock will develop.

Even though our shares of common stock are currently listed on Nasdaq, there can be no assurance that we will be able to comply with the listing requirements to maintain the listing despite our efforts. In addition, there can be no assurance that any broker will be interested in trading our common stock. Therefore, it may be difficult to sell any shares you acquire if you desire or need to sell them. We cannot provide any assurance that an active and liquid trading market in our common stock will develop or, if developed, that the market will continue.

Our Certificate of Incorporation and our by-laws, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Certificate of Incorporation and our by-laws could make it more difficult for a third-party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 500,000 shares of preferred stock, of which 20,000 shares have been designated as Series A Preferred Stock, of which 10,650 shares are issued and outstanding; 200,000 shares have been designated as Series B Preferred Stock of which 190,786 outstanding shares have been redeemed; and 50,000 shares have been designated as Series C Preferred Stock, of which 50,000 shares are issued and outstanding. The remaining preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third-party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation, by-laws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Certificate of Incorporation and bylaws and Delaware law, as applicable, among other things:

- provide for a classified board of directors;
- provide the board of directors with the ability to alter the by-laws without stockholder approval;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) as the exclusive forum for certain types of claims that the federal courts do not have exclusive jurisdiction, which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable.

Article Fourteenth of our Certificate of Incorporation specifies that unless we consent in writing to the selection of an alternative forum, the court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders; (b) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law ("DGCL") or Certificate of Incorporation or our by-laws; or (c) or any action asserting a claim against us that is governed by the internal affairs doctrine. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act where the state courts have concurrent jurisdiction and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes against us and our directors, officers and other employees, which may discourage such lawsuits, or may require increased costs to bring a claim. The exclusive forum provision does not apply to actions brought to enforce a duty or liability created by the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

General Risk Factors

We are an "emerging growth company" and a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are not electing to delay such adoption of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our December 2021 offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements. We will continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and drug approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the United States require well defined disclosure and procedures and internal control over financial reporting that Allarity A/S did not have as a Danish company and that are expensive and time-consuming requiring our management to devote substantial time to compliance matters.

As a publicly traded company in the U.S., we will continue to incur significant additional legal, accounting and other expenses that Allarity A/S did not incur as a Danish company. For example, as a Danish company with our ordinary shares listed on the Nasdaq First North Growth Market in Stockholm, we were not required to have, and did not have, well defined disclosure controls and procedures and internal controls over financial reporting that are generally required of U.S. publicly held companies. In connection with our review of our previously existing internal controls as part of our preparations for becoming a U.S. publicly traded company, we determined that our internal control over financial reporting for prior periods were ineffective and included material weaknesses that needed to be remedied. See "*Risk Factors — We have identified material weaknesses in our internal controls over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price*" and *"We have determined that our disclosure controls and procedures were not effective based on the material weaknesses identified in our internal control over financial reporting and our failure to timely file our period reports."* Although we have taken, and are continuing to take, additional steps to remedy these material weaknesses in order to assure compliance with our future financial reporting obligations, there can be no assurance that we will be able to do so in a timely manner or at all, or that additional material weaknesses may not exist.

These reporting obligations associated with being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from our reporting obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, as amended, (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, as amended, (the "Dodd-Frank Act"), and the listing requirements of the stock exchange on which our securities are to be listed. These rules require the establishment and maintenance of effective disclosure controls and procedures and internal controls over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under the Sarbanes-Oxley Act related to our disclosure controls and procedures or internal controls over our financial reporting in the future, or, if we discover additional material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.

We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities, or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we have limited experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to several factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- difficulties and additional expenses associated with supporting legacy drugs and hosting infrastructure of the acquired business;

- difficulty converting the customers, if any, of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business, and financial position may suffer.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the U.S., numerous federal and state laws, and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the U.S., these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed because of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California recently enacted the California Consumer Privacy Act (the "CCPA"), which became effective in January 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. At this time, we do not collect personal data on residents of California, but should we begin to do so, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

Foreign data protection laws, including EU General Data Protection Regulation (the "GDPR"), may also apply to health-related and other personal information obtained outside of the U.S. The GDPR, which came into effect in 2018, introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20.0 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S., and the efficacy and longevity of current transfer mechanisms between the EU and the U.S. remains uncertain. For example, in 2016, the EU and U.S. agreed to a transfer framework for data transferred from the EU to the U.S., called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Because we undertake clinical trials in Europe, we are subject to the GDPR and as a result will increase our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our therapeutic candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud, or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our therapeutic candidates could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future therapeutic candidates could be delayed.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of common stock could decline.

The trading market for common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market, or competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, our share price and trading volume would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. This report does not discuss any such tax legislation or the way it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive office is in Boston, MA USA, where we lease at-will, month-to-month virtual office space in a technology park, where we are not bound by any lease. Our current monthly rent for the office space is approximately $85 per month. We believe this office is sufficient to support our U.S.-based executive team members, all of whom are based on the East Coast of the U.S. In each of the fiscal years ended December 31, 2022, and 2021, we paid approximately $1,110 in lease payments. We believe that our current existing facilities will be adequate for our current needs.

Our principal laboratory and R&D facility is in Hoersholm, Denmark (just north of Copenhagen), where we lease a space in a technology park consisting of approximately 4,283 square feet, for $8,107 per month. As of January 31, 2023, the facility lease is continuing on a month-to-month basis. In each of the fiscal years ended December 31, 2022 and 2021, we paid approximately $97,284 in lease payments.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. To the best knowledge of management, there are no material legal proceedings pending against us.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 - MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Stock

Our common stock is listed on Nasdaq Global Market under the symbol "ALLR." Prior to the consummation of the Recapitalization Share Exchange on December 20, 2021, Allarity Therapeutics A/S ordinary shares were listed on the Nasdaq First North Growth Market: Stockholm under the symbol "ALLR:ST."

Holders of Record of Common Stock

As of the date of this report, we had 2 stockholders of record for our common stock. The foregoing number of stockholders of record does not include an unknown number of stockholders who hold their stock in "street name."

Dividend Policy

On November 22, 2022, our Board declared a dividend of Series B Preferred Stock to the stockholders of record of common stock and Series A Preferred Stock as of December 5, 2022 (the "Record Date"). On the Record Date, each share of common stock outstanding received 0.016 of a share of Series B Preferred Stock and each share of Series A Preferred Stock outstanding received 1.744 shares of Series B Preferred Stock. We issued an aggregate of 190,786 shares of Series B Preferred Stock, which were redeemed on February 3, 2023.

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our common stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

From January 1, 2022 to December 31, 2022, pursuant to a series of exercise of conversion of Series A Preferred Stock by 3i, LP, we issued a total of 7,801,831 shares of common stock to 3i, LP upon the conversion of 6,214 shares of Series A Preferred Stock based on a conversion price ranging from $0.22 to $9.91. No proceeds were received by the Company upon such conversion. Subsequent to December 31, 2022, pursuant to the exercise of conversion by the 3i, LP, we issued 14,102,155 shares of Common Stock to the 3i, LP upon the conversion of 2,936 shares of Series A Preferred Stock based on a conversion price ranging from $0.18 to $0.26. No proceeds were received by the Company upon such conversion. As of the date of this report, we had 10,650 shares of Series A Preferred Stock issued and outstanding.

On February 28, 2023, we entered into a Securities Purchase Agreement (the "SPA") with 3i, L.P. for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock, par value of $0.0001 per share (the "Series C Preferred Stock"), at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million (the "Series C Offering"). The 50,000 shares of Series C Preferred Stock (the "Shares") are convertible into shares of the Company's common stock, $0.0001 per share subject to the terms of the COD.

In July 2022, in connection with the appointment of Dr. Roth as our independent director, we granted him options to purchase 23,000 shares of common stock at an exercise price of $1.28 per share, subject to vesting of 1/36 per month over 36 months following the grant date. The expiration date for the options is five years from date of grant.

In October 2022, in connection with the appointment of Mr. McLaughlin as our independent director, we granted him options to purchase 23,000 shares of common stock at an exercise price of $1.10 per share, subject to vesting of 1/36 per month over 36 months following the grant date. The expiration date for the options is five years from date of grant.

The offers, sales, and issuances of the option to Dr. Roth and Mr. McLaughlin, and the Series C Offering were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act. The conversions of Series A Preferred Stock into common stock were exempt pursuant to Section 3(a)(9).

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2022:

	Number of securities to be issued upon exercise of outstanding options, and settlement of RSUs (a)	Weighted-average exercise price of outstanding options, and issuance price of RSUs (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a) (c)
Equity compensation plans approved by security holders[1]	630,949	$ 6.55	-
Equity compensation plans approved by security holders[2]	46,000		1,165,364[2]
Total	676,949	$ 6.55	1,165,374[2]

(1) Upon the closing of the Recapitalization Share Exchange and as of December 31, 2021, we had converted compensatory options to purchase ordinary shares of Allarity Therapeutics A/S to options to purchase 1,174,992 shares of our common stock. Such shares were assumed under the 2021 Plan but are excluded from the number of reserved shares described in footnote 2 below.

(2) Consists of 1,211,374 shares of our common stock initially reserved under the 2021 Equity Incentive Plan ("2021 Plan"). The number of shares reserved for issuance under our 2021 Plan increases automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our Board of Directors. There was no increase for January 1, 2022. Our Board of Directors approved an increase of 5% of the outstanding shares of common stock at December 30, 2022, or 794,892 shares, effective as of January 1, 2023. As a result, as of January 1, 2023, there was a total of 2,006,266 shares of common stock reserved under the 2021 Plan, of which 1,960,266 were available for issuance.

ITEM 6 – [RESERVED]

ITEM 7. - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of Allarity consolidated results of operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and notes thereto included elsewhere in this report. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this report. Unless otherwise indicated or the context otherwise requires, references in this Management's Discussion and Analysis of Financial Condition and Results of Operations section to "Allarity," "we," "us," "our," and other similar terms refer to Allarity Therapeutics, Inc. and its consolidated subsidiaries.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a pharmaceutical company focused on discovering and developing highly targeted anti-cancer drug candidates. Using its Drug Response Predictor (DRP®) platform, the Company identifies the value in drug assets that have otherwise been discontinued by identifying patient populations where these drugs are active. The Company's three lead drug candidates are: the tyrosine kinase inhibitor (TKI) dovitinib, the poly-ADP-ribose polymerase (PARP) inhibitor stenoparib, and the microtubule inhibitor agent IXEMPRA.

Recent Corporate Developments

Bridge Loan

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement with 3i, LP (the "Secured Note Purchase Agreement") for a bridge loan to extend the Company's cash runaway beyond December 31, 2022, in order to provide the Company with more time to complete the process of amending its Certificate of Incorporation to increase it authorized share capital and proposed reverse stock split to facilitate additional capital investments (the "Bridge Loan"). Under the Secured Note Purchase Agreement, the Company has authorized the sale and issuance of three 3i Promissory Notes, with the first note in an aggregate principal amount of $350,000 to be issued at closing (which loan was received in November 2022); the second note in the principal amount of $1,666,640 to be issued at closing and which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Certificate of Designations, that began to accrue on July 14, 2022; and the third note in an aggregate principal amount of $650,000 with respect to a new loan to be funded upon the Company filing a registration statement with SEC in connection with a registered offering. As of December 31, 2022, all of the notes have been issued and are outstanding. Each 3i Promissory Note matures on January 1, 2024, carries an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to the Security Agreement. In addition, 3i, LP may exchange the 3i Promissory Notes for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of the 3i Promissory Notes. In addition, each 3i Promissory Note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing.

Amendment to the Certificate of Designation of Series A Preferred Stock

On November 22, 2022, the Company amended Section 12 of the Certificate of Designation of Series A Preferred Stock to provide for voting rights. Subject to a 9.99% beneficial ownership limitation, the holders of Series A Preferred Stock were granted the right to vote on all matters presented to the stockholders for approval together with the shares of common stock, voting together as a single class, on an "as converted" basis using the "Conversion Price" (initially $9.9061 per share before any adjustment) (rounded down to the nearest whole number and using the record date for determining the stockholders of the Company eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in the Company's Certificate of Incorporation or the Certificate of Designations of Series A Preferred Stock. The voting rights described above expired on February 28, 2023.

Modification to Conversion Price of Series A Preferred Stock

On December 9, 2022, the Company and 3i, LP, the holder of outstanding shares of Series A Preferred Stock, entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations, the parties agreed that the Conversion Price (as defined in such Certificate of Designations) was modified to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations) on the trading date immediately preceding the Conversion Date (as defined in the Certificate of Designations) and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Certificate of Designations) through and inclusive of January 19, 2023. On January 23, 2023, the Company and 3i, LP amended the Letter Agreement to provide the term Conversion Price will be in effect until terminated by the Company and 3i, LP.

Establishment of Series B Preferred Stock

On November 22, 2022, the Company's Board of Directors established the Series B Preferred Stock, par value $0.0001 per share ("Series B Preferred Stock"). Each share of Series B Preferred Stock has 400 votes and is subject to certain redemption rights and voting limitations. See description in exhibit titled "*Description of Capital Stock – Series B Preferred Stock.*"

Issuance of Series B Preferred Stock Dividend

Effective December 5, 2022, the Company issued a stock dividend to be distributed as follows to stockholders of record as of close of business on December 5, 2022: (i) 0.016 shares of Series B Preferred Stock for each outstanding share of common stock; and (ii) 1.744 shares of Series B Preferred Stock for each outstanding share of Series A Preferred Stock. An aggregate of 190,786 shares of Series B Preferred Stock were issued as a stock dividend.

Annual Stockholder Meeting and Redemption of Series B Preferred Stock

On February 3, 2023, we held our previously adjourned annual meeting of stockholders (the "Annual Meeting"). Nine proposals were submitted to our stockholders for a vote at the Annual Meeting including a proposal to increase the number of authorized shares and a proposal to effect a reverse stock split. Upon conclusion of the Annual Meeting, all of the 190,786 shares of Series B Preferred Stock were automatically redeemed, with the holders of the Series B Preferred Stock only having a right to receive the purchase price for the redemption, which was $0.01 per share of Series B Preferred Stock. In addition, the proposals to increase the number of authorized shares and to effect a reverse stock split did not pass by the requisite shareholder vote at the Annual Meeting. In light of our financing needs and our obligations to 3i, L.P., as holder of the Series A Preferred Stock and PIPE Warrant, we conducted a private placement offering pursuant to which we issued 50,000 shares of Series C Preferred Stock.

Establishment of Series C Preferred Stock and Sale of Series C Preferred Stock

On February 24, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock (the "Series C COD") with the Delaware Secretary of State designating 50,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock with a stated value of $27.00 per share. On February 28, 2023, the Company filed a Certificate of Amendment to the Series C COD (the "COD Amendment") to clarify the terms of conversion price and floor price based on definitions provided in the Series C COD (the COD Amendment, together with the Series C COD, the "COD"). Each share of Series B Preferred Stock has 620 votes and is subject to certain redemption rights and voting limitations. See description in exhibit titled "*Description of Capital Stock - Series C Preferred Stock.*"

On February 28, 2023, we entered into a Securities Purchase Agreement (the "SPA") with 3i, L.P. for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock, par value of $0.0001 per share of Series C Preferred Stock at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million (the "Series C Offering"). The Shares are convertible into shares of the Company's common stock, subject to the terms of the COD. The conversion price for the Series C Preferred Stock is initially equal the lower of: (i) $0.182, which is the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day (as defined in the COD) immediately preceding the Original Issuance Date (as defined in the COD); and (ii) the lower of: (x) the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Conversion Date or such other date of determination; and (y) the average of the official closing prices of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) for the five (5) Trading Days immediately preceding the Conversion Date (as defined in the COD) or such other date of determination, subject to adjustment herein (the "Conversion Price"), with the Conversion Price being no less than $0.0370 (the "Floor Price"). In the event that the Conversion Price on a Conversion Date would have been less than the applicable Floor Price if not for the immediately preceding sentence, then on any such Conversion Date the Company will pay the Holder an amount in cash, to be delivered by wire transfer out of funds legally and immediately available therefor pursuant to wire instructions delivered to the Company by the Holder in writing, equal to the product obtained by multiplying (A) the higher of (I) the highest price that the Common Stock trades at on the Trading Day immediately preceding such Conversion Date and (II) the applicable Conversion Price and (B) the difference obtained by subtracting (I) the number of shares of Common Stock delivered (or to be delivered) to the Holder on the applicable Share Delivery Date with respect to such conversion of Series C Preferred Stock from (II) the quotient obtained by dividing (x) the applicable Conversion Amount that the Holder has elected to be the subject of the applicable conversion of Series C Preferred Stock, by (y) the applicable Conversion Price without giving effect to clause (x) of such definition. The Offering closed on February 28, 2023.

In connection with the Series C Offering, concurrently with the SPA, the Company entered into a registration rights agreement with 3i, L.P. (the "RRA") pursuant to which the Company is required to file a registration statement with the SEC to register for resale the shares of Common Stock that are issued upon the potential conversion of the Shares. Under the terms of the RRA, if we fail file an Initial Registration Statement (as defined in the RRA) on or prior to its Filing Date (as defined in the RRA), or fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments, in cash and as partial liquidated damages and not as a penalty, equal to 2.0% of 3i, L.P.'s subscription amount of the Shares pursuant to the SPA. In addition, if we fail to pay any partial liquidated damages in full within seven days after the date payment, we will have to pay interest at a rate of 18.0% per annum, accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The Company has also agreed to pay all fees and expenses incident to the performance of the RRA, except for any broker or similar commissions. In connection with the Series C Offering, the Company and 3i, L.P. entered into a limited waiver agreement pursuant to which 3i, L.P. confirmed that the sale and issuance of the Shares will not give rise to any, or trigger any, rights of termination, defaults, amendment, anti-dilution or similar adjustments, acceleration or cancellation under the existing agreements with 3i, L.P.

Special Meeting of Stockholders

Pursuant to a proxy statement filed with the SEC on or about March 6, 2023 (the "Proxy Statement"), the Company will be holding a Special Meeting of Stockholders (the "Special Meeting") virtually online on March 20, 2023. Stockholders of record of our outstanding shares of Common Stock and Series C Preferred Stock on March 3, 2023 (the "Record Date") will be entitled to notice of, and to vote at, the Special Meeting and any adjournments, continuations or postponements thereof that may take place At the Special Meeting, the stockholders of Common Stock and Series C Preferred Stock will be voting on the following proposals: (1) to approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares from 30,500,000 to 750,500,000, and to increase the number of our common stock from 30,000,000 to 750,000,000, in substantially the form attached to the Proxy Statement as Appendix A (the "Share Increase Proposal"); and (2) to approve an amendment to our Certificate of Incorporation, as amended, in substantially the form attached to the Proxy Statement as Appendix B, to, at the discretion of the Board of Directors of the Company (the "Board"), effect a reverse stock split with respect to the Company's issued and outstanding common stock, par value $0.0001 per share, at a ratio between 1-for-20 and 1-for-35 (the "Range"), with the ratio within such Range to be determined at the discretion of the Board (the "Reverse Stock Split Proposal") and included in a public announcement. Under the terms of the Series C Preferred Stock, the holders thereof may only vote on Proposal 1 (Share Increase Proposal) and Proposal 2 (Reverse Stock Split Proposal) and for no other matters. Each holder of one share of Series C Preferred Stock is entitled to 620 votes representing 31,000,000 votes in the aggregate assuming 50,000 shares of Series C Preferred Stock is outstanding.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Impacts of COVID-19 on our Business

In March 2020, the World Health Organization declared COVID-19 a global pandemic. COVID-19 has had an impact on our operations as it caused some unexpected delays in our clinical program activities as clinical trials were delayed. Management is unable to estimate the future financial effects, if any, to our business as a result of COVID-19 because of the high level of uncertainties and unpredictable outcomes of this disease.

We are continuing to evaluate the impact of COVID-19 pandemic on our business and are taking proactive measures to protect the health and safety of our employees, as well as to maintain business continuity. Based on guidance issued by federal, state, and local authorities, we transitioned to a remote work model for our employees, effective March 16, 2020. During the 2022 restrictions due to COVID-19 have lifted significantly and as a result, our Danish employees have returned to work. Our North American employees are continuing to work remotely. We will continue to closely monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate. The COVID-19 pandemic has not directly impacted our supply chains to date however, there is a threat of potential ongoing delays in our clinical trials due to backup at ethical committees and staff shortages causing delays at processing the trials at the investigator sites resulting in delayed and slow patient enrollment.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trial, healthcare systems or the global economy. However, these effects could harm our operations, and we will continue to monitor the COVID-19 situation closely.

Impact of the Russia-Ukraine War

There have been immense flows of refugees to Europe and Denmark is ready to facilitate and to accept refugees from the Ukraine. It is far too early to estimate how many migrants Denmark will facilitate, but immigration officials have begun preparing to accept Ukrainian refugees. Being a North Atlantic Treaty Organization (NATO) member, Denmark will strengthen its own national preparedness as well as that of the NATO defense alliance. The Ukraine crisis has become a new a destabilizing factor in the Danish and global economy. It dampens growth and increases inflation at a time when inflation and capacity utilization is already high. While the Danish economy is generally robust and able to handle new challenges, and it is expected to enter a pause in growth. However, there are risks of a fall in activity in the Danish economy in general. To date the war has not yet had a direct impact on our results of operations, however our costs for clinical supply in both the United States and Europe have increase by 5% to 10% due to inflation.

Financial Operations Overview

Since our inception in September of 2004, we have focused substantially all our resources on conducting research and development activities, including drug discovery and preclinical studies, establishing, and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, hiring personnel, raising capital and providing general and administrative support for these operations. In recent years, we have recorded very limited revenue from collaboration activities, or any other sources. We have funded our operations to date primarily from convertible notes and the issuance and sale of our securities.

Since our inception of our predecessor, Allarity Therapeutics A/S, we have incurred losses and have an accumulated deficit of $82.6 million as of December 31, 2022. Our net losses were $16.1 million and $26.6 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, our cash deposits of $2.0 million were determined to be insufficient to fund our current operating plan and planned capital expenditures for the next twelve months. Substantially all our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance drug candidates through clinical trials;
- pursue regulatory approval of drug candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new drug candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

Components of Operating Expenses

Research and Development Expenses

Research and development expenses include:

- expenses incurred under agreements with third-party contract organizations, and consultants;
- costs related to production of drug substance, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical trials; and
- employee-related expenses, which include salaries, benefits and stock-based compensation.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks and estimates of services performed using information and data provided to us by our vendors and third-party service providers. Non-refundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and accounted for as prepaid expenses. The prepayments are then expensed as the related goods are delivered and as services are performed.

To date, most of these expenses have been incurred to advance our lead drug candidates, dovitinib, stenoparib, and IXEMPRA.®

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our drug candidates, as our drug candidates advance into later stages of development, and as we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our drug candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, and accounting services. Personnel-related costs consist of salaries, benefits, and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our drug candidates and because of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services.

Results of Operations

Comparison of years ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	For the years ended December 31,		Increase/
	2022	2021	(Decrease)
	(In thousands)		
Operating expenses:			
Research and development	$ 6,930	$ 14,196	$ (7,266)
Impairment of intangible assets	17,571	—	17,571
General and administrative	9,962	12,360	(2,398)
Total operating costs and expenses	34,463	26,556	7,907
Loss from operations:	$ (34,463)	$ (26,556)	$ (7,907)

Research and Development Expenses

We currently do not track our research and development costs by product candidate. A breakdown by nature of type of expense for the years ended December 31, 2022 and 2021, is provided below.

	For the year ended December 31,		Increase/ (Decrease)
	2022	2021	
	(In thousands)		
Research study expenses	$ 1,847	$ 2,329	$ (482)
Tax credit	(711)	(875)	164
Milestone payments	1,417	5,000	(3,583)
Manufacturing & supplies	350	1,105	(755)
Contractors	1,778	2,765	(987)
Patents	268	273	(5)
Staffing	1,915	3,429	(1,514)
Amortization	60	103	(43)
Other	6	67	(61)
	$ 6,930	$ 14,196	$ (7,266)

For the year ended December 31, 2022, versus December 31, 2021:

The decrease of $7.3 million in research and development cost was primarily due to decreases in milestone payments of $3.6 million, staffing costs of $1.5 million, contractor costs of $1.0 million, research study expenses of $480 thousand, other of $61 thousand, amortization of $43 thousand and patents of $5 thousand, offset by a $164 thousand decrease in tax credits.

Overall, the decrease in research and development costs in the year ended December 31, 2022, was because during the year ended December 31, 2021, our research and development activity increased as activity in the clinical trials came back to a pre-pandemic level. Also, we incurred a 2021 milestone payment of $5 million due to Novartis because of the NDA filing; and manufacturing & supplies, and contractor costs were higher in 2021 because of preparation of our NDA filing for Dovitinib. Milestone expenses fluctuate depending upon our contracts as described in our financial statement notes. Staffing costs decreased in 2022 primarily because stock option grants and bonuses were higher in 2021.

Impairment of Intangible Assets

As a result of both the Company's February 15, 2022, receipt of a Refusal to File ("RTF") from the U.S. Food and Drug Administration regarding the Company's new drug application ("NDA") for Dovitinib, and the current depressed state of the Company's stock price, the Company has performed an impairment assessment on its individual intangible assets utilizing a discounted cash flow model with a weighted average cost of capital ("WACC") of 16%, and recognized an impairment charge of $14.0 million during the quarter ended March 31, 2022. During the quarter ended December 31, 2022, because of continued downward pressure on the Company's common stock, we performed a further impairment assessment on the Company's individual intangible asset utilizing a discounted cash flow model with a WACC of 26% and recognized a further impairment charge of $3.6 million.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, and accounting services. Personnel-related costs consist of salaries, benefits, and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. Legal costs incurred in connection with patents are accounted for as general and administrative expenses. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our drug candidates and because of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq, additional insurance expenses, investor relations activities and other administrative and professional services.

General and administrative expenses decreased by $2.4 million for the year ended December 31, 2022, compared to the year ended December 31, 2021. The decrease was primarily due to decreased staffing costs of $3.8 million, listings expenses of $485 thousand, and other administrative costs of $168 thousand; offset by increases in insurance costs of $1.5 million, financial consultants' fees of $245 thousand, audit and legal fees of $224 thousand, communications expenses of $43 thousand and premises expenses of $2 thousand. Staffing costs decreased primarily because of reduced stock option costs. Insurance costs were higher in 2022 because we incurred a full year of directors' and officers' insurance expenses versus one month in 2021. Listings expenses decreased in 2022 versus 2021 because our initial costs of listing on Nasdaq in the U.S. in 2021 were higher than maintenance costs in 2022.

Other Income (Expenses)

Other income (expense) of $16.9 million recognized in the year ended December 31, 2022, consisted primarily of a $17.1 million fair value adjustment of derivative and warrant liabilities, $1.8 million of other income received in connection with the sale of intangible IP assets, and $30 thousand of interest income, offset by ($913) thousand in net foreign exchange losses, ($800) thousand penalty on our Series A preferred stock liability, loss on investment of ($115) thousand, and ($223) thousand in interest expenses.

Other income (expense) of $41 thousand recognized in the year ended December 31, 2021, consisted primarily of a $2.1 million fair value adjustment to warrants and derivative liabilities, and $1.0 million in other income received in connection with our sale of intangible IP assets to Lantern Pharma, offset by ($1.3) million in finance expenses, ($499) thousand in interest expenses, ($495) thousand in loss on our equity investment in Lantern Pharma, Inc., a ($474) thousand change in fair value of convertible debt, a ($141) thousand loss on extinguishment of convertible debt, and net foreign exchange losses of ($95) thousand.

Changes in the fair value of our derivative and warrant liabilities and convertible debt are measured using level 3 inputs as described in our consolidated financial statements.

Income taxes

During the years ended December 31, 2022 and 2021, we recognized $1.5 million and ($133) thousand in income tax recovery (expense) respectively.

Liquidity, Capital Resources and Plan of Operations

Since our inception through December 31, 2022, our operations have been financed primarily by the sale of preferred stock, convertible promissory notes, and the sale and issuance of our ordinary shares. As of December 31, 2022, we had $2.0 million in cash, and an accumulated deficit of $82.6 million.

In the year ended December 31, 2022, we received $1.0 million in proceeds from convertible debt. We also paid $1.5 million in cash on the conversion of Series A preferred shares as well as $800 thousand in penalties on the Series A preferred share liability. Our investing activities included the receipt of $809 thousand on the sale of IP and expenditures of $18 thousand on the purchase of property and equipment.

In the year ended December 31, 2021, we received $20.0 million in gross proceeds from the issuance of Series A preferred stock, $14.9 million in gross proceeds from the issuance of shares, and $1.1 million in proceeds from convertible debt. We also received and repaid a bridge loan of $2.9 million, and we received $1.0 million in proceeds from the sale of IP.

Our primary use of cash is to fund operating expenses, which consist of research and development as well as regulatory expenses related to our most advanced therapeutic candidate, dovitinib, and clinical programs for stenoparib and IXEMPRA®, and to a lesser extent, general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

As of December 31, 2022, the Company's cash deposits of $2.0 million were determined to be insufficient to fund its current operating plan and planned capital expenditures for at least the next 12 months. We estimate that as of the date of this filing, our cash reserves are sufficient for approximately 3 months. These conditions give rise to substantial doubt over the Company's ability to continue as a going concern.

Management's plans to mitigate the conditions or events that raise substantial doubt include additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter other such arrangements when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

Cash Flows

The following table summarizes our cash flows for the years indicated:

(In thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021
Net Cash used in operating activities	$ (16,817)	$ (14,886)
Net Cash provided by investing activities	791	1,005
Net Cash (used in) provided by financing activities	(1,311)	33,818
Net (decrease) increase in cash	$ (17,337)	$ 19,937

Operating Activities

During the year ended December 31, 2022, cash used in operating activities of $16.8 million was attributable to a net loss of $16.1 million, $400 thousand in net non-cash charges, and a $300 thousand change in net operating assets and liabilities.

The non-cash charges consisted of intangible asset impairment of $17.6 million, stock-based compensation of $1.7 million, non-cash interest of $138 thousand, loss on investment of $115 thousand, depreciation and amortization of $60 thousand, and unrealized loss on foreign currency of $450 thousand, offset by a $17.1 million fair value adjustment to derivative liabilities, a $1.8 million gain from the sale of IP and deferred tax benefit of $1.6 million. The change in operating assets and liabilities of $300 thousand was primarily due to a $4.7 million decrease in accrued liabilities, an increase in prepaid expenses of $618 thousand, a decrease in income taxes payable of $19 thousand, a $1.1 million increase in other current assets, and a decrease in operating lease liability of $99 thousand, offset by a $6.2 million increase in accounts payable.

During the year ended December 31, 2021, cash used in operating activities of $14.9 million was attributable to a net loss of $26.6 million, offset by $6.9 million in net non-cash charges and a $5.6 million change in net operating assets and liabilities.

The non-cash charges consisted of stock-based compensation of $6.4 million, deferred tax expense of $20 thousand, non-cash interest of $238 thousand, loss on investment of $495 thousand, non-cash finance costs of $1.3 million, an increase in fair value adjustment of convertible debt of $474 thousand, loss on extinguishment of convertible debt of $141 thousand, depreciation and amortization of $106 thousand, and loss on foreign currency of $95 thousand, offset by a $2.1 million fair value adjustment to derivative liabilities and $1.0 million gain from the sale of IP. The change in operating assets and liabilities of $5.6 million was primarily due to a $7.2 million increase in accrued liabilities, a decrease in prepaid expenses of $130 thousand, and a decrease in income taxes receivable of $8 thousand, offset by a $1.3 million decrease in accounts payable, a $330 thousand increase in other current assets, and a decrease in operating lease liability of $124 thousand.

Investing Activities

During the year ended December 31, 2022, the Company received $809 thousand in proceeds from the sale of IP and invested $18 thousand in property and equipment.

During the year ended December 31, 2021, the Company received $1.0 million in proceeds from the sale of IP.

Financing Activities

During the year ended December 31, 2022, cash used by financing activities of $1.3 million consisted of $1.0 million in proceeds from the issuance of convertible debt offset by $1.5 million in cash paid on the conversion of Series A preferred shares and $800 thousand in penalties on the Series A preferred share liability.

During the year ended December 31, 2021, cash provided by financing activities of $33.8 million was related to proceeds of $20 million from the sale of Series A preferred stock, $14.9 million from common stock issuance, and convertible loan proceeds of $1.1 million, offset by $1.6 million in Series A preferred stock issuance costs, $484 thousand in share issuance costs, and $84 thousand repayment of our line of credit. We also received and repaid $2.9 million in loan funding during the year ended December 31, 2021.

Contractual Obligations and Commitments

The following table summarizes our commitments and contractual obligations as of December 31, 2022:

	Payments Due By Period				
	Total	Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
			(In thousands)		
Milestone payments	$ 4,900	$ 4,900	$ —	$ —	$ —

We enter into agreements in the normal course of business with vendors for preclinical studies, clinical trials and other service providers for operating purposes. We have not included these payments in the table of contractual obligations above since these contracts are generally cancellable at any time by us following a certain period after notice and therefore, we believe that our non-cancellable obligations under these agreements are not material.

Operating Capital and Capital Expenditure Requirements

We believe that our existing cash and cash equivalents as of the date of this report, based on our anticipated expenditures and commitments for the next twelve months including contractual obligations for milestone payments, will not enable us to fund our operating expenses and capital expenditure requirements for at least twelve (12) months from the date of this report. Our estimate as to how long we expect our cash to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

In November 2022, we entered into a Secured Note Purchase Agreement with 3i, LP for a bridge loan to extend our cash runaway beyond December 31, 2022, in order to provide us with more time to complete the process of amending its Certificate of Incorporation to increase our authorized share capital and proposed reverse stock split to facilitate additional capital investments (the "Bridge Loan"). Under the Secured Note Purchase Agreement, we authorized the sale and issuance of three promissory notes, with the first note in an aggregate principal amount of $350,000 to be issued at closing, which was received in November 2022; the second note in the principal amount of $1,666,640 to be issued at closing and which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Series A Certificate of Designations, that began to accrue on July 14, 2022; and the third note in an aggregate principal amount of $650,000 with respect to a new loan to be funded upon our filing of a registration statement with SEC in connection with a registered offering. As of January 28, 2023, all of the notes have been issued and are outstanding.

On February 3, 2023, we held our previously adjourned annual meeting of stockholders (the "Annual Meeting"). Nine proposals were submitted to our stockholders for a vote at the Annual Meeting including a proposal to increase the number of authorized shares and a proposal to effect a reverse stock split. Such proposals did not pass by the requisite stockholder vote at the Annual Meeting. In light of our financing needs and our obligations to 3i, L.P. as holder of the Series A Preferred Stock and PIPE Warrant, we conducted the a private placement offering for the purchase and sale of 50,000 shares of Series C Preferred Stock, par value of $0.0001 per share at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million. The proceeds were used to fund operating expenses.

As discussed before, we do not have sufficient cash to support our anticipated expenditures and commitments and the Company is seeking capital to support its current and planned operations.

No assurances can be given that any ongoing discussions will be successful or that we will be able to raise additional capital on favorable terms, or at all. Our failure to raise capital or enter into other such arrangements when needed would have a negative impact on our business, results of operations and financial condition and our ability to maintain current operations and develop our product candidates which in turn may force us to seek protection under the U.S. bankruptcy laws. We are actively exploring raising capital through equity and debt financing which may require collateralizing debt financing with our assets. However, if the share increase and/or reverse stock split proposals are not approved by the required stockholder vote, we will be limited in the ways we can raise additional capital.

We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our drug candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing, or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining regulatory approval for our drug candidates, as well as to build the sales, marketing, and distribution infrastructure that we believe will be necessary to commercialize our drug candidates, if approved, we may require substantial additional funding in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our audited condensed consolidated financial statements for the years ended December 31, 2022, and 2021, which have been prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the Series A preferred shares, warrants, convertible debt and the accrual for research and development expenses, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering reasonable changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

While our significant accounting policies are described in the notes to our consolidated financial statements for the years ended December 31, 2022, and 2021, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the Series A preferred shares, warrants, convertible debt, and the accrual for research and development expenses, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering reasonable changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

Acquired in-process research and development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquired as part of a business combination and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third-party. Management assesses its acquired IPR&D for impairment at year end as well as when events and circumstances indicate there is a potential impairment. Significant quantitative indicators considered are the Company's market capitalization, market share, length of remaining clinical trials, and projected revenue per treatment. The projected discounted cash flow models used to estimate the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

Once brought into use, intangible assets are amortized over their estimated useful economic lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated. The Company has recorded impairment losses of $17,571 on its intangible assets in the year ended December 31, 2022.

Research contract costs and accruals

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Convertible debt instruments

The Company follows ASC 480-10, *Distinguishing Liabilities from Equity* in its evaluation of the accounting for a hybrid instrument. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer's equity shares; or (c) variations inversely related to changes in the fair value of the issuer's equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with remeasurements reported in change on fair value expense in the accompanying Statements of Operations and Comprehensive Loss.

Additionally, the Company accounts for certain convertible debt ("Convertible Notes") issued under the fair value option election of ASC 825, Financial Instruments wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently re-measured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized as other income (expense) in the accompanying consolidated statements of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss. Convertible Notes are settled with shares at fair value of the stock issued with any differences recorded to other income (expense), as a gain or (loss) on extinguishment.

Warrants

When the Company issues warrants it evaluates the proper balance sheet classification to determine classification as either equity or as a derivative liability on the consolidated balance sheets. In accordance with ASC 815-40, Derivatives and Hedging-Contracts in the Entity's Own Equity ("ASC 815-40"), the Company classifies a warrant as equity so long as it is "indexed to the Company's equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to the Company's equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to the Company's equity or it has net cash settlement that results in the warrants to be accounted for under ASC 480, Distinguishing Liabilities from Equity, or ASC 815-40, it is classified as a derivative liability, which is carried on the Consolidated Balance Sheet at fair value with any changes in its fair value recognized immediately in the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2022 and 2021, the Company had warrants outstanding for share-based compensation that were classified as equity, and outstanding investor warrants that were classified as derivative liabilities and classified as "Warrant liabilities" in the Consolidated Balance Sheets.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the Consolidated Statements of Operations and Comprehensive Loss each reporting period. Bifurcated embedded derivatives are classified as "Derivative liabilities" in the Consolidated Balance Sheets.

Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's consolidated statements of operations and comprehensive loss.

The Company records the expense for option awards using either a graded or straight-line vesting method. The Company accounts for forfeitures as they occur. For share-based awards granted to employees, directors and non-employee consultants, the measurement date is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews stock award modifications when there is an exchange of original award for a new award. The Company calculates the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards.

Recently Issued Accounting Pronouncements

See the sections titled "*Recently adopted accounting pronouncements"* in Note 2*(cc)* and *"Recently issued accounting pronouncements*" in Note 2*(dd)* to the Company's consolidated financial statements for the year ended December 31, 2022, appearing elsewhere herein.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item begin on page F-1 with the index to financial statements followed by the financial statements.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Current Auditor

On September 9, 2022, our Audit Committee approved the engagement of Wolf & Company, P.C. as our independent registered public accounting firm. Wolf & Company re-audited our financial statements for the year ended December 31, 2021, and audited our financial statements for the year ended December 31, 2022. During the two fiscal years ended December 31, 2022 and 2021 and through the subsequent interim period to the date of this Form 10-K, neither the Company, nor anyone on its behalf, consulted with Wolf & Company regarding any accounting or auditing issues involving the Company, including (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered with respect to the consolidated financial statements of the Company; or (ii) any matter that was the subject of a "disagreement" (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a "reportable event" (as that term is defined in Item 304(a)(1)(v) of Regulation S-K).

Former Auditors

On August 8, 2022, our former independent registered public accounting firm, Marcum LLP ("Marcum") notified us in writing that our client-auditor relationship had ceased to be effective as of August 5, 2022. Marcum's reports on the financial statements for the year ended December 31, 2021, did not contain an adverse opinion or a disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope, or accounting principles but it included an explanatory paragraph concerning the uncertainty of the Company's ability to continue as a going concern.

In our Form 8-K filed with the SEC on August 12, 2022, we reported that during the fiscal year ended December 31, 2021, and subsequent interim period preceding Marcum's resignation on August 5, 2022, there were no disagreements with Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Marcum, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its report. Additionally, during this time period, there were no reportable events as described in Item 304(a)(1)(v) of Regulation S-K, except that, as previously disclosed in our Form 10-K for the year ended December 31, 2021, and Form 10-Q for the quarterly period ended March 31, 2022, we identified material weaknesses in our internal controls over financial reporting because we did not have a formal process for period end financial closing and reporting, we historically had insufficient resources to conduct an effective monitoring and oversight function independent from our operations and we lacked accounting resources and personnel to properly account for accounting transactions such as the issuance of warrants with a derivative liability component.

On August 12, 2022, we provided Marcum with a copy of the disclosures that we were making in response to Item 4.01 on the Form 8-K and requested that Marcum furnish us with a letter addressed to the SEC stating whether it agrees with our statements contained in the Form 8-K and, if not, stating the respects in which it does not agree.

On August 23, 2022, Marcum provided a letter regarding our disclosure contained in our Form 8-K filed on August 12, 2022, which agreed with our statements made in the third sentence of the preceding paragraph regarding the existence of material weaknesses in our internal control over financial reporting; however, Marcum disagreed regarding the description of such material weaknesses. Marcum indicated that the material weaknesses as disclosed in our Form 10-K for the year ended December 31, 2021, and Form 10-Q for the quarterly period ended March 31, 2022, were as follows: (i) a lack of accounting resources required to fulfill US GAAP and SEC reporting requirements; (ii) a lack of comprehensive US GAAP accounting policies and financial reporting procedures; (iii) lack of adequate procedures and controls to appropriately account for accounting transactions including liability and the valuation allowance on the deferred tax asset relating to the net operating losses; and (iv) a lack of segregation of duties given the size of the finance and accounting team. In addition, Marcum stated that our disclosure did not include any reference to its resignation because of the impairment of its independence. Finally, Marcum indicated that our disclosure did not provide disclosure of a reportable event under Item 304(a)(1)(v)(C) of Regulation S-K, as Marcum indicated that information had come to its attention during the time period covered by Item 304(a)(1)(iv) of Regulation S-K, that if further investigated may have caused Marcum to be unwilling to rely on management's representations or be associated with our financial statements; however, due to the Marcum's resignation as a result of the impairment of its independence, Marcum did not conduct such further investigation.

With regards to Marcum's August 23, 2022, letter as it relates to material weaknesses in our internal controls over financial reporting, we believe that we have provided the information required under Item 304(a)(1)(v)(A) in the Form 8-K. With regards Marcum's statement in its August 23, 2022, letter regarding management's representations, we respectfully disagree that there were events that occurred that rose to a level that would have impaired independence, or there was information, if further investigated, would require disclosure under Item 304(a)(1)(v)(C). Prior to its resignation, Marcum did not inform the Audit Committee of the information stated in their letter and if they had done so, we believe that we would have addressed any issues Marcum would have raised with the Audit Committee to the satisfaction of Marcum. A copy of Marcum's letter to the SEC required by Item 304(a) of Regulation S-K is included as Exhibit 16.1 to the registration statement of which this report forms a part.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, as of the end of the period covered by this report, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Act of 1934. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be included in our SEC reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, relating to the Company, including our consolidated subsidiaries, and was made known to them by others within those entities, particularly during the period when this report was being prepared. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2022 because of the material weaknesses identified in our internal controls over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As of December 31, 2022, management assessed the effectiveness of the Company's internal control over financial reporting based on the criteria for effective internal control over financial reporting established in "Internal Control - Integrated Framework," issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). A material weakness is a control deficiency (within the meaning of Public Company Accounting Oversight Board (United States) Auditing Standard No. 5) or a combination of control deficiencies that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Based on such assessment, management concluded that as of December 31, 2022, our internal control over financial reporting was not effective. Management has identified the following material weakness:

In connection with the audit of our financial statements for the years ended December 31, 2022 and 2021, we identified material weaknesses in our internal controls over financial reporting because we did not have a formal process for period end financial closing and reporting, we historically had insufficient resources to conduct an effective monitoring and oversight function independent from our operations and we lack accounting resources and personnel to properly account for accounting transactions such as the issuance of warrants with a derivative liability component. In particular, the material weaknesses identified were:

- a lack of accounting resources required to fulfill US GAAP and SEC reporting requirements;

- a lack of comprehensive US GAAP accounting policies and financial reporting procedures and personnel;

- a lack of adequate procedures and controls to appropriately account for accounting transactions including liability and the valuation allowance on the deferred tax asset relating to the net operating losses; and

- a lack of segregation of duties given the size of our finance and accounting team.

We have implemented and are continuing to implement various measures to address the material weaknesses identified; these measures include:

- as of June 30, 2022, upon separation with our former Chief Financial Officer, our Director of Financial Reporting, a CPA (Illinois) in 2021 who is experienced with public company reporting and is conversant in US GAAP and SEC accounting issues, was promoted to Interim Chief Financial Officer. Effective January 1, 2023, our Interim Chief Financial Officer was promoted to our full time Chief Financial Officer. With this hire we are continuing to address our ongoing development of our comprehensive US GAAP accounting policies, financial reporting procedures and internal controls over financial reporting;

- retaining independent US GAAP consulting services to assist with the accounting treatment of complex financial instruments; and

- engaged an independent US based tax consulting firm.

A significant deficiency is a control deficiency, or a combination of control deficiencies, that adversely affects our ability to initiate, authorize, record, process, or report external financial data reliably in accordance with US GAAP such that there is more than a remote likelihood that a misstatement of our annual or interim financial statements that is more than inconsequential will not be prevented or detected by our employees.

A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of our annual or interim financial statements will not be prevented or detected by our employees. In response, we have begun the process of evaluating our internal control over financial reporting and to address the material weaknesses identified.

We intend to continue to take steps to remediate the material weaknesses described above and further evolve our accounting processes, controls, and reviews. We plan to continue to assess our internal controls and procedures and intend to take further action as necessary or appropriate to address any other matters we identify or are brought to our attention.

We believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal controls over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal controls over financial reporting, which may necessitate further action.

This Annual Report on Form 10-K does not include an attestation report of the Company's independent registered public accounting firm regarding the effectiveness of the Company's internal control over financial reporting, as such report is not required due to the Company's status as a smaller reporting company.

Change in Internal Control over Financial Reporting

Except as discussed above, there have been no changes in the Company's internal controls over financial reporting during the year ended December 31, 2022 other than as noted above, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTION THAT PREVENTS INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors, Executive Officers and Significant Employees

The following table and text set forth the names and ages of our current directors and executive officers as of February 1, 2023. The number of directors is fixed at five and is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. There are currently four members on our Board of Director. Our directors receive compensation in the form of cash and equity grant for their services on the Board of Directors.

Name	Age	Position(s)
Executive Officers		
James G. Cullem, J.D.	54	Chief Executive Officer, Chief Business Officer, Senior Vice President, Corporate Development and Director
Joan Brown	69	Chief Financial Officer and Director of Financial Reporting
Thomas H. Jensen	44	Senior Vice President, Investor Relations and Director
Steen Knudsen, Ph.D.	61	Chief Scientific Officer
Marie Foegh, M.D.	80	Chief Medical Officer
Non-Employee Directors		
David Roth, M.D. (1)	60	Director
Gerald McLaughlin (2)	55	Director

(1) Member of our compensation committee and nominating and corporate governance committee.

(2) Chair of our audit committee, compensation committee and nominating and corporate governance committee.

Business Experience

Executives

James G. Cullem, J.D. was appointed to the Board of Directors on July 7, 2022. Mr. Cullem has been our Interim Chief Executive Officer since June 2022, and our Chief Business Officer and Senior Vice President, Corporate Development since July 2021. Mr. Cullem is an experienced biotechnology executive and previously served as the Vice President, Corporate Development of our predecessor from August 2014 to September 2019. From 2017 to 2020, Mr. Cullem was the co-founder and a board member of 2X-Oncology, Inc. (later Oncology Venture US, Inc.), our subsidiary. From July 2014 to September 2018, he was the Vice President of Corporate Development of the Medical Prognosis Institute, an international precision medicine company with a mission to help find personalized cures for cancer. He brings 20+ years of diverse experience in life sciences organizational management, business development & licensing, intellectual property & technology transfer/commercialization, partnership creation/management, and strategic planning as a member of executive teams. During his tenure, Mr. Cullem has been responsible for the identification and acquisition of most of our lead clinical oncology assets, including big pharma therapeutics dovitinib (from Novartis) and stenoparib (from Eisai). He leads the company's business development discussions as well as clinical program out-licensing and partnership negotiations, both in the U.S. and worldwide. Mr. Cullem has experience in designing and negotiating a broad span of life science deals, has founded and led several early-stage biotech companies, and is a catalyst for businesses taking the next step in the fields of precision medicine and predictive/companion diagnostics, novel drug targets, proteomics and genomics, and clinical-stage cancer therapeutic development. He holds a B.S. degree in Biochemistry from The University of California at Davis, a Juris Doctorate (JD) degree from The University of New Hampshire Franklin Pierce School of Law, specializing in patent & I.P. law, and is a registered patent attorney before the United States Patent & Trademark Office. Based on the above qualifications and Mr. Cullem's extensive experience in business development within the life sciences industry, the Company believes that Mr. Cullem is well qualified to serve on our Board of Directors.

Joan Brown. Ms. Brown has been our Interim Chief Financial Officer since July 2022 and has served as our Director of Financial Reporting since September 21, 2021. From June 2016 to May 2021, Ms. Brown provided financial reporting services as a consultant to various publicly listed and private companies, including as our financial reporting consultant (contract) from September 2020 to April 2021. Ms. Brown's consulting experience includes public company reporting in accordance with US GAAP and IFRS, SEC correspondence, tax compliance, and audit and operations support. From August 2018 to May 2019, Ms. Brown was a senior manager at MNP, LLP, Chartered Professional Accountants, a chartered accounting firm in Vancouver, B.C., Canada, where she was responsible for auditing Canadian and US publicly listed companies pursuant to the requirements of CPAB and PCAOB, respectively. From November 2014 to May 2016, Ms. Brown was a director of Prudential Supervision for the Financial Institutions Commission (FICOM) in Vancouver, B.C., Canada. Ms. Brown received her degree in Business Administration from Simon Fraser University in 1986, and is a Chartered Accountant in Canada (CPA, CA) (since 1998) and a Registered Certified Public Accountant licensed in the State of Illinois (since 2004).

Thomas H. Jensen was appointed to the Board of Directors on July 7, 2022. Mr. Jensen has been our Senior Vice President, Investor Relations since July 2022, and was previously our Senior Vice President, Information Technology since July 2021, and the Senior Vice President, Information Technology of Allarity Therapeutics A/S, our predecessor, since June 2020. Since January 2006, Mr. Jensen has served as the Chief Technology Officer of the Medical Prognosis Institute. Mr. Jensen previously served as the Chief Technology Officer of our predecessor from 2004 to June 2020. Mr. Jensen co-founded Allarity Therapeutics A/S in 2004. Mr. Jensen also established and currently leads our laboratories in Denmark. Alongside nurturing our global laboratories, Mr. Jensen is instrumental in building our investor relations operations, securing operational financing, and fostering the business growth of Allarity Therapeutics. Amongst Mr. Jensen's accolades are his inventions of molecular biological guidelines combined with techniques for high quality reproducible RNA extraction and downstream processing. This allows for high resolution analysis of cancer patients' biopsies. Mr. Jensen's inventions are an important foundation of the DRP® -Drug Response Prediction platform. Mr. Jensen holds a Bachelor of Science degree in Biology from the Technical University of Denmark and conducted further studies in Biology at the University of Copenhagen. The Company believes that Mr. Jensen is well qualified to serve on our Board of Directors based on the above qualifications and his experience in investor relations, business operations and strong track record with the ongoing development of the Company.

Steen Knudsen, Ph.D. has been our Chief Scientific Officer since July 2021. Dr. Knudsen is a co-founder of our predecessor Allarity Therapeutics A/S and the inventor of DRP®, the Drug Response Prediction Platform, which is our core technology and companion diagnostics platform, and was the Chief Scientific Officer of Allarity Therapeutics A/S since 2006. Dr. Knudsen is also a former Professor of Systems Biology with extensive expertise in mathematics, bioinformatics, biotechnology, and systems biology. He co-founded our predecessor in 2004 and served as its CEO from 2004 to 2006. Dr. Knudsen also previously served as a member on our predecessor's Board of Directors from 2016 to 2020. In addition, Dr. Knudsen also currently serves as the Chief Executive Officer of MPI, Inc., our operating subsidiary in the U.S. Dr. Knudsen holds an M.Sc. degree in Engineering from the Technical University of Denmark and a Ph.D. degree in Microbiology from the University of Copenhagen. He received Postdoctoral training in computational biology from Harvard Medical School.

Marie Foegh, M.D. has been our Chief Medical Officer since July 2021. Dr. Foegh was the Chief Medical Officer of Allarity A/S, our predecessor, since January 2018, and previously served as Chief Medical Officer of our subsidiary, 2X-Oncology, Inc. (later Oncology Venture US, Inc.) from 2016 to 2018. Dr. Foegh brings thirty years of experience in the pharmaceutical and biotechnology industries to our senior management team and has a strong track record leading successful clinical development of therapeutics, including regulatory and medical affairs. She is also Adjunct Clinical Professor at Georgetown University, Department of Medicine and Adjunct Professor at New York Medical College, Department of Pharmacology. Dr. Foegh was the Chief Medical Officer and cofounder of Ell Imaging, LLC, an ultrasound device company, from 2014 to 2016. She serves as the Chair of the Board of Directors at the device company, Injecto A/S, since 2014. Dr. Foegh leads clinical development of our current precision medicine oncology pipeline, including our lead assets stenoparib, dovitinib, and IXEMPRA®. Dr. Foegh previously led the successful development and regulatory approval of more than 10 novel drug products in the U.S. and U.K., within oncology, endocrinology and cardiology. Dr. Foegh has fluency in regulatory interactions with the FDA and EMEA, including INDs, NDAs, IDEs (for predictive biomarkers and/or companion diagnostics), and product issues. She also manages interactions with the oncology key opinion leaders including our Scientific Advisory Board. Dr. Foegh holds both a Medical Doctorate (M.D.) degree and a Doctorate of Science (Dr.Sc.) degree from Copenhagen University, Denmark, and is a member of the American College of Physicians (ACP), American Medical Association (AMA), the American Society of Clinical Oncology, and the American College of Obstetricians and Gynecologists (ACOG).

Non-Employee Directors

David A. Roth, M.D. was appointed to the Board of Directors in July 2022. Dr. Roth is currently the Chief Medical Officer of Syros Pharmaceuticals, Inc. (Nasdaq: SYRS) since December 2015. Dr. Roth has served in numerous executive management positions, including as Chief Medical Officer, executive vice president and senior vice president with Infinity Pharmaceuticals, Inc., and as Vice President of Early Development and interim Co-head of Clinical Development with Pfizer Inc. in its oncology business unit. Prior to joining the pharmaceutical industry, Dr. Roth's experience included over ten years in research and clinical practice as an academic hematologist, and he served on the full-time faculty at Harvard Medical School and Beth Israel Deaconess Medical Center in Boston. Dr. Roth completed his fellowship in Hematology and Oncology at the New England Medical Center in Boston, and his residency at the New England Deaconess Hospital in Boston. Dr. Roth received his Bachelor of Science degree from the Massachusetts Institute of Technology and his medical degree from Harvard Medical School in the Harvard-M.I.T. Division of Health Sciences and Technology. As an accomplished academic researcher and physician-scientist with more than 25 years of experience in corporate leadership positions in the biotechnology industry and academic clinical research and based on Dr. Roth's strong track record of successful oncology and hematology drug development, including in areas of biomarker-directed targeted therapies, the Company believes Dr. Roth is qualified to serve on our Board of Directors.

Gerald McLaughlin was appointed to the Board of Directors in October 2022 and has been our Chairman since January 2023. Mr. McLaughlin has extensive experience serving as a senior executive and board member in the biopharmaceutical industry, including financings, mergers & acquisitions, licensing, product development, commercialization, lifecycle management, and operations. Mr. McLaughlin is currently the chief executive officer and board member of Life Biosciences LLC, a biotechnology company, since 2021. Previously, Mr. McLaughlin was the President and CEO for Neos Therapeutics, Inc., a commercial stage pharmaceutical company from 2018 to 2021. He also served as president and CEO of AgeneBio, Inc., a clinical-stage biopharmaceutical company developing therapies for neurological and psychiatric diseases from 2014 to 2018. Mr. McLaughlin holds a B.A. in Economics from Dickinson College and an MBA from the Villanova School of Business. Based on the above qualifications and Mr. McLaughlin's extensive experience in leading operational and executive management roles in the life sciences industry, the Company believes Mr. McLaughlin is well qualified to serve on our Board of Directors.

Involvement in Certain Legal Proceedings

To the best of our knowledge, during the past ten years, none of our directors or executive officers were involved in any of the following: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; and (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated.

Family Relationships and Arrangements

There are no family relationships among any of our directors or named executive officers. There are no arrangements or understandings with any other person under which our directors and officers was elected or appointed as a director or named executive officer.

Director Independence

As required under the Nasdaq listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. Our Board of Directors consults with our legal counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in Nasdaq listing standards, as in effect from time to time. Consistent with these considerations, after review of all relevant identified transactions or relationships between each of our directors, or any of his or her family members, and the Company, its senior management and its independent auditors, our Board of Directors affirmatively determined that all of our directors, except Messrs. Cullem and T. Jensen who are not considered independent because they are our executive officers, are independent directors as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Role of the Board of Directors and Composition

Our Board of Directors oversees and provides guidance for our business and affairs. Our Board of Directors oversees the development of our strategy and business planning process and management's implementation of them and oversees management. Mr. McLaughlin serves as Chair of our Board of Directors. The primary responsibilities of our Board of Directors are to provide oversight, strategic guidance, counseling, and direction to our management. Our Board of Directors meets on a regular basis and additionally as required under the Nasdaq rules.

In accordance with the terms of our Bylaws, subject to the rights of holders of any series of preferred stock, the Board of Directors may establish the authorized number of directors from time to time by resolution. The Board of Directors consists of four members and is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Our Board of Directors is divided into the following classes:

- Class I, consists of Mr. Jensen;
- Class II, consists of Dr. Roth and Mr. McLaughlin; and
- Class III, consists of Mr. Cullem.

Board of Directors Leadership Structure

The positions of Chairman of our Board of Directors and Chief Executive Officer are separated. The Chairman of our Board of Directors has authority, among other things, to call and preside over Board of Directors meetings, to set meeting agendas and to determine materials to be distributed to our directors. The Chairman has substantial ability to shape the work of our Board of Directors. We believe that separation of the positions of chairman and chief executive officer reinforces the independence of our Board of Directors in its oversight of our business and affairs. In addition, we believe that separation of the positions of chairman and chief executive officer creates an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of our Board of Directors to monitor whether management's actions are in our best interests and in the best interests of our stockholders. As a result, we believe that having the positions of chairman and chief executive officer separated can enhance the effectiveness of our Board of Directors as a whole.

In addition, we have a separate chair for each committee of our Board of Directors. The chair of each committee is expected to report to our Board of Directors from time to time, or whenever so requested by our Board of Directors, on the activities of the committee he or she chairs in fulfilling its responsibilities as detailed in its respective charter or specify any shortcomings should that be the case.

Board of Directors Diversity

Our Board of Directors is committed to fostering a diversity of backgrounds and perspectives so that our Board of Directors positions our company for the future. The members of our Board of Directors represent a mix of ages, genders, races, ethnicities, geographies, cultures, and other perspectives that we believe expand our Board of Directors' understanding of the needs and viewpoints of our partners, employees, stockholders, and other stakeholders. The matrix below provides certain information regarding the composition of our Board of Directors as of the date of this report. Each of the categories listed in the below table has the meaning as it is used in Nasdaq Stock Market Rule 5605(f).

Board of Directors Diversity Matrix

	Female	Male
Part I: Gender Identity		
Directors	0	4
Part II: Demographic Background		
African American or Black	0	0
White	0	4

Director Independence

As required under the Nasdaq listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. Our Board of Directors consults with our legal counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in Nasdaq listing standards, as in effect from time to time. Consistent with these considerations, after review of all relevant identified transactions or relationships between each of our directors, or any of his or her family members, and the Company, its senior management and its independent auditors, our Board of Directors affirmatively determined that all of our directors, except Messrs. Cullem and T. Jensen who are not considered independent because they are our executive officers, are independent directors as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

2023 Change in Board of Directors

On January 19, 2023, Mr. Moore and Ms. Maderis resigned as directors, including their positions on each committee on which they serve and, effective February 4, 2023, Mr. Soren Gade Jensen also resigned all of his board positions. The resignations by Messrs. Moore and Jensen, and Ms. Maderis are for personal reasons and not due to any disagreement with the Company's management team or the Company's Board on any matter relating to the operations, policies or practices of the Company or any issues regarding the Company's accounting policies or practices. As a result of the resignations by Mr. Moore and Ms. Maderis, on January 19, 2023, the Board of the Company decreased the fixed number of authorized directors on the Board from seven to five. In addition, Mr. McLaughlin was appointed as chairperson of the Board and as a member of the Nominating Committee. Dr. Roth, was appointed as a member of the Compensation Committee and a member of the Nominating Committee.

Board of Directors Committees

Our Board of Directors has established an Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee comprised of the members identified below. The Board of Directors has also adopted charters for each of these committees, which comply with the applicable requirements of current SEC and Nasdaq rules. Copies of the charters for each committee are available at *www.allarity.com*. Our Board of Directors has determined that all committee members are independent under applicable Nasdaq and SEC rules for committee memberships.

Board of Directors Oversight of Risk

One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various standing committees of our Board of Directors that address risks inherent in their respective areas of oversight. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure, and our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements and reviews our information technology and data security policies and practices and assesses cybersecurity related risks. The Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance practices, including oversight of processes and procedures designed to prevent illegal or improper conduct. The Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Audit Committee

The Audit Committee consists of Mr. McLaughlin whom the Board of Directors has determined satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of the Audit Committee is Dr. McLaughlin, who the Board of Directors has determined is an "Audit Committee financial expert" within the meaning of SEC regulations. Each member of the Audit Committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the Board of Directors has examined each Audit Committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the Audit Committee is to provide assistance to our Board of Directors in fulfilling the Board of Directors' responsibility to our stockholders relating to our accounting and financial reporting practices, system of internal controls, the audit process, the quality and integrity of our financial reporting, and our process for monitoring compliance with laws and regulations and our code of conduct. Specific responsibilities of the Audit Committee are to:

- Appoint, compensate, and oversee the work of any independent auditor;
- Resolve any disagreements between management and the independent auditor regarding financial reporting;
- Pre-approve all audit and permitted non-audit services by the independent auditor;
- Retain independent counsel, independent registered accounting firm, or other advisors or consultants to advise and assist the Audit Committee in carrying out its duties, without needing to seek approval for the retention of such advisors or consultants from the Board of Directors, and determine the appropriate compensation for any such advisors or consultants retained by the Audit Committee;
- Seek any information it requires from our employees or any direct or indirect subsidiary of ours (each, a "Subsidiary"), all of whom are directed to cooperate with the Audit Committee's requests, or external parties;
- Meet with any of our officers or employees (or officers or employees of any Subsidiary), our independent auditor or outside counsel, as necessary, or request that any such persons meet with any members of, or advisors or consultants to, the Audit Committee; and
- Oversee that management has established and maintained processes to assure our compliance with applicable laws, regulations and corporate policy.

Compensation Committee

The Compensation Committee consists of Dr. Roth and Mr. McLaughlin. The chair of the Compensation Committee is Mr. McLaughlin. The Board of Directors has determined that each member of the Compensation Committee is independent under the Nasdaq listing standards and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of the Compensation Committee is to discharge the responsibilities of the Board of Directors relating to compensation of our directors and executive officers, to assist the Board of Directors in establishing appropriate incentive compensation and equity-based plans and to administer such plans, and to oversee the annual process of evaluation of the performance of our management. Specific responsibilities of the Compensation Committee are to:

- Establish a compensation policy for executive officers designed to (i) enhance our profitability and increase stockholder value, (ii) reward executive officers for their contribution to our growth and profitability, (iii) recognize individual initiative, leadership, achievement, and other contributions and (iv) provide competitive compensation that will attract and retain qualified executives.

- Subject to variation where appropriate, the compensation policy for executive officers shall include (i) base salary, which shall be set on an annual or other periodic basis, (ii) annual or other time or project based incentive compensation, which shall be awarded for the achievement of predetermined financial, project, research or other designated objectives applicable to us as a whole and of the executive officers individually and (iii) long-term incentive compensation in the forms of equity participation and other awards with the goal of aligning, where appropriate, the long-term interests of executive officers with those of our stockholders and otherwise encouraging the achievement of superior results over an extended time period.

- Review competitive practices and trends to determine the adequacy of the executive compensation program.

- Annually review and recommend to the Board of Directors corporate goals and objectives relevant to CEO compensation, evaluate the CEO's performance in light of those goals and objectives, and recommend to the Board of Directors the CEO's compensation levels based on this evaluation; the CEO may not be present during any deliberations or voting with respect to the CEO's compensation.

- Annually review and approve compensation of our executive officers other than the CEO.

- Annually review and approve compensation of our directors, including with respect to any equity-based plan.

- As deemed necessary or appropriate, approve employment contracts, severance arrangements, change in control provisions and other agreements.

- Approve and administer cash incentives and deferred compensation plans for executive officers (including any modification to such plans) and oversight of performance objectives and funding for executive incentive plans.

- Approve and oversee reimbursement policies for directors and executive officers.

- Periodically review and make recommendations to the Board of Directors with respect to equity-based plans that are subject to approval by the Board of Directors. The Compensation Committee shall oversee our compliance with the requirement under Nasdaq rules that, with limited exceptions, stockholders approve equity compensation plans. Subject to such stockholder approval, or as otherwise required by the Exchange Act, or other applicable law, the Compensation Committee shall have the power to manage all equity-based plans.

- If we are required by applicable Securities and Exchange Commission ("SEC") rules to include a Compensation Discussion and Analysis ("CD&A") in our SEC filings in the future, review the CD&A prepared by management, discuss the CD&A with management and, based on such review and discussions, recommend to the Board of Directors that the CD&A be included in our Annual Report on Form 10-K, proxy statement, or any other applicable filing as required by the SEC.

- Review all compensation policies and practices for all employees to determine whether such policies and practices create risks that are reasonably likely to have a material adverse effect on our business or financial condition.

- Recommend to the Board of Directors that our stockholders approve, on an advisory basis, the compensation of our named executive officers, as disclosed in our proxy statement, if such proposal will be contained in the proxy statement.

- Recommend to the Board of Directors the frequency of holding a vote on the compensation of our named executive officers, if such proposal will be contained in our proxy statement.

- Periodically review executive supplementary benefits and, as appropriate, our retirement, benefit, and special compensation programs involving significant cost.

- Make regular reports to the Board of Directors.

- Annually review and reassess the adequacy of the Compensation Committee Charter and recommend any proposed changes to the Board of Directors for approval.

- Annually evaluate its own performance.

- Oversee the annual process of performance evaluations of our management.

- Fulfill such other duties and responsibilities as may be assigned to the Compensation Committee, from time to time, by the Board of Directors and/or the Chairman of the Board of Directors.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee consists of Dr. Roth and Mr. McLaughlin. The chair of the Nominating and Corporate Governance Committee is Mr. McLaughlin. The Board of Directors has determined that each member of the Nominating and Corporate Governance Committee is independent under the Nasdaq listing standards.

The primary purpose of the Nominating and Corporate Governance Committee is (1) to assist the Board of Directors by identifying qualified candidates for director, and to recommend to the Board of Directors the director nominees for the next annual meeting of stockholders; (2) to lead the Board of Directors in its annual review of the Board of Directors' performance; (3) to recommend to the Board of Directors director nominees for each Board of Directors committee; and (4) to develop and recommend to the Board of Directors our corporate governance guidelines. Specific responsibilities of the Nominating and Corporate Governance Committee are to:

- Evaluate the current composition, organization, and governance of the Board of Directors and its committees and make recommendations to the Board of Directors for approval.

- Annually review for each director and nominee, the experience, qualifications, attributes, or skills that contribute to the Board of Directors' conclusion that the person should serve or continue to serve as one of our directors, as well as how the directors' skills and background enable them to function well together as a Board of Directors.

- Determine desired member skills and attributes and conduct searches for prospective directors whose skills and attributes reflect those desired. Evaluate and propose nominees for election to the Board of Directors. At a minimum, nominees for service on the Board of Directors must meet the threshold requirements set forth in the *Nominating and Corporate Governance Committee Policy Regarding Qualifications of Directors*. Each nominee will be considered both on his or her individual merits and in relation to existing or other potential members of the Board of Directors, with a view to establishing a well-rounded, diverse, knowledgeable, and experienced Board of Directors.

- Administer the annual Board of Directors' performance evaluation process, including conducting surveys of director observations, suggestions, and preferences.

- Evaluate and make recommendations to the Board of Directors concerning the appointment of directors to Board of Directors' committees, the selection of Board of Directors committee chairs, and proposal of the slate of directors for election to the Board of Directors.

- Consider bona fide candidates recommended by stockholders for nomination for election to the Board of Directors in accordance with Section 2.12 of our Bylaws.

- As necessary in the Nominating and Corporate Governance Committee's judgment from time to time, retain and compensate third-party search firms to assist in identifying or evaluating potential nominees to the Board of Directors.

- Evaluate and recommend termination of membership of individual directors in accordance with the Board of Directors' governance principles, for cause or for other appropriate reasons.

- Oversee the process of succession planning for the Chief Executive Officer and as warranted, other senior officers.

- Develop, adopt and oversee the implementation of a Code of Business Conduct and Ethics for all directors, executive officers and employees.

- Review and maintain oversight of matters relating to the independence of the Board of Directors and committee members, keeping in mind the independence standards of the Sarbanes-Oxley Act of 2002 and applicable Nasdaq rules.

- Oversee and assess the effectiveness of the relationship between the Board of Directors and our management.

- Form and delegate authority to subcommittees when appropriate, each subcommittee to consist of one or more members of the Nominating and Corporate Governance Committee. Any such subcommittee, to the extent provided in the resolutions of the Nominating and Corporate Governance Committee and to the extent not limited by applicable law, shall have and may exercise all the powers and authority of the nominating and corporate governance committee.

- Make regular reports to the Board of Directors concerning its activities.

- Annually review and reassess the adequacy of the Nominating and Corporate Governance charter and the appendices thereto and recommend any proposed changes to the Board of Directors for approval.

- Annually evaluate its own performance.

- Maintain appropriate records regarding its process of identifying and evaluating candidates for election to the Board of Directors.

- Fulfill such other duties and responsibilities as may be assigned to the Nominating and Corporate Governance Committee, from time to time, by the Board of Directors and/or the Chairman of the Board of Directors.

Director Qualifications

In accordance with its charter, the Nominating and Corporate Governance Committee develops and recommends to our Board of Directors appropriate criteria, including desired qualifications, expertise, skills and characteristics, for selection of new directors and periodically reviews the criteria adopted by our Board of Directors and, if appropriate, recommends changes to such criteria.

Board of Directors Diversity

Our Board of Directors desires to seek members from diverse professional backgrounds who combine a strong professional reputation and knowledge of our business and industry with a reputation for integrity. Our Board of Directors does not have a formal policy with respect to diversity and inclusion but is in the process of establishing a policy on diversity. Diversity of experience, expertise and viewpoints is one of many factors the Nominating and Corporate Governance Committee considers when recommending director nominees to our Board of Directors. Further, our Board of Directors is committed to actively seeking highly qualified women and individuals from minority groups to include in the pool from which new candidates are selected. Our Board of Directors also seeks members that have experience in positions with a high degree of responsibility or are, or have been, leaders in the companies or institutions with which they are, or were, affiliated, but may seek other members with different backgrounds, based upon the contributions they can make to our company. We believe that our current board composition reflects our commitment to diversity in the areas of gender and professional background.

Code of Conduct and Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. We will provide any person, without charge, a copy of our Code of Conduct upon written request to Investor Relations, Allarity Therapeutics, Inc., 24 School Street, 2nd Floor, Boston, Massachusetts 02108. The Code of Conduct is available at the Investors section of our website at *www.allarity.com*. Information contained on or accessible through this website is not a part of this report, and the inclusion of such website address in this report is an inactive textual reference only. Any amendments to the Code of Conduct, or any waivers of its requirements, are expected to be disclosed on its website to the extent required by applicable SEC and Nasdaq rules and requirements.

Limitation on Liability and Indemnification of Directors and Officers

Our Certificate of Incorporation limits a director's liability to the fullest extent permitted under the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any breach of the director's duty of loyalty to the corporation or its stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for unlawful payment of dividend or unlawful stock purchase or redemption pursuant to the provisions of Section 174 of the DGCL; and
- for any transaction from which the director derived an improper personal benefit.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Delaware law and our bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment, or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we intend to enter into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as one of our directors or officers or any other company or enterprise to which the person provides services at our request.

We anticipate maintaining a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe these provisions in the Certificate of Incorporation and bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial statements of beneficial ownership, reports of changes in ownership and Annual Reports concerning their ownership, of Common Stock and other of our equity securities on Forms 3, 4, and 5, respectively. Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely on our review of Forms 3, 4 and 5 and amendments thereto filed electronically with the SEC during the most recent fiscal year, we believe that all reports required by Section 16(a) for transactions in the year ended December 31, 2022, were timely filed.

ITEM 11. EXECUTIVE COMPENSATION

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our President and Chief Executive Officer to the median of the annual total compensation of all of its employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Act.

Overview

The Compensation Committee of our Board of Directors assists in discharging our Board of Directors' responsibilities regarding the compensation of our executive officers and of our Board of Directors members. The Compensation Committee is currently comprised of the following two non-employee members of our Board of Directors: Mr. Roth and Mr. McLaughlin.

2022 Named Executive Officer Compensation

The table below shows the compensation awarded to or paid to or earned by our named executive officers for the years ended December 31, 2022 and 2021. Messrs. Carchedi and Knudsen resigned as officers of the Company in June 2022. Upon their departure, Mr. Cullem, our Chief Business Officer, was appointed to also serve as our Chief Executive Officer and Ms. Brown, our Director of Financial Reporting, was appointed to also serve as Chief Financial Officer.

Summary Compensation Table

The following table provides information regarding total compensation awarded to, earned by, and paid to our named executive officers for services rendered to the Company in all capacities for the fiscal years ended December 31, 2022 and 2021.

Name and Principal Position	Year	Salary*	Bonus[1]*	Option Awards[2]*	All Other Compensation ($)*	Total*
Steve R. Carchedi,	2021	$ 427,083	$ 225,000	$ 3,796,636	$ 17,500[4]	$ 4,466,219
former Chief Executive Office[3]	2022	$ 281,310	$ —	—	$ 251,049[5]	$ 532,359
Jens E. Knudsen,	2021	$ 253,125[6]	$ 80,500	$ 249,718	—	$ 583,343
former Chief Financial Officer[3]	2022	$ 194,013	$ —	$ —	$ 139,620[7]	$ 333,633
Marie Foegh,	2021	$ 291,600	$ 132,480	$ 866,188	—	$ 1,290,268
Chief Medical Officer	2022	$ 340,309	$ —	$ —	—	$ 340,309
James G. Cullem,	2021	$ 237,938	118,910	$ 1,474,234	—	$ 1,831,082
Chief Executive Officer, Chief Business Officer[8]	2022	$ 343,410	$ —	$ —	—	$ 343,410
Joan Brown	2021	$ 44,950	$ 9,600	$ —	$ 62,000[10]	116,550
Chief Financial Officer, Director of Financial Reporting[9]	2022	$ 180,000	$ —	$ —	—	$ 180,000

* All compensation amounts are in full numbers and not presented in $1,000's.

(1) The bonuses reported in this column for 2021 consist of cash payments and were earned in 2021 and paid in 2022.

(2) The amounts reported in this column represent the aggregate grant date fair value of service-based option grants awarded to the named executive officer during 2022 and 2021, calculated based on a Black Scholes model. Such grant date fair values do not consider any estimated forfeitures related to service-vesting conditions. This calculation assumes that the named executive officer will perform the requisite service for the award to vest in full as required by SEC rules. The assumptions used in calculating the grant date fair values of the equity awards reported in this column are set forth in Note 18 of the Audited Consolidated Financial Statements for the twelve months ended December 31, 2021, appearing in our Form 10-K. The amounts reported in this column reflect the accounting cost for these equity awards and do not correspond to the actual economic value that may be realized by named executive officers upon the vesting of the stock options, the exercise of the stock options or the sale of the securities underlying such stock options.

(3) Resigned in June 2022.

(4) Consists of life insurance premiums.

(5) Consists of consulting fees, and severance payment of $233,549.

(6) Mr. Knudsen was appointed as Chief Financial Officer in November 2020. Total compensation reflects pro-rata compensation since appointment in November 2020.

(7) Consists of severance payment of $139,620.

(8) Appointed as Chief Executive Officer in June 2022.

(9) Appointed as Interim Chief Financial Officer in June 2022.

(10) Consists of consulting fees.

Outstanding Equity Awards as of December 31, 2022

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2022.

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (USD)	Option Expiration Date
James G. Cullem,	09/24/2019	28,191	—(2)	—	13.30	09/21/2029
Chief Executive Officer, Chief Business Officer	11/24/2021	80,543	52,782(1)		5.19	03/11/2026
Joan Brown	—	—	—	—		—
Chief Financial Officer, Director of Financial Reporting						
Marie Foegh						
Chief Medical Officer	11/24/2021	47,315	31,020(1)	—	5.19	11/23/2026

(1) This option vests as to 25% on November 24, 2021, the grant date, and the remaining 75% vests over 36 months.

(2) This option vests 25% on grant, 25% 12 months from grant, 25% 18 months from grant and 25% 24 months from grant & balance on listing on the Nasdaq Stock Market. The Company listed on Nasdaq Stock Market on December 2021 resulting in the options becoming fully vested.

Pension Benefits

The Company maintains a 401(k) Plan for its full-time employees in the U.S. The 401(k) Plan allows employees of the Company to contribute up to the Internal Revenue Code prescribed maximum amount. Employees may elect to contribute from 1 to 100 percent of their annual compensation to the 401(k) Plan. The 401(k) Plan includes a 3% safe harbor contribution. Both employee and employer contributions vest immediately upon contribution. During fiscal year ended December 31, 2022, the Company did not make a contributions to the 401(k) Plan.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, nor earn any benefits under, a nonqualified deferred compensation plan during the fiscal year ended December 31, 2022.

Employment Agreements and Arrangements

As of the year ended December 31, 2022, we had an employment or consultancy agreement with each of the following named executive officers, Mr. Cullem, Ms. Foegh and Ms. Brown. The employment or consultancy agreement with each of the following individuals provides for the initial annual base salary as of December 31, 2022, current base salary and bonus set forth below. With the departure of Mr. Carchedi, the Board of Directors appointed James G. Cullem, the Company's Chief Business Officer, to also serve as the interim Chief Executive Officer of the Company, effective as of June 29, 2022, and a director of the Company. In connection with Mr. Cullem's new position as interim Chief Executive Officer, the Company increased his base salary from $270,250 to $350,000. In addition, with the departure of Mr. Knudsen, the Board of Directors appointed Joan Brown, the Company's Director of Financial Reporting, to also serve as the interim Chief Financial Officer of the Company effective as of June 29, 2022. In connection with Ms. Brown's additional position, the Company increased her salary from $160,000 to $200,000.

Named Executive Officers and Position	Annual Base Salary as of December 31, 2022 ($)*	Proposed Annual Base Salary ($)*
James G. Cullem, Chief Executive Officer, Chief Business Officer[1]	$ 350,000	$ 425,000(3)
Joan Brown, Chief Financial Officer[2] *Director of Financial Reporting*	$ 200,000	$ 250,000(3)
Marie Foegh, Chief Medical Officer	$ 331,200	$ 331,200

* All compensation amounts are in full numbers and not presented in $1,000's.

(1) Appointed Chief Executive Officer in June 2022.

(2) Appointed Chief Financial Officer in June 2022.

(3) Proposed Annual Base Salary under employment agreements entered into in January 2023 (see below section titled "2023 Compensation Decisions"

Named Executive Officer	Discretionary Annual Bonus for 2022
Marie Foegh, Chief Medical Officer	up to 40% of annual base salary
James G. Cullem, Chief Executive Officer, Chief Business Officer	up to 40% of annual base salary
Joan Brown, *Chief Financial Officer, Director of Financial Reporting*	up to 20% of annual base salary

Material Terms of Employment Agreements

During the fiscal year ended December 31, 2022, the Company had an employment agreement with the named executive officers. Unless otherwise indicated, the following material terms of employment agreements applied to all of the named executive officers. The employment agreements with each of the named executive officers provide for at-will employment and may be terminated in writing with 30 days prior written notice. The Chief Executive Officer may accelerate termination after notice; however, the employee will still be paid as if they worked the full 30 days. In the event of change of control (as defined below in the 2021 Equity Incentive Plan, or any other change in control of us similar in effect to that definition) the employment agreement provides for 12 months' pay at the base salary. If the employment agreement is terminated voluntarily by an employee without good reason, by us for cause, or because of the employee's incapacity, salary and benefits will cease at the effective date of termination. The named executive will have no duty to attempt to mitigate the severance pay amounts payable by us by seeking employment or otherwise, and no amounts earned from other employment shall reduce the amounts due.

James G. Cullem. In the event the employment agreement with Mr. Cullem is terminated without cause by us or for good reason by Mr. Cullem, the employment agreement provides for severance payment equal to 8 months' pay at the base salary rate.

Marie Foegh. In the event the employment agreement with Ms. Foegh is terminated without cause by us or for good reason by Ms. Foegh, the employment agreement provides for severance payment equal to 6 months' pay at the base salary rate.

Bonus and Annual Bonus Plan

Our executive officers are entitled to bonuses subject to and pursuant to the terms of their respective employment or consultancy agreement.

Other Benefits

Our employees are eligible to participate in various employee benefit plans, including medical, dental, and vision care plans, flexible spending accounts for health and dependent care, life, accidental death and dismemberment, disability, and paid time off. As of January 1, 2023, the Company pays 100% for health, dental and vision care benefits.

Employee Benefit Plans

Equity-based compensation has been and will continue to be an important foundation in executive compensation packages as we believe it is important to maintain a strong link between executive incentives and the creation of stockholder value. We further believe that performance and equity-based compensation can be an important component of the total executive compensation package for maximizing stockholder value while, at the same time, attracting, motivating, and retaining high-quality executives. Formal guidelines for the allocations of cash and equity-based compensation have not yet been determined, but it is expected that the 2021 Equity Incentive Plan ("2021 Plan") described below will be an important element of our compensation arrangements for both executive officers and directors.

2021 Equity Incentive Plan

Our 2021 Plan became effective on December 20, 2021. It was approved by stockholders in connection with the Recapitalization Share Exchange. Our 2021 Plan authorizes the award of stock options, Restricted Stock Awards ("RSAs"), Stock Appreciation Rights ("SARs"), Restricted Stock Units ("RSUs"), cash awards, performance awards and stock bonus awards. We initially reserved 1,211,374 shares of our common stock under the 2021 Plan. The number of shares reserved for issuance under our 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our Board of Directors. There was no adjustment to increase on January 1, 2022. Our Board of Directors approved an increase of 5% of the outstanding shares of common stock at December 30, 2022, or 794,892 shares, effective as of January 1, 2023. As a result, as of January 1, 2023, there was a total of 2,006,266 shares of common stock reserved under the 2021 Plan, of which 1,960,266 were available for issuance.

Upon the closing of the Recapitalization Share Exchange and as of December 31, 2021, we had converted compensatory options to purchase ordinary shares of Allarity Therapeutics A/S to options to purchase 1,174,992 shares of our common stock. Except as specifically provided above, following the effective time of our Recapitalization Share Exchange, each Converted Option continues to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

As of December 31, 2022, there was an option to purchase 676,949 shares of common stock issued and outstanding.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2021 Plan:

- shares subject to options or SARs granted under our 2021 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;

- shares subject to awards granted under our 2021 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2021 Plan that otherwise terminate without such shares being issued;
- shares subject to awards granted under our 2021 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof); and
- shares subject to awards under our 2021 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

Purpose. The purpose of our 2021 Plan is to provide incentives to attract, retain, and motivate eligible persons whose present and potential contributions are important to the success of the Company, and any Parents, Subsidiaries, and Affiliates that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards.

Administration. Our 2021 Plan is expected to be administered by our Compensation Committee, all of the members of which are outside directors as defined under applicable federal tax laws, or by our Board of Directors acting in place of our Compensation Committee. Subject to the terms and conditions of the 2021 Plan, the Compensation Committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2021 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the plan or any award granted thereunder. The 2021 Plan provides that the Board of Directors or Compensation Committee may delegate its authority, including the authority to grant awards, to one or more executive officers to the extent permitted by applicable law, provided that awards granted to non-employee directors may only be determined by our Board of Directors.

Eligibility. Our 2021 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors.

Options. The 2021 Plan provides for the grant of both incentive stock options intended to qualify under Section 422 of the Code, and non-statutory stock options to purchase shares of our common stock at a stated exercise price. Incentive stock options may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2021 Plan must be at least equal to the fair market value of our common stock on the date of grant. Incentive stock options granted to an individual who holds, directly or by attribution, more than 10% of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations, or similar events, no more than 7,009,980 shares may be issued pursuant to the exercise of incentive stock options granted under the 2021 Plan.

Options may vest based on service or achievement of performance conditions. Our Compensation Committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of options granted under our 2021 Plan is 10 years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who holds, directly or by attribution, more than 10% of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted stock awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the Compensation Committee. Holders of RSAs will have the right to vote and any dividends or stock distributions paid pursuant to unvested RSAs will be accrued and paid when the restrictions on such shares lapse. Unless otherwise determined by the Compensation Committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested shares may be forfeited to or repurchased by us.

Stock appreciation rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our Compensation Committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions and may not have a term that is longer than 10 years from the date of grant.

Restricted stock units. RSUs represent the right to receive shares of our common stock at a specified date in the future and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than 10 years from the date of grant.

Performance awards. Performance awards granted pursuant to the 2021 Plan may be in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock bonus awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject to such award as determined by our Compensation Committee. The awards may be granted as consideration for services already rendered, or at the discretion of the Compensation Committee, may be subject to vesting restrictions based on continued service or performance conditions.

Cash awards. A cash award is an award that is denominated in, or payable to an eligible participant solely in, cash.

Dividend equivalents rights. Dividend equivalent rights may be granted at the discretion of our Compensation Committee and represent the right to receive the value of dividends, if any, paid by us in respect of the number of shares of our common stock underlying an award. Dividend equivalent rights will be subject to the same vesting or performance conditions as the underlying award and will be paid only at such time as the underlying award has become fully vested. Dividend equivalent rights may be settled in cash, shares or other property, or a combination thereof as determined by our Compensation Committee.

Change of control. Our 2021 Plan provides that, in the event of a corporate transaction, as defined in the 2021 Plan, outstanding awards under our 2021 Plan shall be subject to the agreement evidencing the corporate transaction, any or all outstanding awards may be (a) continued by us, if we are the successor entity; (b) assumed or substituted by the successor corporation, or a parent or subsidiary of the successor corporation, for substantially equivalent awards (including, but not limited to, a payment in cash or the right to acquire the same consideration paid to the stockholders of the company pursuant to the corporate transaction); (c) substituted by the successor corporation of equivalent awards with substantially the same terms for such outstanding awards; (d) accelerated in full or in part as to the exercisability or vesting; (e) settled in the full value of such outstanding award in cash, cash equivalents, or securities of the successor entity (or its parent, if any) with a fair market value equal to the required amount, followed by the cancellation of such awards; or (f) cancelled for no consideration. If applicable, the number and kind of shares and exercise prices of awards being continued, assumed, or substituted shall be adjusted pursuant to the terms of the 2021 Plan.

Adjustment. In the event of a change in the number of outstanding shares of our common stock without consideration by reason of a stock dividend, extraordinary dividend or distribution, recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, appropriate proportional adjustments will be made to the number and class of shares reserved for issuance under our 2021 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Exchange, repricing, and buyout of awards. Our Compensation Committee may, with the consent of the respective participants, issue new awards in exchange for the surrender and cancelation of any or all outstanding awards. Our Compensation Committee may also reduce the exercise price of options or SARs or buy an award previously granted with payment in cash, shares, or other consideration, in each case, subject to the terms of the 2021 Plan.

Director compensation limits. No non-employee director may receive awards under our 2021 Plan with a grant date value that when combined with cash compensation received for his or her service as a director, exceeds $750,000 in a calendar year or $1,000,000 in the calendar year of his or her initial service.

Clawback; transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our Board of Directors (or a committee thereof) or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2021 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Amendment and termination. Our Board of Directors may amend our 2021 Plan at any time, subject to stockholder approval as may be required. Our 2021 Plan will terminate 10 years from the date our Board of Directors adopts the plan unless it is terminated earlier by our Board of Directors. No termination or amendment of the 2021 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws.

Separation Agreements

Effective as of June 29, 2022, Mr. Carchedi resigned from all positions in the Company and all positions of its subsidiaries, including his role of Chief Executive Officer and as a director of the Company. Pursuant to the terms set forth in a letter agreement dated June 24, 2022 (the "Carchedi Separation Agreement"), the termination of Mr. Carchedi's employment and resignation from his positions are effective June 29, 2022 (the "Carchedi Separation Date"). Under the Carchedi Separation Agreement, Mr. Carchedi will be entitled to his final pay for wages earned through the Separation Date, plus accrued and unused vacation time. In addition, pursuant to the Carchedi Separation Agreement, the Company agreed to provide Mr. Carchedi with certain payments and benefits comprising of: (i) continued payments of his base salary for a certain time period and (ii) COBRA coverage for a certain number of months ("Carchedi Severance Benefits"). In exchange for the Carchedi Severance Benefits, among other things as set forth in the Carchedi Separation Agreement, Mr. Carchedi agreed to a release of claims in favor of the Company and to certain restrictive covenant obligations, and also reaffirmed his commitment to comply with his existing restrictive covenant obligations. In addition, as of the Carchedi Separation Date, Mr. Carchedi's unvested options were terminated. Mr. Carchedi is entitled to exercise his vested options for a period of 90 days from the Carchedi Separation Date. Thereafter, all vested options will expire. Mr. Carchedi's resignation as a director was not the result of any dispute or disagreement with the Company or the Company's Board of Directors on any matter relating to the operations, policies or practices of the Company.

Effective as of June 27, 2022, Mr. J. Knudsen resigned from all positions in the Company, and all positions of its subsidiaries, including his role of Chief Financial Officer of the Company. Pursuant to the terms set forth in a letter agreement dated June 25, 2022 (the "Knudsen Separation Agreement"), the termination of Mr. Knudsen's employment and resignation from his positions are effective June 27, 2022 (the "Knudsen Separation Date"). Under the Knudsen Separation Agreement, Mr. Knudsen will be entitled to his final pay for wages earned through the Separation Date, plus accrued and unused vacation time. In addition, pursuant to the Knudsen Separation Agreement, the Company agreed to provide Mr. Knudsen with certain payments and benefits comprising of: (i) continued payments of his base salary for a certain time period, and (ii) COBRA coverage for a certain number of months ("Knudsen Severance Benefits"). In exchange for the Knudsen Severance Benefits, among other things as set forth in the Knudsen Separation Agreement, Mr. Knudsen agreed to a release of claims in favor of the Company and to certain restrictive covenant obligations, and also reaffirmed his commitment to comply with his existing restrictive covenant obligations. In addition, as of the Knudsen Separation Date, Mr. Knudsen's unvested options were terminated. Mr. Knudsen is entitled to exercise his vested options for a period of 90 days from the Knudsen Separation Date. Thereafter, all vested options will expire.

2023 Compensation Decisions

On January 12, 2023, upon the approval of the Compensation Committee of the Board, the Company entered into a new separate employment agreement with Mr. Cullem, our Chief Executive Officer (the "Cullem Employment Agreement"), and Ms. Brown, our Chief Financial Officer, the "Brown Employment Agreement" and together with Cullem Employment Agreement, the "New Employment Agreements") in connection with the additional executive officer positions that they were appointed to in June 2022.

The effectiveness of the New Employment Agreements are contingent upon the Company securing a new capital raise of at least $7 million dollars by or before February 15, 2023, unless the capital raise requires audited financial statements for the year ending December 31, 2022, then on or before April 30,2023 (a "New Financing"). In the event the New Financing does not occur, Mr. Cullum's prior employment contract as Chief Business Officer of the Company and Ms. Brown's employment contract as director of financial reporting of the Company will continue to remain in full force and effect. In the event the New Financing occurs, subject to the survival of any terms as reflected in the Employment agreement, the prior employment agreements will be superseded by the New Employment Agreements.

Under their respective New Employment Agreements, Mr. Cullem and Ms. Brown will, among other things, be (i) entitled to participate in all of the Company's employee benefit plans and programs as generally maintained and made available to its executive officers by the Company; (ii) eligible for grants of equity compensation as determined at the sole discretion of the Compensation Committee; (iii) entitled to certain severance and change of control benefits contingent upon such employee's agreement to a general release of claims in favor of the Company following termination of employment; and (iv) entitled to reimbursement of expenses in the course and scope of authorized Company business. In addition, each respective employment agreement includes customary confidentiality and assignment of intellectual property obligations.

Cullem Employment Agreement

The Cullem Employment Agreement provides for an annual base salary of $425,000 (as of January 1, 2023), which, upon agreement by Mr. Cullem and the Board, Mr. Cullem may elect to receive up to $30,000 of such base salary in restricted stock grants in the Company. Any such restricted stock grants will be made quarterly, at the start of each calendar quarter, at the stock fair market value ("FMV") on the 1st day of each calendar quarter. In addition, commencing with the calendar year 2023, Mr. Cullem will be eligible to receive an annual bonus representing up to 50% of Mr. Cullem's base salary based on the achievement of individual and corporate performance targets, metrics and/or management-by-objectives to be determined and approved by the Company. The Board has the discretion to pay such annual bonus in restricted stock grants in lieu of cash, depending on the financial circumstances of the Company, at the FMV on the date of grant no later than March 1st of the grant year.

In addition, subject to and concurrently with the closing of a New Financing, the Company agreed to grant Mr. Cullem the following stock options, which will have an exercise price equal to the FMV of the Company's shares on the grant date and a term of 10 years, and be subject to the vesting schedule provided below:

- Stock options in the amount of 3.5% of the Company's issued and outstanding shares of common stock immediately after such closing; provided, however, that such amount will not exceed 50% of the options available to be granted under the Company's 2021 Equity Incentive Plan (the "Grant Limitation"). In addition, such grant will be subject to any shareholder approval required by law, regulation or applicable listing rule (the "Requisite Approval") and will vest ratably over a 48-month period commencing July 1, 2022.

- Stock options for an additional 2.0% of the Company's issued and outstanding shares of common stock immediately after the closing of such New Financing; provided however, that such grant will not exceed the Grant Limitation and such grant will be subject to any Requisite Approval. Such option grant will provide for 100% vesting upon the completion of a Phase 2 clinical trial involving the Company's drug candidates, Stenoparib or Dovitinib, in combination with another drug or therapeutic candidate in ovarian cancer, renal cell carcinoma, or other indication or therapy determined by the Company's Board.

In the event the stock options exceed the Grant Limitation, the Company agreed to seek shareholder approval at its next annual meeting to increase the number of options available under the Company's 2021 Equity Incentive Plan in order to have sufficient options to cover the grants. In consideration of the grant of new options described above, upon grant of such options, all prior vested and unvested options previously granted to Mr. Cullem (under any prior employment agreement with the Company) will be deemed waived and forfeited by Mr. Cullem and null and void. In the event new stock options are not granted to Mr. Cullem under the Cullem Employment Agreement, all options (vested and unvested) previously granted under prior employment agreements with Company will remain in full force and effect.

The Cullem Employment Agreement can be terminated, in writing with 30 days' prior written notice, by the Company for or without Cause (as such term is defined in the Cullem Employment Agreement) and Mr. Cullem can resign with or without Good Reason (as such term is defined in the Cullem Employment Agreement). If Mr. Cullem is terminated without Cause or resigns with Good Reason or is terminated by the Company as a result of a Change-of-Control (as such term in defined in the Cullem Employment Agreement), the Company agreed to provide Mr. Cullem with severance pay in an amount equal to 12 months' pay at Mr. Cullem's final base salary rate, payable in the form of salary continuation. Such severance payments are conditioned upon Mr. Cullem's execution and non-revocation of a general release of claims.

Brown Employment Agreement

The Brown Employment Agreement provides for an annual base salary of $250,000 (as of January 1, 2023). In addition, commencing with calendar year 2023, Mr. Brown will be eligible to receive an annual bonus representing up to 40% of Mr. Brown's base salary based on the achievement of individual and corporate performance targets, metrics and/or management-by-objectives to be determined and approved by the Company. The Board has the discretion to pay such annual bonus in restricted stock grants in lieu of cash, depending on the financial circumstances of the Company, at the stock FMV on the date of grant no later than March 1st of the grant year.

In addition, concurrently with the closing of a New Financing, the Company agreed to grant Ms. Brown stock options in the amount of 0.75% of the Company's issued and outstanding shares of common stock immediately after the closing, which grant will be subject to any Requisite Approval and granted pursuant to the 2021 Equity Incentive Plan. The exercise price will be the FMV of Company's shares on the date of grant. The stock options will vest ratably over a 48-month period commencing July 1, 2022, and have a term of 10 years.

The Brown Employment Agreement can be terminated, in writing with 30 days' prior written notice, by the Company for or without Cause (as such term is defined in the Brown Employment Agreement) and Ms. Brown can resign with or without Good Reason (as such term is defined in the Brown Employment Agreement). If Ms. Brown is terminated without Cause or resigns with Good Reason or is terminated by the Company as a result of Change-of-Control (as defined in the Brown Employment Agreement), the Company agreed to provide Ms. Brown with severance pay in an amount equal to five months' pay at Ms. Brown's final base salary rate, payable in the form of salary continuation. Such severance payments are conditioned upon Ms. Brown's execution and non-revocation of a general release of claims.

Non-Employee Director Compensation

The following table sets forth information concerning the compensation of non-employee directors for services rendered for the year ended December 31, 2022. Mr. Carchedi, our former Chief Executive Officer, also previously served as our director before his resignation in June 2022, and Mr. Carchedi's compensation as named executive officer is set forth above under "Summary Compensation Table." Mr. Thomas Jensen, our Senior Vice President, Investor Relations and director, did not receive any compensation for his services on the Board.

Name	Fees Earned or Paid in Cash $*	Option Awards[(1)(2)] $*	Total $*
Duncan Moore	$ 91,250	$ -	$ 91,250
Søren G. Jensen	$ 56,750[(3)]	$ -	$ 56,750
Gail Maderis	$ 56,750	$ -	$ 56,7500
David Roth	$ 20,000	$ 29,440	$ 49,440
Gerald McLaughlin	$ 12,500	$ 25,300	$ 37,800

* All compensation amounts are in full numbers and not presented in $1,000's.

(1) Amounts reported represent the aggregate grant date fair value of stock options granted to such non-employee directors and have been computed based on a Black Scholes model and excludes the effect of estimated forfeitures. The assumptions used in calculating the grant date fair values of the equity awards reported in this column are set forth below. The amounts reported in this column reflect the accounting cost for these equity awards and do not correspond to the actual economic value that may be realized by the directors upon the vesting of the stock options, the exercise of the stock options or the sale of the securities underlying such stock options.

The fair value of stock options granted in the period ended December 31, 2022, were estimated using the Black-Scholes option pricing model, based on the following assumptions:

	December 31, 2022 (unaudited)
Exercise price	$ 1.10 - 1.28
Share price	$ 1.10 - 1.28
Risk-free interest	4.36%
Expected dividend yield	(0)%
Contractual life (years)	5.0
Expected volatility	120.22%

(2) The table below lists the aggregate number of shares subject to option awards outstanding for each of the non-employee directors as of December 31, 2022.

Name	Number of Shares Subject to Outstanding Options
Duncan Moore	41,994
Søren G. Jensen	26,242
Gail Maderis	26,242
David Roth	23,000
Gerald McLaughlin	23,000

Director Compensation

Our non-employee directors are entitled to an annual director fee of $50,000. In addition, a director who serves as a lead independent director or chair or on a committee of the Board of Directors will receive the following additional annual fee:

Position	Annual Chair/Lead Fee	Annual Member Fee
Chairman of the Board of Directors or Lead Independent Director	$ 30,000	$ —
Audit Committee	$ 15,000	$ 7,500
Compensation Committee	$ 10,000	$ 5,000
Nominating and Corporate Governance Committee	$ 8,000	$ 4,000

Annual fees may be paid in cash or equity at the option of the director. In addition, subject to discretion of the Board of Directors and recommendation of the Compensation Committee, new directors who join the Board of Directors may receive an initial grant of stock options to purchase 23,000 shares of common stock, subject to vesting of 1/36 per month over 36 months following the grant date and with the expiration date of five years from date of grant.

In connection with the appointment of Dr. Roth and Mr. McLaughlin as independent directors of the Company, each received an annual retainer fee of $50,000, payable in cash. In addition, the Board of Directors granted Dr. Roth and Mr. McLaughlin options to purchase 23,000 shares of common stock at an exercise price of $1.28 and $1.10 per share, respectively, which options are subject to vesting of 1/36 per month over 36 months following the grant date. The expiration date for the options is five years from date of grant.

ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table and accompanying footnotes set forth information regarding the beneficial ownership of our Common Stock, including shares issuable upon the exercise or conversion of securities that entitle the holders to obtain Common Stock upon exercise or conversion) as of the date of this report, or Record Date, by:

- each person who is known to be the beneficial owner of more than 5% of our Common Stock;
- each of our current executive officers and each of our current directors; and
- all of our executive officers and directors as a group.

Under the rules and regulations of the SEC, a person is a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or to direct the voting of the security, or "investment power," which includes the power to dispose of or to direct the disposition of the security or has the right to acquire such powers within 60 days.

The beneficial ownership of our Common Stock is based on 30,000,000 shares of Common Stock issued and outstanding as of the Record Date. As of the Record Date, there were 50,000 shares of Series C Preferred Stock outstanding which are not reflected in the columns relating to beneficial ownership of Common Stock below since as of such date no shares of Series C Preferred Stock are convertible into Common Stock because there were not convertible as of the Record Date.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons and entities named in the table have sole voting and investment power with respect to their beneficially owned Common Stock. Additionally, in order to illustrate the outstanding voting power of the respective beneficial owners as of the Record Date, the following table does not reflect record or beneficial ownership of any shares of Common Stock issuable upon exercise of warrants, options, or convertible preferred stock, to the extent such securities are exercisable or convertible within 60 days of the Record Date since the Company does not have any shares of Common Stock authorized to issue upon exercise or conversion.

Name of Beneficial Owner [1]	Number of Common Stock Beneficially Owned	Percentage of Class
5% and Greater Holders:		
3i, L.P. [2]	2,992,551	9.98%
Directors and Executive Officers:		
James G. Cullem [3]	-	-
Joan Brown	-	-
Marie Foegh [4]	3,988	*
Steen Knudsen [5]	124,977	*
Thomas H. Jensen [6]	17,842	*
David Roth [7]	-	-
Gerald McLaughlin [8]	-	-
All directors and executive officers as a group (7 individuals)	146,807	*

* Less than 1%

(1) Unless otherwise noted, the business address of each of the following entities or individuals is c/o Allarity Therapeutics, Inc., 24 School Street, 2nd Floor, Boston, MA 02108.

(2) Based on Schedule 13G jointly filed by 3i, LP, 3i Management LLC and Maier J. Tarlow (the "Reporting Persons") with the SEC on March 2, 2023, reflecting ownership of 2,992,551 shares of common stock. Interests excludes shares of Common Stock issuable pursuant to exercise of shares of Series A Preferred Stock and Warrant, subject to the beneficial ownership limitation of 9.99%. Also excludes shares of Common Stock issuable upon conversion of Series C Preferred Stock which are not exercisable within 60 days as of the Record Date. The principal business address of the Reporting Persons is 140 Broadway, 38th Floor, New York, NY 10005. 3i, L.P.'s principal business is that of a private investor. Maier Joshua Tarlow is the manager of 3i Management, LLC, the general partner of 3i, L.P., and has sole voting control and investment discretion over securities beneficially owned directly or indirectly by 3i Management, LLC and 3i, L.P.

(3) Excludes 119,842 shares of Common Stock issuable upon exercise of vested options within 60 days since the Company did not have any authorized shares of Common Stock available for issuance as of the Record Date.
(4) Interests shown include 3,988 shares of Common Stock. Excludes 53,839 shares of Common Stock issuable upon exercise of vested options within 60 days since the Company did not have any authorized shares of Common Stock available for issuance as of the Record Date.
(5) Interests shown include 124,977 shares of Common Stock. Excludes 53,839 shares of Common Stock issuable upon exercise of vested options within 60 days since the Company did not have any authorized shares of Common Stock available for issuance as of the Record Date.
(6) Interests shown include 17,842 shares of Common Stock. Excludes 111,027 shares issuable upon exercise of vested options within 60 days since the Company did not have any authorized shares of Common Stock available for issuance as of the Record Date.
(7) Excludes 5,750 shares of Common Stock issuable upon exercise of vested options within 60 days since the Company did not have any authorized shares of Common Stock available for issuance as of the Record Date.
(8) Excludes 4,472 shares of Common Stock issuable upon exercise of vested options within 60 days since the Company did not have any authorized shares of Common Stock available for issuance as of the Record Date.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Transactions with Related Parties

The Company did not enter into any related party transaction required to be disclosed under Item 404 of Regulation S-K.

Related Person Transactions Policy

We intend to adopt a written related person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration, and oversight of "related person transactions." For purposes of policy only, a "related person transaction" is a transaction, arrangement, or relationship (or any series of similar transactions, arrangements or relationships) in which we or any of our subsidiaries are participants involving an amount, as long as we are a SEC smaller reporting company, that exceeds the lesser of (a) $120,000 or (b) 1% of the average of our total assets for the last two completed fiscal years, in which any "related person" has a material interest.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities (including our common stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of our voting securities, an officer with knowledge of a proposed transaction, must present information regarding the proposed related person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our Board of Directors) for review. To identify related person transactions in advance, we will rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related person transactions, our audit committee will take into account the relevant available facts and circumstances, which may include, but are not limited to:

- the risks, costs, and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products;
- the terms available to or from, as the case may be, unrelated third parties; and
- our audit committee will approve only those transactions that it determines are fair and in our best interests.

Director Independence

A majority of our Board of Directors are independent directors, see the discussion above under the section "Item 10. Directors, Executive Officers and Corporate Governance–Director Independence."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

On September 9, 2022, our Audit Committee approved the engagement of Wolf & Company as our independent registered public accounting firm. Wolf & Company re-audited our financial statements for the year ended December 31, 2021, and audited our financial statements for the year ended December 31, 2022.

Fees Paid to Principal Independent Registered Public Accounting Firm

The aggregate fees billed by our current auditors Wolf & Company, P.C. and our former auditors Marcum LLP and PWC for the years ended December 31, 2022, and 2021 are as follows:

	2022	2021
Audit fees (1)	$ 1,135,616	$ 1,253,363
Tax fees (2)	—	247,816
Audit related fees (3)	377,582	2,626
Total	$ 1,513,198	$ 1,503,805

(1) 2021 Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our quarterly financial statements and. This information is presented as of the latest practicable date for this annual report. The audit fees for 2021 also include the services provided in reviewing our Registration Statement on Form S-1.

(2) Our former auditor PwC provided us with tax advice and tax planning services as part of our reorganization completed on December 20, 2021, before we became a US domestic filer.

(3) All other fees include fees billed by our independent auditors for products or services other than as described in the immediately preceding two categories including those services normally provided in connection with statutory or regulatory filings or engagements including comfort letters, consents and other services related to SEC matters.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee's policy is to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm, the scope of services provided by our independent registered public accounting firm and the fees for the services to be performed. These services may include audit services, audit-related services, tax services and other services. Pre-approval is detailed as to the service or category of services and is generally subject to a specific budget.

Our independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by our independent registered public accounting firm in accordance with this preapproval, and the fees for the services performed to date.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this annual report on Form 10-K:

(1) Financial Statements

The following financial statements of Allarity, and the Reports of Independent Registered Public Accounting Firms, are included at the end of this report beginning on page F-1:

(2) Financial Statement Schedules

All schedules have been omitted because the required information is included in the financial statements or notes thereto or because they are not required.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed in subparagraph (b) below.

(b) Exhibits:

The following exhibits are filed as part of this Annual Report.

Exhibit No	Description
2.1[(e)]	Amended and Restated Plan of Reorganization and Asset Purchase Agreement by and among Allarity Therapeutics, Inc. a Delaware corporation, Allarity Acquisition Subsidiary, a Delaware corporation and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark, dated as of September 23, 2021
3.1[(a)]	Certificate of Incorporation of Allarity Therapeutics, Inc.
3.2[(b)]	Certificate of Amendment to the Certificate of Incorporation of Allarity Therapeutics, Inc.
3.3[(c)]	Amended and Restated Bylaws of Allarity Therapeutics, Inc.
3.4[(m)]	Amendment No. 1 to Amended and Restated Bylaws of Allarity Therapeutics, Inc.
3.5[(g)]	Certificate of Designations of Allarity Therapeutics, Inc. relating to the Series A Convertible Preferred Stock
3.6[(q)]	Amendment to Certificate of Designation of the Series A Convertible Preferred Stock
3.7[(q)]	Certificate of Designation of the Series B Preferred Stock
3.8[(s)]	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock
3.9[(s)]	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock
4(vi)[*]	Description of Capital Stock
4.1[(b)]	Specimen Common Stock Certificate of Allarity Therapeutics, Inc.
4.2[(a)]	Form of Warrant (3i LP)
10.1#[(e)]	Allarity Therapeutics, Inc. 2021 Equity Incentive Plan
10.2†[(a)]	Exclusive License Agreement between Oncology Venture A/S and Smerud Medical Research International As Dated as of June 26, 2020
10.3†[(a)]	Amended and Restated License Agreement between Allarity Therapeutics A/S and LiPlasome Pharma ApS, dated January 2021
10.4†[(a)]	Exclusive License Agreement between Oncology Venture, APS and 2-BBB Medicines BV, dated as of March 27, 2017
10.5†[(c)]	Development, Option and License Agreement between Oncology Venture ApS and R-Pharm US Operating LLC, dated March 1, 2019
10.6†[(c)]	Exclusive License Agreement between Oncology Venture, ApS and Eisai, Inc., dated as of July 6, 2017
10.7†[(c)]	License Agreement between Novartis Pharma Ag and Oncology Venture, ApS, dated April 6, 2018
10.8+[(a)]	Securities Purchase Agreement dated May 20, 2021 between Allarity Therapeutics, Inc. and 3i, LP
10.9[(a)]	Registration Rights Agreement dated May 20, 2021 between Allarity Therapeutics, Inc. and 3i, LP
10.10†[(a)]	Asset Purchase Agreement dated July 23, 2021 between Allarity Therapeutics A/S and Lantern Pharma Inc.
10.11[(c)]	First Amendment to the Exclusive License Agreement between Eisai and Allarity Therapeutics A/S dated December 20, 2020.
10.12[(d)]	Second Amendment to Exclusive License Agreement between Oncology Venture, ApS and Eisai, Inc. dated as of August 3, 2021.
10.13#[(f)]	Employment Agreement by and between Allarity Therapeutics, Inc. and James G. Cullem
10.14#[(f)]	Employment Agreement by and between Allarity Therapeutics, Inc. and Marie Foegh, M.D.
10.15[(h)]	Asset Purchase Agreement between Allarity Therapeutics, Inc. and Allarity Therapeutics A/S dated December 17, 2021
10.16[(k)]	Assignment and Assumption Agreement between Allarity Therapeutics, Inc. and Allarity A/S
10.17†[(k)]	Exclusive License Agreement with Oncoheroes Bioscience, Inc. dated January 2, 2022 (Stenoparib)
10.18†[(k)]	Exclusive License Agreement with Oncoheroes Bioscience, Inc. dated January 2, 2022 (Dovitnib)

10.19†[k]	Amended and Restated License Agreement among Allarity Therapeutics Europe ApS, LiPlasome Pharma ApS, and Chosa ApS dated March 28, 2022
10.20†[k]	Support Agreement between Allarity Therapeutics A/S and LiPlasome Pharma ApS, dated March 28, 2022
10.21[i]	First Amendment to License Agreement between Novartis Pharma Ag and Allarity Therapeutics Europe ApS
10.22[i]	Convertible Promissory Note
10.23[j]	Forbearance Agreement and Waiver
10.24[l]	First Amendment to Forbearance and Waiver dated June 6, 2022
10.25†#[o]	Separation Agreement with Steve Carchedi
10.26†#[o]	Separation Agreement with Jens Knudsen
10.27[o]	Second Amendment to Development Option & License Agreement
10.28†[p]	Second Amendment to License Agreement
10.29[q]	Secured Note Purchase Agreement
10.30[q]	Form of Secured Promissory Note
10.31[q]	Security Agreement
10.32*	Letter Agreement with 3i, LP
10.33#[r]	Employment Agreement with James G. Cullem dated January 12, 2023
10.34#[r]	Employment Agreement with Joan Brown dated January 12, 2023
10.35*	Letter Agreement with 3i, LP dated January 23, 2023
10.36+[s]	Form of Securities Purchase Agreement – Series C Preferred Stock
10.37[s]	Form of Registration Rights Agreement
10.38[s]	Limited Waiver Agreement
16.1[n]	Letter from Marcum, LLP dated August 23, 2022, regarding Change in Independent Registered Public Accounting Firm
21.1*	Subsidiaries of the Registrant
31.1*	Certifications of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act
31.2*	Certifications of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act
32.1*	Certifications of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act
32.2*	Certifications of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(a) Incorporated by reference from the Registration Statement on Form S-4 filed with the SEC on August 20, 2021.
(b) Incorporated by reference from Amendment No. 1 to Registration Statement on Form S-4 as refiled with the SEC on October 20, 2021.
(c) Incorporated by reference from Amendment No. 2 to Registration Statement on Form S-4 as refiled with the SEC on October 20, 2021.
(d) Incorporated by reference from Amendment No. 4 to Registration Statement on Form S-4 as filed with the SEC on November 2, 2021.
(e) Incorporated by reference from Amendment No. 2 to Registration Statement on Form S-1 as filed with the SEC on December 6, 2021.
(f) Incorporated by reference from Form 8-K as filed with the SEC on December 10, 2021.
(g) Incorporated by reference from Form 8-K as filed with the SEC on December 20, 2021.
(h) Incorporated by reference from Form 8-K filed with the SEC on December 22, 2021.
(i) Incorporated by reference from Form 8-K filed with the SEC on April 18, 2022.
(j) Incorporated by reference from Form 8-K filed with the SEC on May 6, 2022.
(k) Incorporate by reference from Form 10-K filed with the SEC on May 17, 2022.
(l) Incorporated by reference from Form 8-K filed with the SEC on June 10, 2022.
(m) Incorporated by reference from Form 8-K filed with the SEC on July 11, 2022.
(n) Incorporated by reference from Form 8-K filed with the SEC on August 12, 2022, as amended on August 24, 2022.
(o) Incorporated by reference from Form 10-Q filed with the SEC on October 7, 2022.
(p) Incorporated by reference from Form 8-K filed with the SEC on September 30, 2022.
(q) Incorporated by reference from Form 8-K filed with the SEC on November 25, 2022.
(r) Incorporated by reference from Form 8-K filed with the SEC on January 19, 2023.
(s) Incorporated by reference from Form 8-K filed with the SEC on February 28, 2023.

† Certain portions of this exhibit were be omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
* Filed herewith.
# Indicates management contract or compensatory plan or arrangement.
+ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

ITEM 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALLARITY THERAPEUTICS, INC.

By: /s/ James G. Cullem
Name: James G. Cullem
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ James G. Cullem James G. Cullem	Chief Executive Officer and Director (*Principal Executive Officer*)	March 10, 2023
/s/ Joan Brown Joan Brown	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 10, 2023
/s/ Gerald McLaughlin Gerald McLaughlin	Chairman of the Board	March 10, 2023
/s/ David A. Roth David A. Roth	Director	March 10, 2023
/s/ Thomas Jensen Thomas Jensen	Director	March 10, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Allarity Therapeutics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Allarity Therapeutics, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of a Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and accumulated deficit that raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2022.

Boston, MA
March 9, 2023

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
As of December 31, 2022 and 2021
(U.S. dollars in thousands, except for share and per share data)

	2022	2021
ASSETS		
Current assets:		
Cash	$ 2,029	$ 19,555
Other current assets	1,559	625
Prepaid expenses	591	36
Investment in Lantern Pharma Inc. stock	—	350
Tax credit receivable	789	838
Total current assets	4,968	21,404
Non-current assets:		
Property, plant and equipment, net	21	8
Operating lease right of use assets	6	86
Intangible assets	9,549	28,135
Total assets	$ 14,544	$ 49,633
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,251	$ 698
Accrued liabilities	1,904	8,590
Income taxes payable	41	60
Operating lease liabilities, current	8	98
Warrant liability	374	11,273
Convertible debt	2,644	—
Total current liabilities	11,222	20,719
Non-current liabilities:		
Convertible promissory note and accrued interest, net of debt discount	1,083	979
Derivative liabilities		7,181
Operating lease liabilities, net of current portion	—	9
Deferred tax	349	1,961
Total liabilities	12,654	30,849
Commitments and contingencies (Note 21)		
Redeemable preferred stock (500,000 shares authorized)		
Series A Convertible Preferred stock $0.0001 par value (20,000 shares designated) shares issued and outstanding at December 31, 2022 and 2021 were 13,586 and 19,800, respectively	2,001	632
Series B Preferred stock $0.0001 par value (200,000 shares designated) shares issued at December 31, 2022 and 2021 were 190,786 and 0, respectively	2	—
Total redeemable preferred stock	2,003	632
Stockholders' (deficit) equity		
Common stock, $0.0001 par value (30,000,000 shares authorized) shares issued and outstanding at December 31, 2022 and 2021 were 15,897,845 and 8,096,014, respectively	2	1
Additional paid-in capital	83,156	85,243
Accumulated other comprehensive loss	(721)	(600)
Accumulated deficit	(82,550)	(66,492)
Total stockholders' (deficit) equity	(113)	18,152
Total liabilities, preferred stock and stockholders' (deficit) equity	$ 14,544	$ 49,633

See report of independent registered accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For the years ended December 31, 2022 and 2021
(U.S. dollars in thousands, except for share and per share data)

	2022	2021
Operating expenses:		
Research and development	$ 6,930	$ 14,196
Impairment of intangible assets	17,571	—
General and administrative	9,962	12,360
Total operating expenses	34,463	26,556
Loss from operations	(34,463)	(26,556)
Other income (expenses)		
Gain from the sale of IP	1,780	1,005
Interest income	30	—
Interest expenses	(223)	(499)
Finance costs	—	(1,347)
Loss on investment	(115)	(495)
Foreign currency transaction losses, net	(913)	(95)
Change in fair value adjustment of derivative and warrant liabilities	17,125	2,087
Penalty on Series A Preferred stock liability	(800)	—
Change in fair value of convertible debt	—	(474)
Non-cash interest expense related to beneficial conversion feature of convertible debt	—	(141)
Total other income, net	16,884	41
Net loss before tax recovery (expense)	(17,579)	(26,515)
Income tax recovery (expense)	1,521	(133)
Net loss	(16,058)	(26,648)
Deemed dividend of 8% on Preferred stock	(1,572)	—
Cash obligations on converted Series A Preferred stock	(3,421)	—
Net loss attributable to common stockholders	$ (21,051)	$ (26,648)
Basic and diluted net loss per share applicable to common stockholders	$ (2.21)	$ (4.19)
Basic and diluted weighted-average common shares outstanding	9,527,111	6,358,988
Net loss	$ (16,058)	$ (26,648)
Other comprehensive loss, net of tax:		
Change in cumulative translation adjustment	(121)	(1,966)
Change in fair value attributable to instrument specific credit risk	—	(9)
Total comprehensive loss attributable to common shareholders	$ (16,179)	$ (28,623)

See report of independent registered accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
For the years ended December 31, 2022 and 2021
(U.S. dollars in thousands, except for share data)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2020 carried forward	—	$ —	4,252,021	$ 1	$ 62,907	$ 1,375	$ (39,844)	$ 24,439
Units issued for cash	20,000	1,318	2,417,824	—	12,125	—	—	12,125
Fair value of investor warrants (TO3)	—	—	—	—	(2,000)	—	—	(2,000)
Warrants and options exercised for cash	—	—	295,537	—	2,972	—	—	2,972
Units issued for share issuance costs	—	—	482,250	—	2,384	—	—	2,384
Share issuance costs	—	(679)	—	—	(2,475)	—	—	(2,475)
Convertible debt conversion and related beneficial conversion feature and settlement of accounts payable	—	—	628,192	—	2,880	—	—	2,880
Stock based compensation	—	—	—	—	6,368	—	—	6,368
Cumulative translation adjustment	—	—	—	—	—	(1,966)	—	(1,966)
Fair value of instrument specific credit risk	—	—	—	—	—	(9)	—	(9)
Conversion of preferred stock into common stock	(200)	(7)	20,190	—	7	—	—	7
Reclassification of derivative liabilities related to converted preferred stock	—	—	—	—	75	—	—	75
Net loss	—	—	—	—	—	—	(26,648)	(26,648)
Balance, December 31, 2021	19,800	$ 632	8,096,014	$ 1	$ 85,243	$ (600)	$ (66,492)	$ 18,152

See report of independent registered accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
For the years ended December 31, 2022 and 2021
(U.S. dollars in thousands, except for share data)

	Series A Convertible Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2021 carried forward	19,800	**$ 632**	—	$ —	8,096,014	$ 1	$ 85,243	$ (600)	$ (66,492)	$ 18,152
Conversion of preferred stock into common stock	(6,214)	(203)	—	—	7,801,831	1	202	—	—	203
Floor price liability			—	—	—	—	(3,421)	—	—	(3,421)
Reclassification of derivative liabilities related to converted preferred stock	—	—	—	—	—	—	954	—	—	954
Deemed dividend of 8% on preferred stock		1,572	—	—	—	—	(1,572)	—	—	(1,572)
Series B preferred stock dividend	—	—	190,786	2	—	—	(2)	—	—	(2)
Stock based compensation	—	—	—	—	—	—	1,752	—	—	1,752
Cumulative translation adjustment	—	—	—	—	—	—	—	(121)	—	(121)
Net loss	—	—	—	—	—	—	—	—	(16,058)	(16,058)
Balance, December 31, 2022	13,586	$ 2,001	190,786	$ 2	15,897,845	$ 2	$ 83,156	$ (721)	$ (82,550)	$ (113)

See report of independent registered accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2022 and 2021
(U.S. dollars in thousands)

	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,058)	$ (26,648)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from the sale of IP	(1,780)	(1,005)
Depreciation and amortization	60	106
Intangible asset impairment	17,571	—
Stock-based compensation	1,752	6,368
Non-cash interest expense	138	238
Non-cash finance expense	—	1,347
Loss on investment	115	495
Unrealized foreign exchange loss	450	95
Loss on extinguishment of convertible debt	—	141
Change in fair value adjustment of convertible debt	—	474
Change in fair value of warrant and derivative liabilities	(17,125)	(2,087)
Deferred income taxes	(1,612)	20
Changes in operating assets and liabilities:		
Other current assets	(1,077)	(330)
Prepaid expenses	(618)	130
Accounts payable	6,207	(1,311)
Accrued liabilities	(4,722)	7,197
Income taxes payable	(19)	8
Operating lease liability	(99)	(124)
Net cash used in operating activities	(16,817)	(14,886)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of IP	809	1,005
Purchase of property and equipment	(18)	—
Net cash provided by investing activities	791	1,005
CASH FLOWS FROM FINANCING ACTIVITIES:		
Line of credit	—	(84)
Proceeds from common stock units and preferred stock issuance	—	32,125
Proceeds from exercise of warrants and stock options for common stock	—	2,765
Share issuance costs	—	(2,041)
Cash paid in connection with conversion of Series A Preferred Stock	(1,511)	—
Penalty on Series A Preferred Stock liability	(800)	—
Proceeds from convertible loans	1,000	1,140
Loan proceeds	—	2,858
Repayment of loan	—	(2,945)
Net cash provided by (used in) financing activities	(1,311)	33,818
Net increase (decrease) in cash	(17,337)	19,937
Effect of exchange rate changes on cash	(189)	(680)
Cash, beginning of year	19,555	298
Cash, end of year	$ 2,029	$ 19,555

See report of independent registered accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (cont.)
For the years ended December 31, 2022 and 2021
(U.S. dollars in thousands)

	2022	2021
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 12	$ 118
Cash paid for interest	$ 85	$ 262
Supplemental disclosure of non-cash investing and financing activities:		
Offset of payable against receivable from sale of IP	$ 971	$ —
Conversion of floor price liability to convertible debt	$ 1,667	$ —
Conversion of convertible debt to common stock and settlement of accounts payable	$ —	$ 2,880
Conversion of derivative liability to common stock	$ —	$ 206
Conversion of Series A Convertible Preferred stock to equity	$ 1,157	$ 7
Deemed 8% dividend on Series A Preferred shares	$ 1,572	$ —
Series B Preferred share dividend	$ 2	—
Reclassification of derivative liabilities related to converted preferred stock	$ 954	$ 75
Non-cash share issuance costs	$ —	$ 2,384
Right of use asset modification	$ —	$ 145

See report of independent registered accounting firm and accompanying notes to consolidated financial statements.

1. Nature of the business

(a) Reorganization

Effective December 20, 2021, and in connection with the Plan of Reorganization and Asset Purchase Agreement, which was amended and restated on September 23, 2021, between Allarity Therapeutics, Inc. a Delaware corporation (the "Company"), Allarity Acquisition Subsidiary Inc., the Company's wholly owned Delaware subsidiary ("Acquisition Sub"), and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark ("Allarity A/S"), the Company completed an Asset Purchase Agreement with Acquisition Sub and Allarity A/S pursuant to which Allarity A/S sold, and Acquisition Sub purchased, all of Allarity A/S' assets and certain specified liabilities in connection with Allarity A/S' business for an aggregate purchase price of 8,075,824 shares of the Company's common stock plus the assumption of specified liabilities. Thereafter, Allarity A/S is in the process of being dissolved and liquidated in accordance with Part 14 of Danish Companies Act.

While the Company was the legal acquirer of Allarity A/S, for accounting purposes, the Merger is treated similarly to a reverse recapitalization, whereby Allarity A/S is deemed to be the accounting acquirer, and the historical financial statements of Allarity A/S became the historical financial statements of the Company upon the closing of the reorganization. Under this method of accounting, the Company was treated as the "acquired" company and Allarity A/S is treated as the acquirer for financial accounting purposes. Accordingly, for accounting purposes, the reorganization was treated as the equivalent of Allarity A/S issuing stock for the net assets of the Company accompanied by a recapitalization. Because the reorganization is a common control transaction the net assets and prior year financial statements were stated at historical cost, with no goodwill or other intangible assets recorded. In accordance with ASC 805, the legal capital of Allarity A/S has been retroactively adjusted to reflect the capital of the legal acquirer (accounting acquiree) the Company.

(b) Principal Operations and Activities

The Company's principal operations are located at Venlighedsvej 1, 2970 Horsholm, Denmark. The Company's United States operations are located at 24 School Street, 2nd Floor, Boston, MA 02108, United States of America.

The Company develops drugs for the personalized treatment of cancer using drug specific companion diagnostics (cDx) generated by its proprietary drug response predictor technology, DRP®. Additionally, the Company, through its Danish subsidiary, Allarity Therapeutics Denmark ApS (formerly OV-SPV2ApS) ("Allarity Denmark," or "OV-SPV2"), specializes in the research and development of anti-cancer drugs.

(c) Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

(d) Going Concern

The accompanying consolidated financial statements have been prepared on going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

1. Nature of the business (cont.)

The Company expects its costs and expenses to increase as it continues to develop its product candidates and progress its current clinical programs and cost associated with being a public company.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these consolidated financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the consolidated financial statements are issued, and (2) it is probable that the plan, when implemented will mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financial statements are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in management's evaluation under the requirements of ASC 205-40.

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, clinical expenses, recruiting management and technical staff, and securing funding via collaborations. The Company has historically funded its operations with proceeds received from its collaboration arrangements, sale of equity capital and proceeds from sales of convertible notes.

The Company has incurred significant losses and has an accumulated deficit of $82.6 million as of December 31, 2022. Management expects to continue to generate operating losses in the foreseeable future, particularly as the Company advances its preclinical activities and clinical trials for its product candidates in development. The Company plans to seek additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in these endeavors. If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development programs, or reduce product candidate expansion, which could adversely affect its business prospects. Currently, our cash is insufficient to fund our current operating plan and planned capital expenditures through December 2023 since our current cash reserves are only sufficient for the next 3 months. These conditions give rise to substantial doubt over the Company's ability to continue as a going concern.

(e) Impact of Covid-19 on our Business

In March 2020, the World Health Organization declared the novel strain of coronavirus (COVID-19) a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has been evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

As a result of COVID-19, all the Company's clinical trials experienced significant delays throughout the year ended December 31, 2020. The Company has been slowly ramping up its clinical trial sites in 2021. Management continues to closely monitor the impact of the COVID-19 pandemic on all aspects of the business, including how it will impact operations and the operations of customers, vendors, and business partners. The extent to which COVID-19 impacts the future business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time, such as the continued duration of the outbreak, new information that may emerge concerning the severity or other strains of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If the Company or any of the third parties with which it engages, however, were to experience shutdowns or other business disruptions, the ability to conduct business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on business, results of operations and financial condition. The estimates of the impact on the Company's business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national, and international markets. Management has not identified any events which would result in any significant impairment losses in the carrying values of assets because of the pandemic and are not aware of any specific related event or circumstance that would require management to revise estimates reflected in these consolidated financial statements.

1. Nature of the business (cont.)

(f) Impact of the Russia-Ukraine War

There have been immense flows of refugees to Europe and Denmark is ready to facilitate and to accept refugees from the Ukraine. It is far too early to estimate how many migrants Denmark will facilitate, but immigration officials have begun preparing to accept Ukrainian refugees. Being a North Atlantic Treaty Organization (NATO) member, Denmark will strengthen its own national preparedness as well as that of the NATO defense alliance. The Ukraine crisis has not yet had an impact on our results of operations, however we expect it may have an impact on the costs of materials we purchase for our laboratory operations in Denmark, but we cannot predict the impact at this point in time.

(g) Emerging Growth Companies

Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has chosen not to make an election to opt out of new or revised accounting standards.

2. Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements have been prepared on an accrual basis of accounting, in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

As a result of the recapitalization share exchange (also described in Notes 1 and 3), to these consolidated financial statements, all outstanding shares, warrants, and options were exchanged on a 50:1 basis as of December 20, 2021, and accordingly, all share, warrant, option and per share disclosure in these consolidated financial statements has been retroactively adjusted to reflect the 50:1 reverse split unless otherwise stated.

(b) Organization and Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries:

Name	Country of Incorporation
Allarity Acquisition Subsidiary Inc.	United States
Allarity Therapeutics Europe ApS (formerly Oncology Venture Product Development ApS)	Denmark
Allarity Therapeutics Denmark ApS (formerly OV-SPV2 ApS)	Denmark
MPI Inc.*	United States
Oncology Venture US Inc.*	United States

*In the process of being dissolved because inactive.

All intercompany transactions and balances, including unrealized profits from intercompany sales, have been eliminated upon consolidation.

2. Summary of Significant Accounting Policies (cont.)

(c) Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the Series A preferred shares, warrants, convertible debt, and the accrual for research and development expenses, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering reasonable changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

(d) Foreign currency and currency translation

The functional currency is the currency of the primary economic environment in which an entity's operations are conducted. The Company and its subsidiaries operate mainly in Denmark and the United States. The functional currencies of the Company's subsidiaries are their local currency.

The Company's reporting currency is the U.S. dollar. The Company translates the assets and liabilities of its Denmark subsidiaries into the U.S. dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of changes in redeemable convertible preferred stock and stockholders' equity as a component of accumulated other comprehensive loss.

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are re-measured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net loss for the respective periods.

Adjustments that arise from exchange rate translations are included in other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss as incurred. The Company recorded a foreign exchange translation loss of $121 and $1,966 and a fair value adjustment to instrument specific credit risk of $0 and ($9), included in accumulated other comprehensive loss for the years ended December 31, 2022 and 2021, respectively.

(e) Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. The Company maintains its cash in financial institutions in amounts that could exceed government-insured limits. The Company does not believe it is subject to additional credit risks beyond those normally associated with commercial banking relationships. The Company has not experienced losses on its cash accounts and management believes, based upon the quality of the financial institutions, that the credit risk regarding these deposits is not significant. The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply its requirements for supplies and raw materials related to these programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

(f) Cash

Cash consists primarily of highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company had no cash equivalents or restricted cash on December 31, 2022 and 2021.

2. Summary of Significant Accounting Policies (cont.)

(g) Property, plant and equipment

Property, plant, and equipment are stated at cost, less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful Economic Life
Leasehold property improvements	Lesser of lease term or useful life
Laboratory equipment	5 years
Furniture and office equipment	3 years

Upon retirement or sale, the cost of assets disposed of, and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. As of December 31, 2022 and 2021, there have been no significant asset retirements to date. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

(h) Grants

Grants are recognized when the conditions for receipt are met and there is reasonable assurance that the grant will be received.

Grants that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Company with no future related costs are recognized in profit or loss in the period in which they become receivable.

(i) Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment, and intangible assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. An impairment loss would be recognized as a loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group or the estimated return on investment are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flow or return on investment calculations.

(j) Business combinations

Business combinations are accounted for in accordance with ASC Topic 805 “Business Combinations”. The total purchase price of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management’s judgment and often involves the use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, probabilities of success, discount rates, and asset lives, among other items. Assets acquired and liabilities assumed are recorded at their estimated fair values.

2. Summary of Significant Accounting Policies (cont.)

(k) Acquired patents

Acquired patents are measured in the balance sheet at the lower of cost less accumulated amortization and impairment charges, if any. The legal costs incurred to renew or extend the term of the acquired patents are expensed as incurred. Cost comprises the acquisition price and the depreciation period are estimated at approximately 5 years with no residual value. Depreciation methods, useful lives and residual values are reviewed every year.

(l) Acquired in-process research and development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquired as part of a business combination and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third-party. Management assesses its acquired IPR&D for impairment at year end date as well as when events and circumstances indicate there is a potential impairment. Significant quantitative indicators considered are the Company's market capitalization, market share, length of remaining clinical trials, and projected revenue per treatment. The projected discounted cash flow models used to estimate the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

Once brought into use, intangible assets are amortized over their estimated useful economic lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated. The Company has recorded impairment losses of $17,571 and $0 on its intangible assets in the years ended December 31, 2022 and 2021, respectively.

(m) Fair value measurements of financial instruments

The carrying value of the Company's financial instruments of cash, other current assets, accounts payable and accrued liabilities, approximate their fair value due to their short-term nature. The Company's other financial instruments include an equity investment, preferred shares, convertible debt, and warrant derivative liabilities. The equity investment is adjusted to fair market value at the end of every period based upon unadjusted quoted prices. The convertible debt and derivative liabilities that are freestanding equity-linked financial instruments are fair valued at the end of every period using level 3 inputs.

2. Summary of Significant Accounting Policies (cont.)

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 — defined as observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

(n) Segment and geographic information

Operating segments are defined as components of a business for which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and its chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment. The Company operates in two geographic areas: Denmark and the United States.

(o) Operating lease right-of-use assets

The Company determines whether an arrangement contains a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, current portion of operating lease liabilities, and net of current portion of operating lease liabilities on our consolidated balance sheets. Lease ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. As the Company's leases do not provide an implicit rate, an incremental borrowing rate is used based on the information available at the commencement date in determining the present value of lease payments. The Company does not include options to extend or terminate the lease term unless it is reasonably certain that the Company will exercise any such options. Rent expense is recognized under the operating leases on a straight-line basis. The Company's facilities operating leases have lease and non-lease components to which the Company has elected to apply a practical expedient to account for all components as one single component. The Company does not recognize right-of-use assets or lease liabilities for short-term leases, which have a lease term of twelve months or less, and instead will recognize lease payments as expense on a straight-line basis over the lease term.

2. Summary of Significant Accounting Policies (cont.)

(p) Revenue recognition

The Company's revenues are generated primarily through research and development services provided to pharmaceutical and biotechnology companies. The terms of these arrangements may include (i) the grant of intellectual property rights (IP licenses) to therapeutic drug candidates against specified targets, (ii) performing research and development services to optimize drug candidates, and (iii) the grant of options to obtain additional research and development services or licenses for additional targets, or to optimize product candidates, upon the payment of option fees. Research and development service revenue is recognized over time as services are rendered. Revenue generated from the grant of IP licenses is recognized when probable. The Company has not recognized revenue to the date of these financial statements.

The Company has adopted ASC Topic 606—Revenue from Contracts with Customers ("ASC 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performs the following steps:

(i) identify the promised goods or services in the contract;

(ii) determine whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation.

(q) Milestone and royalty revenue recognition

Milestone payments: At the inception of each arrangement that includes research and development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant cumulative revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

2. Summary of Significant Accounting Policies (cont.)

(r) Research contract costs and accruals

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, facilities costs and laboratory supplies, depreciation, amortization and impairment expense, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials. Typically, upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed. As of December 31, 2022 and 2021, the Company has recorded milestone payment liabilities of $1,400 and $5,000, respectively, as accrued liabilities.

The Company has entered into various research and development contracts with companies in Europe, the United States, and other countries. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

(s) Research and development incentives and receivable

Denmark Tax Incentives

Denmark allows loss making companies the opportunity to apply for a payment equal to the tax value (22%) of negative taxable income related to R&D costs. The negative taxable income is calculated on the total negative income of the companies participating in the joint taxation. Tax payment according to this rule cannot exceed an amount of DKK 5.5 million, corresponding to a tax loss relating to R&D expenditure of DKK 25 million. The tax credit is recorded as tax receivable and other income within research and development expenses. In the years ended December 31, 2022 and 2021, the Company recorded $711 and $875 in tax credits respectively, thereby reducing research and development expenses.

European Agency Grants

The Company, through its subsidiaries in Denmark, from time-to-time receives reimbursements of certain research and development expenditures as part of a European agency's research and development cost relief program. Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time. The Company records these research and development expense reimbursements as a reduction to research and development expenses in the consolidated statements of operations and comprehensive loss, as the research and development cost reimbursements are not dependent on the Company generating future taxable income, the Company's ongoing tax status, or tax position. The Company recognizes a receivable for the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. During the years ended December 31, 2022 and 2021, respectively, the Company has not received or recorded government grants receivable.

(t) Investments

In accordance with ASC 321, the Company's investments in equity securities are measured at readily determinable fair value ("RDFV") in the balance sheet with changes in fair value recognized in net loss. For investments in equity securities that are traded in an active market, RDFV is equivalent to the market value at the balance sheet date and changes in fair value are recognized in other income (expenses). Investments in equity securities are classified as either current or long-term depending upon management's intentions.

2. Summary of Significant Accounting Policies (cont.)

(u) Convertible debt instruments

The Company follows ASC 480-10, *Distinguishing Liabilities from Equity* in its evaluation of the accounting for a hybrid instrument. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer's equity shares; or (c) variations inversely related to changes in the fair value of the issuer's equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with remeasurements reported in change on fair value expense in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

Additionally, the Company accounts for certain convertible debt ("Convertible Notes") issued under the fair value option election of ASC 825, Financial Instruments wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently re-measured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized as other income (expense) in the accompanying consolidated statements of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss. Convertible Notes are settled with shares at fair value of the stock issued with any differences recorded to other income (expense), as a gain (loss) on extinguishment.

(v) Warrants

When the Company issues warrants it evaluates the proper balance sheet classification to determine classification as either equity or as a derivative liability on the consolidated balance sheets. In accordance with ASC 815-40, Derivatives and Hedging-Contracts in the Entity's Own Equity ("ASC 815-40"), the Company classifies a warrant as equity so long as it is "indexed to the Company's equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to the Company's equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to the Company's equity or it has net cash settlement that results in the warrants to be accounted for under ASC 480, Distinguishing Liabilities from Equity, or ASC 815-40, it is classified as a derivative liability, which is carried on the Consolidated Balance Sheet at fair value with any changes in its fair value recognized immediately in the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2022 and 2021, the Company had warrants outstanding for share-based compensation that were classified as equity, and outstanding investor warrants that were classified as derivative liabilities and classified as "Warrant liabilities" in the Consolidated Balance Sheets.

(w) Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the Consolidated Statements of Operations and Comprehensive Loss each reporting period. Bifurcated embedded derivatives are recorded as "Derivative liabilities" in the Consolidated Balance Sheets.

(x) Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's Consolidated Statements of Operations and Comprehensive Loss.

2. Summary of Significant Accounting Policies (cont.)

The Company records the expense for option awards using either a graded or straight-line method. The Company accounts for forfeitures as they occur. For share-based awards granted to both employee and non-employee consultants, the measurement date for non-employee awards is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews all stock award modifications including when there is an exchange of original award for a new award. In the case of stock award modifications, the Company calculates for the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards and for the Employee Share Purchase Plan (the "ESPP"). The Black-Scholes model requires several assumptions, of which the most significant are the share price, expected volatility and the expected award term.

Expected term of options granted is calculated using the simplified method being the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. The Company has historically not paid dividends and has no foreseeable plans to pay dividends and, therefore, uses an expected dividend yield of zero in the option pricing model. The risk-free interest rate is based on the yield of U.S. treasury bonds with equivalent terms.

The Company classifies share-based compensation expense in its Consolidated Statements of Operations and Comprehensive Loss in the same way the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

(y) Accumulated other comprehensive loss

Accumulated other comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with shareholders. The Company records unrealized gains and losses related to foreign currency translation and instrument specific credit risk as components of other accumulated comprehensive loss in the Consolidated Statements of Operations and Comprehensive Loss. For the years ended December 31, 2022 and 2021, the Company's other comprehensive loss was comprised of currency translation adjustments and fair value adjustments attributable to instrument specific credit risk.

(z) Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date, the Company evaluates whether a potential loss amount or a potential loss range is probable and reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies.

The Company expenses costs as incurred in relation to such legal proceedings as general and administrative expense within the Consolidated Statements of Operations and Comprehensive Loss.

2. Summary of Significant Accounting Policies (cont.)

(aa) Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not-to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that will more likely than not be realized upon ultimate settlement. Any provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits that are considered appropriate. The Company recognizes interest and penalties related to uncertain tax positions in other (income) expenses.

(bb) Computation of loss per share

Basic net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common stock and common stock equivalents outstanding for the period. The Company adjusts net loss to arrive at the net loss attributable to common stockholders to reflect the amount of dividends accumulated during the period on the Company's redeemable convertible preferred stock, if any. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants and warrants and the if-converted method is used to determine the dilutive effect of the Company's redeemable convertible preferred stock and Convertible Notes. For the years ended December 31, 2022 and 2021, the Company had a net loss attributable to common stockholders, and as such, all outstanding stock options, shares of redeemable convertible preferred stock, and warrants were excluded from the calculation of diluted loss per share. Under the if-converted method, convertible instruments that are in the money, are assumed to have been converted as of the beginning of the period or when issued, if later.

(cc) Recently adopted accounting pronouncements

In May 2021, the FASB issued ASU No. 2021-04 — *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* — to clarify the accounting by issuers for modifications or exchanges of equity-classified written call options. The framework applies to freestanding written call options, such as warrants, that were and remain equity classified by the issuer after the modification and are not in the scope of another Codification Topic. The framework applies regardless of whether the modification is through an amendment to the existing terms or issuance of a replacement warrant. The effect of the modification of the warrant is measured as the difference in its fair value immediately before and after the modification. The effect is recognized in the same manner as if cash had been paid as consideration. Additionally, other modifications may need to be accounted for as a cost to the issuing entity based on the substance of the transaction. The Company is required to apply the amendments within this ASU prospectively to modifications or exchanges occurring on or after the effective date of the amendment. The Company adopted this ASU on January 1, 2022, with no significant impact on its consolidated financial statements and related disclosures.

2. Summary of Significant Accounting Policies (cont.)

In November 2021, the FASB issued ASU 2021-10 — Government Assistance — Disclosures by Business Entities about Government Assistance — to require disclosures about transactions with a government that have been accounted for by analogizing to a grant or contribution accounting model to increase transparency about (1) the types of transactions, (2) the accounting for the transactions, and (3) the effect of the transactions on an entity's financial statements. The ASU is effective prospectively or retrospectively for annual periods beginning after December 15, 2021, with early adoption permitted. The Company adopted this ASU on January 1, 2022, with no significant impact on its consolidated financial statements and related disclosures.

(dd) Recently issued accounting pronouncements

Changes to GAAP are established by the FASB in the form of ASUs to the FASB's Accounting Standards Codification. The Company considers the applicability and impact of all ASUs. All other ASUs issued through the date of these financial statements were assessed and determined not to be applicable or are expected to have minimal impact on the Company's consolidated financial position and results of operations.

3. Acquisition of the Assets and Liabilities of Allarity A/S

As discussed in Note 1, on December 20, 2021 (the "Closing Date"), the Company closed the acquisition of Allarity A/S' assets and business for the aggregate purchase price of 8,075,824 shares of the Company's common stock plus the assumption of specified liabilities (the "Reorganization").

Pursuant to the Plan of Reorganization and Asset Purchase Agreement (the "Reorganization Agreement"), the aggregate consideration paid to stockholders of Allarity A/S at the Closing Date consisted of 8,075,824 shares of the Company's common stock, par value $0.0001 per share ("Common Stock"). At the effective time of the reorganization and subject to the terms and conditions of the Reorganization Agreement, each share of Allarity A/S common stock, par value SEK $0.05 per share that was convertible into a share of Allarity A/S at a one-to-one ratio pursuant to the Allarity A/S certificate of incorporation, was converted into common stock equal to the exchange ratio. In each case, these share amounts were rounded down to the nearest whole number on a holder-by-holder basis and any fractional interest will be settled in cash. The "exchange ratio" means the quotient of the number of Allarity A/S ordinary shares outstanding in Allarity A/S divided by 50 or 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share issued and outstanding (as defined in the Reorganization Agreement), as of immediately prior to the effective time.

At the effective time, each warrant (option) conferring the right to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, was assumed by the Company and converted into an option (each, a "Converted Option") to purchase a number of shares of Common Stock equal to the product (rounded to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio of 50 to 1, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and then converted into U.S. dollars.

As part of the reorganization, the Company is responsible for the liquidation expenses of Allarity A/S, which is estimated to be approximately $200.

4. Other Current Assets

The Company's other current assets are comprised of the following:

	December 31,	
	2022	**2021**
Deposits	$ 51	$ 53
Salary deposit	85	65
Value added tax ("VAT") receivable	82	507
Deferred consulting costs	81	—
Deferred Directors & Officers insurance expense	1,260	—
	$ 1,559	$ 625

5. Investment

The Company owned 43,898 common shares in Lantern Pharma Inc. ("Lantern Pharma") because of a prior license agreement made with Lantern Pharma in 2017. During September 2020 Lantern Pharma became publicly listed. During July 2022, the Company sold its 43,898 common shares in Lantern Pharma in exchange for net proceeds of $235 and recognized a loss of $115.

	December 31,	
	2022	2021
Opening balance	$ 350	$ 845
Less receipt of sale proceeds, net	(235)	—
Loss recognition	(115)	(495)
Ending balance	$ —	$ 350

6. Operating lease right-of-use assets

The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2023. As of February 1, 2021, the Company entered into a new lease contract at its premises in Hoersholm, Denmark. Under the new lease contract, the leased premises were reduced by approximately 137 square meters and the contract period was reduced from an end date of December 31, 2023, to January 31, 2023, with an automatic 12-month renewal period after that date unless termination notice is given. The new lease contract was treated as a modification to the existing lease contract, and we remeasured the lease liability to reflect the modified terms and recognized a corresponding reduction to the ROU asset in the amount of $145.

The exercise of lease renewal options is at the Company's sole discretion and is assessed as to whether to include any renewals in the lease term at inception. As of January 31, 2023, the Company's Denmark lease contract ended and became open ended until terminated by either party. Accordingly, the monthly payments will be expensed on a straight-line-basis and not recognized as a right-of-use asset after January 31, 2023.

The following table summarizes the presentation in our Consolidated Balance Sheets of our right of use assets:

	As of December 31,	
Balance sheet location	**2022**	**2021**
Assets:		
Operating lease assets	$ 6	$ 86
Liabilities:		
Current operating lease liabilities	$ 8	$ 98
Non-current operating lease liabilities	—	9
	$ 8	$ 107

Total lease costs and cash paid for the Company's premises and virtual offices for the years ended December 31, 2022 and 2021, were $104 and $134, respectively.

7. Intangible assets

Intangible assets, impairment charges and adjustments are summarized as follows:

	IPR&D Assets December 31,	
	2022	2021
Opening balance	$ 28,135	$ 30,491
Impairment recognized during the period	(17,571)	—
Foreign translation adjustment	(1,015)	(2,356)
Ending balance	$ 9,549	$ 28,135

7. Intangible assets (cont.)

As a result of both the Company's February 15, 2022, receipt of a Refusal to File ("RTF") from the U.S. Food and Drug Administration regarding the Company's new drug application ("NDA") for Dovitinib, and the current depressed state of the Company's stock price, the Company has performed an impairment assessment on its individual intangible assets utilizing a discounted cash flow model with a weighted average cost of capital ("WACC") of 16%, and recognized an impairment charge of $14,007 during the quarter ended March 31, 2022. During the quarter ended December 31, 2022, as a result of continued downward pressure on the Company's common stock, we performed a further impairment assessment on the Company's individual intangible asset utilizing a discounted cash flow model with a WACC of 26% and recognized a further impairment charge of $3,564. Individually material development projects in progress are as follows:

The Company's IPR&D assets have been classified as indefinite-lived intangible assets. Individually material development projects in progress are as follows:

	December 31,	
	2022	**2021**
Stenoparib	$ 9,549	$ 25,407
Dovitinib	—	2,728
Total	$ 9,549	$ 28,135

8. Accrued liabilities

The Company's accrued liabilities are comprised of the following:

	December 31,	
	2022	**2021**
Development cost liability (Notes 16(a) and (b))	$ 964	$ 6,750
Payroll accruals	221	1,088
Accrued Board member fees	91	54
Accrued audit and legal	239	316
Other	389	382
	$ 1,904	$ 8,590

9. Loan

Effective March 22, 2021, the Company received a loan of up to approximately $2,900, net of a 3% loan origination fee of $87, recorded as finance costs in the Consolidated Statement of Operations and Comprehensive Loss, bearing interest at 3% per month, and due on June 23, 2021. In exchange for the loan, the Company committed to complete a rights offering and issue common shares. The rights offering was completed before June 23, 2021, as described in these consolidated financial statements. As of June 23, 2021, the loan balance of $2,945 and interest of $204 were repaid to the lender.

10. Convertible promissory note and accrued interest, net

On April 12, 2022, Allarity Denmark re-issued a Convertible Promissory Note (the "Promissory Note") to Novartis Pharma AG, a company organized under the laws of Switzerland ("Novartis," and together with Allarity Therapeutics Europe ApS ("Allarity Europe"), the "License Parties") in the principal amount of $1,000. The Promissory Note was re-issued pursuant to the First Amendment to License Agreement, with an effective date of March 30, 2022 (the "First Amendment"), entered into by and between the License Parties, which amended the License Agreement dated April 6, 2018 (the "Original Agreement") previously entered into by the License Parties relating to the Compound (as defined in the Original Agreement). The First Amendment amends and restates Section 11.7 of the Original Agreement to add the revised Note to the list of enforceable claims in the second paragraph of Section 11.7 making the revised Note enforceable under New York law as a legal obligation of Allarity Denmark ApS (formerly OV-SPV2 ApS). All other provisions of the Original Agreement and Promissory Note were unchanged and remain in full force and effect.

10. Convertible promissory note and accrued interest, net (cont.)

On April 6, 2018 ("Effective Date"), Allarity Europe and Novartis entered a license agreement whereby Novartis granted to Allarity Europe (a) an exclusive, royalty-bearing, sublicensable, assignable license under the Licensed Data (as defined in the License Agreement) and Product-Specific Patents (as defined in the License Agreement) and (b) a non-exclusive, royalty-bearing, sublicensable, assignable license under the Platform Patents (as defined in the License Agreement), in the case of (a) and (b) solely to develop and otherwise commercialize the Licensed Product (as defined in the License Agreement) in any and all field related to therapeutic and/or diagnostic uses related to cancer in humans worldwide and to manufacture the compound TKI258 (a.k.a. Dovitinib) for use in a Licensed Product as of the Effective Date.

In consideration of the licenses and rights granted, Allarity Europe paid Novartis a one-time, non-refundable, non-creditable upfront payment consisting of $1,000 ("Upfront Payment") and issued to Novartis a Promissory Note with an initial principal balance equal to $1,000, which Allarity Europe caused its affiliate, Allarity Therapeutics Denmark ApS, to issue to Novartis. In accordance with the terms of the Promissory Note, all payments shall be applied first to accrued interest, and thereafter to principal. The outstanding principal amount of the Note, plus any accrued interest thereon, shall be due and payable on the earlier to occur of: (i) the 7th anniversary of the Effective Date; and (ii) an event of default (the "Maturity Date").

The Promissory Note pays simple interest on the outstanding principal amount from the date until payment in full, which interest shall be payable at the rate of 5% per annum. Interest shall be calculated on the basis of a 360-day year for the actual number of days elapsed. The entire outstanding principal balance of the Promissory Note and all accrued interest shall be fully due and payable on the Maturity Date. The Promissory Note is convertible upon an initial public offering ("IPO") of Allarity Therapeutics Denmark ApS and allows Novartis a one-time right to exchange the Convertible Pro Allarity Therapeutics Denmark ApS Promissory Note for such number of equity securities of Allarity Therapeutics Denmark ApS equal to 3% of outstanding equity securities, calculated on a fully diluted as-converted to common stock basis, held by all holders of equity securities of Allarity Therapeutics Denmark ApS immediately prior to the closing of the IPO.

During the years ended December 31, 2022 and 2021, the Company recorded $106 and $99, respectively, to interest expense and increased the convertible promissory note liability by the same amount. The roll forward of the Promissory Notes as of December 31, 2022 and 2021, is as follows:

	December 31, 2022	December 31, 2021
Convertible promissory note	$ 1,000	$ 1,000
Less debt discount, opening	(215)	(263)
Plus, accretion of debt discount, interest expense	53	48
Convertible promissory note, net of discount	838	785
Interest accretion, opening	194	143
Interest accrual, expense	51	51
Convertible promissory note – net, ending balance	$ 1,083	$ 979

11. Convertible debt

(a) 3i, LP Convertible Secured Promissory Notes

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement ("Purchase Agreement") with 3i, LP ("Holder", or "3i"), whereby the Company authorized the sale and issuance of three Secured Promissory Notes (each a "Note" and collectively, the "Notes"). Effective November 28, 2022, the Company issued: (1) a Note in the principal amount of $1,667 as payment of $1,667 due to 3i, LP in Alternative Conversion Floor Amounts that began to accrue on July 14, 2022; and (2) a Note in the principal amount of $350 in exchange for cash. Effective December 30, 2022, the Company issued an additional Note in the principal amount of $650 in exchange for cash.

11. Convertible debt (cont.)

Each Note matures on January 1, 2024, carries an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to a security agreement (the "Security Agreement"). In addition, the Holder may exchange the Notes for the Company's common stock at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of such promissory note. Lastly, each Note and interest earned thereon may be redeemed by the Company at its option at any time or the holder may demand redemption if a) the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing or b) there is an Event of Default (as defined in the Note agreement).

Discounts to the principal amounts are included in the carrying value of the Notes and amortized to interest expense over the contractual term of the underlying debt. During 2022, the Company recorded a $34 debt discount upon issuance of the Notes related to legal fees paid that were capitalized as debt issuance costs. For the year ended December 31, 2022, interest expense on the Notes totaled $12, comprised of $10 of contractual interest and $2 for the amortization of the debt discount.

The roll forward of the Notes as of December 31, 2022, is as follows:

Face value of the Notes	$	2,667
Debt discount, net		(33)
Carrying value of the Convertible Notes		2,634
Accrued interest		10
	$	2,644

(b) March 31, 2020 Convertible Debt (terminated December 20, 2021)

On March 31, 2020, the Company, through its former parent company, Allarity A/S, entered into a twenty-four-month term agreement to issue up to $10,100 (SEK 100,000) to be funded in tranches of ten non-interest-bearing notes ("Notes") convertible into new shares of the Company, each with a value of $1,010 (SEK 10,000), under the following terms:

a) Fees payable include 5% of the $10,100 Commitment in 2 equal installments of $252, paid on the disbursement of each of the first and second Tranches; and a further 5% of the principal of the notes is to be deducted from the payment of each Tranche.

b) The loan is due for repayment in full 12 months from the date of issuance; or immediately repayable in the event of default, a change of control or a material adverse event. The Investor may in its sole discretion decide to convert the Loan in full or in part (in multiples of $4 (SEK 25) in 1,000's) into new shares.

c) The Conversion Price of the Notes is 95% of the lowest closing volume weighted average price as reported by Bloomberg ("VWAP") of the shares during the applicable pricing period preceding the conversion date. Conversion of the Loan Amount shall be made at a rate equal to the Conversion Price. The Conversion Price cannot be below par value. The number of new Shares issued by the Company to the Investor upon conversion of the Loan Amount shall be calculated as the Loan Amount divided by the Conversion Price. If the Conversion Price is equal to or less than $0.01 (DKK 0.05), the Investor will not be required to convert such Note. If the Investor (contrary to the clear intention in the Agreement) claims repayment of one or more Tranches and not to convert into Shares the Company shall be entitled to deduct the commitment fee in connection with the repayment.

d) Default interest accrues on the overdue amount from the due date up to the date of actual payment at 8% per annum; calculated on a 360-day year and accrues and compounds on a daily basis.

Prior to the Company's share offering in June of 2021 the Company had issued and converted a total of four of the Notes, leaving six Notes available however, pursuant to the Company's agreement with its June Rights Issue investors, this loan agreement was no longer utilized after the end of June 30, 2021.

11. Convertible debt (cont.)

The Company accounted for the Notes issued under the fair value election whereby the financial instrument is initially measured at its issue-date estimated fair value and subsequently re-measured at estimated fair value on a recurring basis at each reporting date. The estimated fair value adjustment is presented as a single line item within other income (expense) in the accompanying consolidated statements of operations under the caption change in fair value of convertible debt and derivative liabilities. We determined the fair value of the Notes using a discounted cash flow valuation technique with a weighted average cost of capital of 15%. The Company estimates the change in fair value attributable to the instrument specific credit risk of the Notes at 1% under the fair value option and accordingly has recognized a recovery of $9 in other comprehensive income during the year ended December 31, 2021. Changes in fair value of convertible debt of ($474) and non-cash interest expense related to beneficial conversion feature of convertible debt of $141 have been recognized in the Company's Consolidated Statements of Operations and Comprehensive loss in the year ended December 31, 2021.

The roll forward of the Notes as of December 31, 2021, is as follows:

Opening fair value balance	$	1,327
Convertible debt issued in the period		1,140
Change in fair value		474
Foreign exchange		(116)
Conversion of notes to common shares		(2,825)
Ending fair value balance	$	—

An effective interest rate determines the fair value of the Notes. The notes are unlisted and therefore, they are categorized as Level 3 in accordance with ASC 820. The Notes were fully converted to shares as of June 30, 2021, and concurrent with the Company's reorganization on December 20th, 2021, are no longer accessible to the Company.

12. Series A Preferred Stock and Common Stock Purchase Warrants

(a) Series A Preferred Stock Terms

On May 20, 2021, we entered into a Securities Purchase Agreement (the "SPA") with 3i, LP, a Delaware limited partnership ("3i") for the purchase and sale of 20,000 shares of our Series A Convertible Preferred Stock (the "Series A Preferred Stock") for $1,000 per share for an aggregate purchase price of $20 million (the "PIPE Investment") with accompanying common stock purchase warrants (the "3i Warrants"). On December 8, 2021, the Board adopted resolutions to create a series of 500,000 shares of preferred stock, par value $0.0001, of which 20,000 shares were designated as Series A Preferred Stock. On December 14, 2021, we filed a Certificate of Designations (the "COD") setting forth the rights, preferences, privileges and restrictions for 20,000 shares of Series A Preferred Stock. On December 20, 2021, we issued 20,000 shares of Series A Preferred Stock at $1,000 per share and a common stock purchase warrant to purchase 2,018,958 shares of common stock at an initial exercise price of $9.9061 to 3i for an aggregate purchase price of $20 million.

All shares of capital stock including other classes of preferred stock are junior in rank to all Series A Preferred Stock with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company.

The Series A Preferred Stock has a liquidation preference equal to an amount per Series A Preferred Stock equal to the sum of (i) the Black Scholes Value (as defined in the Warrants, which was sold concurrent with the Series A Preferred Stock) with respect to the outstanding portion of all Warrants held by such holder (without regard to any limitations on the exercise thereof) as of the date of such event and (ii) the greater of (A) 125% of the Conversion Amount of such Series A Preferred Stock on the date of such payment and (B) the amount per share such holder would receive if such holder converted such Series A Preferred Stock into common stock immediately prior to the date of such payment, and will be entitled to convert into shares of common stock at an initial fixed conversion price of $9.9061 per share, subject to a beneficial ownership limitation of 4.99% which can be adjusted to a beneficial ownership limitation of 9.99% upon 61 days' prior written notice.

12. Series A Preferred Stock and Common Stock Purchase Warrants (cont.)

(a) Series A Preferred Stock Terms (cont.)

Under the terms of the COD, the initial fixed conversion price of the Series A Preferred Stock is $9.9061, subject to adjustment. In the event that (i) the average of the VWAP of the Company's shares for each of the five trading days immediately preceding the date of delivery is less than the fixed conversion price of $9.9061 (a "Price Failure"), or (ii) the sum of (x) the aggregate daily dollar trading volume (as reported on Bloomberg) of our common stock on Nasdaq during the 10 trading day period ending on the trading day immediately preceding such date of determination, divided by (y) 10, is less than $1,500 (a "Volume Maximum Failure"), each share of Series A Preferred Stock is entitled to convert at a price equal to 90% of the sum of the two lowest VWAPs during the 10 trading day period immediately preceding the date of delivery divided by two (the "90% Conversion Price"), but not less than the Floor Price (as defined in the COD), or, at the time of such Price Failure or Volume Maximum Failure, the sum of the average daily U.S. Dollar volume for our common stock during the 10 days previous to conversion divided by 10 is less than $2 million then each share of Series A Preferred Stock is entitled to convert at the lower of the fixed conversion price or a price equal to 80% of the sum of the two lowest VWAPs during the 10 trading day period immediately preceding delivery divided by two (the "80% Conversion Price"), but not less than the Floor Price (such 80% Conversion Price or 90% Conversion Price, as the case may be, the "Alternate Conversion Price").

In addition, the COD and the Warrant provides for an adjustment to the conversion price and exercise of the Warrant in the event of a "new issuance" of our common stock, or common stock equivalents, at a price less than the applicable conversion price of the Series A Preferred Stock or exercise price of the Warrant. The adjustment is a "full ratchet" adjustment in the conversion price of the Series A Preferred Stock and the exercise price of the Warrant equal to the lower of the new issuance price or the then existing conversion price of the Series A Preferred Stock or exercise price of Warrant, with few exceptions required to redeem the shares we were unable to deliver at a price equal to the highest closing price of our common stock during the time between the failure to deliver shares of our common stock and the redemption date.

If certain defined "triggering events" defined in the COD occur, such as a breach of the Registration Rights Agreement (specifically the Company's Form S-1 as filed on SEC Edgar on September 13, 2021 and subsequently amended), suspension of trading, or our failure to convert the Series A Preferred Stock into common stock when a conversion right is exercised, failure to issue our common stock when the Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, or upon a "bankruptcy triggering event" (as defined in the COD), then we may be required to redeem the Series A Preferred Stock for cash in the amount of up to a minimum of 125% of their Conversion Amount (as defined in the COD). In addition, if 30 days after our common stock commences trading on the Nasdaq Stock Market the sum of the average daily dollar volume for the 10 days previous to conversion divided by 10 is less than $2.5 million, then the Series A Preferred Stock will be entitled to a one-time dividend equal to an 8% increase in the stated value of the Series A Preferred Stock, or an $80 dollar increase per share in stated value, resulting in a stated value of $1,080 per Series A Preferred Stock. Additionally, if any of the triggering events are not addressed on a timely basis, we could be liable to pay an 18% per annum dividend.

If the Company experiences a "Change of Control" (as defined in the COD), the Company may also be required to redeem the Preferred Shares for cash at a minimum of 125% of their Conversion Amount. Holders of Series A Preferred Stock will have no voting rights, except as required by law and as expressly provided in the COD.

(b) Amendments to Series A Convertible Preferred Stock

i. Voting Rights

On November 22, 2022, the Company amended Section 12 of the Certificate of Designation of Series A Convertible Preferred Stock to provide for voting rights. Subject to a 9.99% beneficial ownership limitation, the holders of Series A Preferred Stock shall have the right to vote on all matters presented to the stockholders for approval together with the shares of common stock, voting together as a single class, on an "as converted" basis using the "Conversion Price" (initially $9.906 per share before any adjustment) (rounded down to the nearest whole number and using the record date for determining the stockholders of the Company eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in the Company's Certificate of Incorporation or the Certificate of Designations of Series A Convertible Preferred Stock. The voting rights described above shall expire on February 28, 2023, and thereafter holders of preferred stock shall not have voting rights except as required by law.

12. Series A Preferred Stock and Common Stock Purchase Warrants (cont.)

ii. Conversion Price Adjustment for Series A Preferred Stock

On December 9, 2022, the Company and 3i entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations for the Series A Preferred Stock, the parties agreed that the Conversion Price was modified to mean the lower of: (i) the Closing Sale Price on the trading date immediately preceding the Conversion Date and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days through and inclusive of January 19, 2023. Any conversion which occurs shall be voluntary at the election of the Holder, which shall evidence its election as to the Series A being converted in writing on a conversion notice setting forth the then Minimum Price. Management determined that the adjustment made to the Conversion Price is not a modification of the COD which allows for adjustments to the Conversion Price at any time by the Company and the other terms of the Certificate of Designations remained unchanged.

(c) Series A Preferred Stock Triggering Event

As more specifically discussed below, a "Triggering Event" under the COD occurred on April 29, 2022, under Section 5(a)(ii) of the COD, which would have resulted in the following unless 3i, agreed to forebear and/or waive its rights under the COD:

1. An 18% per annum dividend will start to accrue on the stated value of all outstanding Preferred Shares and will continue to accrue until the Triggering Event has been cured. The accrued dividend is added to the stated value prior to the Dividend Payment Date and paid in cash on the first trading day of the Company's next fiscal quarter. A "Late Charge" in the amount of 18% per annum will accrue on any amounts due to be paid to holders of the Preferred Shares if not paid when due, including payments that may be owed under Section (e) of the Registration Rights Agreement ("RRA").

2. A "Triggering Event Redemption Right" will commence and remain open for a period of 20 trading days from the later of the date either the Triggering Event is cured or the receipt by 3i of the Triggering Event Notice. Under the Triggering Event Redemption Right, if elected by the holder of the Preferred Shares, the Company would be obligated to redeem all or a portion of the Preferred Shares for a minimum of 125% of the stated value of the Preferred Shares. Concurrently, under the provisions of the PIPE Warrant, if elected by 3i, the Company would be obligated to redeem the PIPE Warrant for the Black Sholes Triggering Event Value as defined in the warrant agreement.

3. A "Registration Delay Payment" will accrue on April 22, 2022 (the expiration of the Allowable Grace Period under the RRA) in the amount of 2% of 3i's "Purchase Price" as defined in the Securities Purchase Agreement which is approximately 2% of $20 million, or $400 and will continue to accrue at 2% every 30 days thereafter. Additionally, a late charge of 2% per month will accrue on any payments that are not paid when due. The Registration Delay Payments will stop accruing when the post-effective amendment is declared effective by the SEC at which time the registration statement and its prospectus will again be available for the resale of common stock.

On May 4, 2022, the Company and 3i entered into a Forbearance Agreement and Waiver, dated April 27, 2022, wherein 3i confirmed that no Triggering Event as defined under the COD has occurred prior to April 27, 2022, that a Triggering Event under Section 5(a)(ii) will and has occurred on April 29, 2022, and that in consideration for the Registration Delay Payments the Company is obligated to pay under the RRA, and additional amounts the Company is obligated to pay under the COD and 3i's legal fees incurred in the preparation of the Forbearance Agreement and Waiver in the aggregate of $539 paid upon execution of the Forbearance Agreement and Waiver, and so long as the Company pays the Registration Delay Payments that become due and payable under the RRA after the execution of the Forbearance Agreement and Waiver, 3i has agreed to forbear exercising any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the COD (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022 (such period, the "Forbearance Period"). Provided that the Company is not in breach of its obligations under Forbearance Agreement and Waiver, effective as of the Trading Day immediately following the date the Company cures the Triggering Event under Section 5(a)(ii) of the COD, 3i agrees to waive any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a) of the COD and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver.

12. Series A Preferred Stock and Common Stock Purchase Warrants (cont.)

(c) Series A Preferred Stock Triggering Event (cont.)

On June 6, 2022, the Company entered into that certain First Amendment to the Forbearance Agreement and Waiver with 3i, (the "Amendment") to extend the forbearance period date under subsection 5 of Section 2 of the Forbearance Agreement and Waiver dated April 27, 2022 (the "Original Agreement") from June 4, 2022, to June 20, 2022. In addition, the parties agreed that the forbearance period of June 20, 2022 may also be extended for an additional 15 days to July 5, 2022, provided that, on June 20, 2022 the Company will remove the restrictive legend on 441,005 shares of common stock of the Company issued in connection with the conversion of certain shares of Series A Preferred Stock ("Conversion Shares") by 3i pursuant to the conversion notice dated May 2, 2022, and 3i is able to sell the Conversion Shares free of restrictions (including volume restrictions) pursuant to SEC Rule 144(b)(1)(i) (the "Legend Removal").

The Original Agreement was entered into by the Company and 3i because of a delay under the Registration Rights Agreement dated May 20, 2021. Under the Original Agreement, in exchange for certain consideration, 3i agreed to forbear exercising any rights or remedies that it may have had under the COD in connection with certain Triggering Events (as described therein) until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the COD (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the COD and Section 4(c)(ii) of the Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022 (such period, the "Original Forbearance Period"). As a result of the Amendment, the June 4, 2022, date has been amended to June 20, 2022, with the option to extend to July 5, 2022, subject to the Legend Removal.

(*d) 3i Warrant Terms*

Concurrently with the issuance of our Series A Preferred Stock, the Company issued warrants to purchase 2,018,958 shares of the Company's common stock at an exercise price of $9.9061 per share, subject to adjustments ("3i Warrants"). The material terms of the 3i Warrants are as follows:

(i) The warrants have a term of three years and expire on December 20, 2024;

(ii) The exercise of the warrants are subject to a beneficial ownership limitation of 4.99% which can be adjusted to a beneficial ownership limitation of 9.99% upon 61 days' prior written notice;

(iii) The exercise price and the number of 3i Warrant shares issuable upon the exercise of the 3i Warrants are subject to adjustment, as follows:

- In the event of a stock dividend, stock split or stock combination recapitalization or other similar transaction involving the Company's common stock the exercise price will be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event;

- If the Company sells or issues any shares of common stock, options, or convertible securities at an exercise price less than a price equal to the Warrant exercise price in effect immediately prior to such sale (a "Dilutive Issuance"), then immediately after such Dilutive Issuance, the exercise price then in effect shall be reduced to an amount equal to the new issuance price;

- Simultaneously with any adjustment to the exercise price, the number of 3i Warrant shares that may be purchased upon exercise of the 3i Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate exercise price payable hereunder for the adjusted number of 3i Warrant shares shall be the same as the aggregate exercise price in effect immediately prior to such adjustment (without regard to any limitations on exercise) and;

- Voluntary adjustment for the Company to any amount and for any period deemed appropriate by the board of directors of the Company.

12. Series A Preferred Stock and Common Stock Purchase Warrants (cont.)

(*d) 3i Warrant Terms (cont.)*

(iv) In the event of either the Company consolidating or merging with or into another entity (the "Fundamental Transaction"), the sale or assignment of substantially all of the Company's subsidiaries, or a Triggering Event (as defined in the COD), the holder is entitled to require the Company to pay the holder an amount in cash equal to the Black-Scholes value of the 3i Warrants on or prior to the later of the second trading after the date of request for payment and the date of consummation of the Fundamental Transaction; or at any time after the occurrence of the Triggering Event.

(e) Accounting

i. Series A Preferred Stock

The Company evaluated the Series A Preferred Stock under ASC 480-10 to determine whether it represents an obligation that would require the Company to classify the instrument as a liability and determined that the Series A Preferred Stock is not a liability pursuant to ASC 480-10. Management then evaluated the instrument pursuant to ASC 815 and determined that because the holders of the Series A Preferred Stock may be entitled to receive cash, the Series A Preferred stock should be recorded as mezzanine equity given the cash redemption right that is within the holder's control.

Generally, preferred stock that are currently redeemable should be adjusted to their redemption amount at each balance sheet date. If it is probable that the equity instrument will become redeemable, the Company has the option to either accrete changes in the redemption value over the period from the date of issuance (or from the date that it becomes probable that the instrument will become redeemable, if later) to the earliest redemption date of the instrument or to recognize changes in the redemption value immediately as they occur and adjust the carrying amount of the instrument to equal the redemption value at the end of each reporting period. The Company recognizes changes in redemption value when redemption becomes probable to occur.

Through December 9, 2022, the derivative scope exception under ASC 815 is not met because a settlement contingency is not indexed to the Company's stock. Therefore, the redemption feature (derivative liability) has been bifurcated from the Series A Preferred Stock and recorded as a derivative liability. The fair value of the Series A Preferred Stock Redemption Feature (the "Redemption Feature") derivative is the difference between the fair value of the Series A Preferred Stock with the Redemption Feature and the Series A Preferred Stock without the Redemption Feature. The Series A Preferred Stock Redemption Feature has been valued with a Monte Carlo Simulation model, using the inputs as described in Note 13(a).

Subsequent to December 9, 2022, because of the agreed conversion price adjustment (see Note 12(b) ii.), although bifurcation of the conversion feature is still required, the value of the derivative has been determined to be immaterial since the conversion price will always be at market.

iii. 3i Warrants

The 3i Warrants were identified as a freestanding financial instrument and meet the criteria for derivative liability classification, initially measured at fair value. Subsequent changes in fair value are recognized through earnings for as long as the contracts continue to be classified as a liability. The measurement of fair value is determined utilizing an appropriate valuation model considering all relevant assumptions current at the date of issuance and at each reporting period (i.e., share price, exercise price, term, volatility, risk-free rate and expected dividend rate).

12. Series A Preferred Stock and Common Stock Purchase Warrants (cont.)

(f) Series A Preferred Stock Conversions

i. Year ended December 31, 2022

During the year ended December 31, 2022, 3i exercised its option to convert 6,214 shares of Series A Preferred stock for 7,801,831 shares of common stock. As of December 31, 2022, we had 13,586 shares of Series A Preferred Stock issued and outstanding. The fair value of the derivative liability associated with the Series A Preferred Stock converted during the year ended December 31, 2022, as determined by Monte Carlo simulations, was $954.

Because the latest nine conversions in the period January 1, 2022, through December 9, 2022, were completed at less than the agreed floor price, we recorded a floor price liability and recognized a corresponding reduction of additional paid in capital, as follows:

i. During the six months ended June 30, 2022, $1,511 (paid in cash prior to June 30, 2022);

ii. During the three months ended September 30, 2022, $1,646 (See Note 11(a));

iii. On December 9, 2022, we issued 121,018 shares of Common Stock to the Investor upon the conversion of 222 Conversion Shares and recorded a floor price liability of $264.

Additionally, because the Company's average daily dollar volume of stock trading was less than $2.5 million during a ten-day period in January 2022, the Company has recorded a one-time deemed dividend of 8% in the amount of $1,572 on preferred stock converted between February 1, 2022 and March 31, 2022 and the balance of Series A Preferred Stock outstanding as at March 31, 2022 as an increase to the value of the Series A Preferred Stock and a reduction of additional paid in capital. In addition, under the terms of the Registration Rights Agreement ("RRA"), during the period January 1, 2022, through December 31, 2022, the Company has also paid 3i an additional $800 in Registration Delay Payments.

On December 9, 2022, the Company and 3i, entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations for the Series A Preferred Stock, the parties agreed that the Conversion Price (as defined in such Certificate of Designations") was modified to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations) on the trading date immediately preceding the Conversion Date (as defined in the Certificate of Designations and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Certificate of Designations) through and inclusive of January 19, 2023.

ii. Year ended December 31, 2021

On December 21, 2021, when 3i exercised its option to convert 200 shares of Series A Preferred Stock for 20,190 shares of our common stock, the Company determined the fair value was unchanged from the December 20, 2021 fair value, and accordingly reclassified $75 from the Series A Preferred Stock Conversion feature to additional paid-in capital. As of December 31, 2021, the Company recognized a fair value remeasurement adjustment of the carrying amount resulting in a $154 decrease in fair value of the derivative liability and a corresponding change in fair value of derivative liability in the Consolidated Statement of Operations and Comprehensive Loss.

12. Series A Preferred Stock and Common Stock Purchase Warrants (cont.)

The accounting for the Series A Preferred Stock and Warrants is illustrated in the table below:

	Consolidated Balance Sheets				Consolidated Statement of Operations & Comprehensive Loss	
	Warrant liability	Series A Preferred Derivative Liability	Series A Convertible Preferred Stock – Mezzanine	Additional paid-in capital	Finance Costs	Fair value adjustment to derivative and warrant liabilities
Subscription proceeds received on December 20, 2021	$ 11,273	$ 7,409	$ 1,318	$ —	$ —	$ —
Costs allocated and expensed	—	—	(680)	—	877	—
December 21, 2021 conversion of 200 Series A Preferred Stock	—	(74)	(6)	80	—	—
Fair value adjustment at December 31, 2021	—	(154)	—	—	—	(154)
Balance, December 31, 2021	$ 11,273	$ 7,181	$ 632	$ 80	$ 877	$ (154)

	Consolidated Balance Sheets						Consolidated Statement of Operations & Comprehensive Loss
	Warrant liability	Series A Preferred Derivative Liability*	Series A Convertible Preferred Stock – Mezzanine Equity	Share Capital	Additional paid-in capital	Accrued Liabilities	Fair value adjustment to derivative and warrant liabilities
Balances, December 31, 2021	$ 11,273	$ 7,181	$ 632	—	$ 80	—	$ (154)
Conversion of 6,214 shares of Series A Preferred Stock into common stock	—	—	(203)	1	202	—	—
Reclassification of derivative liability relating to converted Series A Preferred stock	—	(954)	—	—	954	—	—
Floor price adjustment on conversion of shares of Series A Preferred stock	—	—	—	—	(3,421)	265	—
8% deemed dividend on Preferred Stock	—	—	1,572		(1,572)	—	—
Fair value adjustment	(10,899)	(6,227)	—	—	1	—	17,125
Balances, December 31, 2022	$ 374	$ —	$ 2,001	$ 1	$ (3,756)	$ 265	$ 17,125

* Valuationof the Series A Preferred Derivative Liability is discussed in Note 12 (e) ii.

13. Derivative Liabilities

(a) Continuity of Warrant Liability and Derivative Liabilities

The derivative liabilities are measured at fair value at each reporting period and the reconciliation of changes in fair value in the years ended December 31, 2022, and 2021, is presented in the following tables:

	3i Warrants	3i Fund Series A Redemption Feature
	Issued December 20, 2021	
Balance as of January 1, 2022	$ 11,273	$ 7,181
Change in fair value	(10,899)	(6,227)
Amount transferred to Equity	—	(954)
Balance as of December 31, 2022	$ 374	$ —
Fair value per 3i Warrant / Series A Preferred share issuable at period end	$ 0.19	$ —

	Settlement Warrants for the termination of the Financing Facility	T02 Warrants	T03 Warrants	3i Warrants	3i Fund Series A Redemption Feature
	Grant date February 23, 2020	Warrants issued December 2019	Warrants issued June 2021	Issued December 20, 2021	
Balance as of January 1, 2021	$ 102	$ 47	$ —	$ —	$ —
Issued during the period	—	—	2,000	11,273	7,409
Change in fair value	(94)	(45)	(1,794)	—	(153)
Amount transferred to Equity	—	—	(206)	—	(75)
Translation effect	(8)	(2)	—	—	—
Balance as of December 31, 2021	$ —	$ —	$ —	$ 11,273	$ 7,181
Fair value per warrant / Series A Preferred share issuable at period end	$ —	$ —	$ —	$ 5.58	$ 363.0

(b) Series A Preferred Stock Conversion Feature – Valuation Inputs

The following inputs were used for the Series A Preferred Stock conversions recorded in the year ended December 31, 2022 and the fair value of the Series A Preferred Derivative liability determined at September 30, 2022 and December 31, 2021:

	January 1, 2022 – September 30, 2022*	December 31, 2021
Initial exercise price	$9.05 - $9.91	$ 9.91
Stock price on valuation date	$1.10 - $10.75	$ 10.37
Risk-free rate	1.03% - 4.23%	0.96%
Time to exercise (years)	2.22 - 2.96	2.97
Equity volatility	70% - 114%	70%
Probability of volume failure	93% - 99%	92%
Rounded 10-day average daily volume (in 1,000's)	$297 - $873	$ 908

* The agreed conversion price adjustment (see Note 12 (b) ii.) resulted in the Series A Preferred liability value derivative being valued at zero at December 9, 2022. Therefore, there were no conversions subsequent to September 30, 2022, which impacted the Series A derivative liability.

13. Derivative Liabilities (cont.)

(c) 3i Warrants – Valuation Inputs

On December 31, 2022, the Company utilized the reset strike options Type 2 model by Espen Garder Haug and Black-Scholes Merton models to estimate the fair value of the 3i Warrants to be approximately $374. On December 31, 2021, the Company utilized Monte Carlo simulations models to estimate the fair value of the 3i Warrants to be approximately $11,273. The 3i Warrants were valued at December 31, 2022 and 2021, using the following inputs:

	December 31, 2022	December 31, 2021
Initial exercise price	$ 9.91	$ 9.91
Stock price on valuation date	$ 0.29	$ 10.50
Risk-free rate	4.33%	0.91%
Expected life of the 3i Warrant to convert (years)	1.97	3.0
Rounded annual volatility	131%	73%
Timing of liquidity event	March 15, 2023	Q3 2022 – Q2 2023
Expected probability of event	100%	90%

(d) Investor Warrants

The exercise price of our investor warrants which were issued by Allarity A/S, described below is denominated in SEK; however, the functional currency of Allarity A/S is DKK. Consequently, the value of the proceeds on exercise is not fixed and will vary based on foreign exchange rate movements. The investor warrants, when issued other than as compensation for goods and services are therefore a derivative for accounting purposes and are required to be recognized as a derivative liability and measured at fair value at each reporting period. Any changes in fair value from period to period are recorded as non-cash gain or loss in the Consolidated Statements of Operations and Comprehensive Loss. Upon exercise, the holders pay the Company the respective exercise price for each investor warrant exercised in exchange for one common share of the Company and the fair value at the date of exercise and the associated non-cash liability will be reclassified to share capital. The non-cash liability associated with any investor warrants that expire unexercised is recorded as a gain in the consolidated statements of comprehensive loss. There are no circumstances in which the Company would be required to pay any cash upon exercise or expiry of the investor warrants.

In connection with subscriptions of units in the rights issues carried out:

i. October — December 2019, 1,006,822 investor warrants ("TO2 warrants") were granted to investors. All Warrants were vested as of the grant date. A warrant gives the right, during a fixed period to subscribe for one common share in the Company for $34.50 per common share. The final exercise period for the warrants of series TO2 took place from September 1 up to and including September 15, 2021. Any TO2 warrants unexercised after September 13, 2021, expired without compensation or payment of any kind to the warrant holders. During the year ended December 31, 2021, a total of 176 warrants of series TO2 were exercised for total proceeds of $6; and

ii. in June 2021, 2,417,824 investor warrants ("TO3 Warrants") were granted to investors and 482,250 TO3 warrants have been granted to underwriters as a non-cash consideration of the share issuance cost amounting $2,384. All TO3 Warrants were vested as of the grant date and were exercisable for $10 per common shares. In accordance with the terms of the Company's outstanding TO3 Warrants, on August 26, 2021, the Company's Board of Directors set an extraordinary and final exercise period for the Company's TO3 Warrants, starting on August 30, 2021, and ending on September 13, 2021. Any TO3 Warrants unexercised after September 13, 2021, expired without compensation or payment of any kind to the warrant holders. During the year ended December 31, 2021, 274,386 TO3 Warrants were exercised for total proceeds of $2,679 and the balance expired unexercised on September 13, 2021.

13. Derivative Liabilities (cont.)

The table below summarizes the number of investor warrants that were outstanding, their weighted average exercise price as of December 31, 2021, as well as the movements during the year.

	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2020	1,086,759	$ 36.0
Granted	2,900,074	$ 10.0
Exercised	(274,562)	$ 10.0
Expired	(3,712,271)	$ 17.0
Outstanding at December 31, 2021	—	$ —
Exercisable at December 31, 2021	—	$ —

There were no investor warrants issued or outstanding during the year ended December 31, 2022.

The fair value of the Company's TO3 warrant liabilities, which all expired as of September 13, 2021, were estimated based upon Monte Carlo simulations under different market conditions, as scheduled below, resulting in a probability weighted value of the TO3 warrants of $2,000 at June 24, 2021, at the grant date. Warrants exercised on September 13, 2021, were re-valued at $206 using a Black-Scholes model with the assumptions noted below.

	June 24, 2021	August 30, 2021
Exercise price	$ 10.05	$ 9.86
Stock price	$ 5.50	$ 10.61
Risk-free interest	(0.55)%	(0.50)%
Expected dividend yield	(0)%	(0)%
Contractual life (years)	1.81	0.04
Expected volatility	106.5%	104%

(e) Financing Facility

Effective November 29, 2018, the Company established a convertible debt facility (the "Facility") for funding of up to SEK 200 million to be funded in up to 20 tranches of SEK 10 million each over a 24-month term and bearing interest at 2% per annum. Five of the tranches receivable under the Facility were at the discretion of the investor and the Facility was convertible into shares and warrants at 50% of the nominal amount of the notes. The Company evaluated the terms of the Financing Facility in accordance with ASC 815-40-15 and ASC 815-40-25 and determined that the instrument is a derivative. Accordingly, the accounting treatment is the same as that described for Investor Warrants in Note 13(b) above.

On June 3, 2019, the Company settled one of the five tranches with a cash payment of $673 and in February 2020 the balance of the committed tranches was settled by receipt of $1,000 from the investor in cash, in exchange for a subscription of 186,600 common shares in the Company ("Settlement Shares") valued at $2,500 and the issuance of 79,937 investor warrants ("Settlement Warrants") valued at $625 as of the February 23, 2020, grant date. All Settlement Warrants immediately vested on the grant date, were exercisable at $20 per common share and expired unexercised as of December 12, 2021.

13. Derivative Liabilities (cont.)

The fair value of the Company's Settlement Warrant derivative liabilities, which all expired as of December 31, 2021, were estimated initially and on a quarterly basis using the Black-Scholes option pricing model and based on the following assumptions:

	Settlement Warrants for the termination of the Financing Facility
	Grant date February 23, 2020
Exercise price	$ 17.0
Share price	$ 13.5
Risk-free interest	(0.38)%
Expected dividend yield	(0)%
Contractual life (years)	3.00
Expected volatility	104.10%

14. Stockholders' Equity

(a) Stockholders' Equity

i. Capital structure

As a result of the recapitalization share exchange described in Notes 1 and 4, to these consolidated financial statements, all outstanding shares, warrants and options were exchanged on a 50:1 basis as of December 20, 2021, and accordingly, all share, warrant, option and per share disclosure in these consolidated financial statements has been retroactively adjusted to reflect the 50:1 reverse split unless otherwise stated.

Our authorized capital stock consists of 30,000,000 shares of common stock, par value $0.0001 per share, and 500,000 shares of preferred stock, par value $0.0001 per share, of which 20,000 shares of preferred stock, have been designated Series A Preferred Stock and 200,000 have been designated as Series B Preferred Stock (see note 14(a)ii.).

Our Certificate of Incorporation authorizes our board of directors to establish one or more series of preferred stock (including convertible preferred stock). Our board of directors may determine, with respect to any series of preferred stock, the powers including preferences and relative participations, optional or other special rights, and the qualifications, limitations, or restrictions thereof, of that series.

As of December 31, 2022 and 2021, the Company's total issued, and outstanding common shares were 15,897,845 and 8,096,014, respectively, with a par value of $0.0001. The shares are fully paid in. The shares are not divided into classes, and no shares enjoy special rights.

ii. Establishment of Series B Preferred Stock

On November 22, 2022, the Company's Board of Directors established the Series B Preferred Stock, par value $0.0001 per share ("Series B Preferred Stock"). Following is a summary of the terms of the Series B Preferred Stock:

a. The number of shares designated as Series B Preferred Stock is 200,000;

b. The holders of Series B Preferred Stock shall not be entitled to receive dividends of any kind;

c. Each outstanding share of Series B Preferred Stock shall have 400 votes per share;

The Series B Preferred Stock shall rank senior to the Common Stock, but junior to the Series A Preferred stock, as to any distribution of assets upon a liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily;

14. Stockholders' Equity (cont.)

All shares of Series B Preferred Stock that are not present in person or by proxy through the presence of such holder's shares of Common Stock or Series A Preferred Stock, in person or by proxy, at any meeting of stockholders held to vote on the Reverse Stock Split, the Share Increase Proposal and the Adjournment Proposal as of immediately prior to the opening of the polls at such meeting (the "Initial Redemption Time") shall automatically be redeemed by the Company at the Initial Redemption Time without further action on the part of the Company or the holder thereof (the "Initial Redemption");

Any outstanding shares of Series B Preferred Stock that have not been redeemed pursuant to an Initial Redemption shall be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board of Directors in its sole discretion, automatically and effective on such time and date specified by the Board of Directors in its sole discretion or (ii) automatically upon the approval by the Company's stockholders of the Reverse Stock Split and the Share Increase Proposal at any meeting of stockholders held for the purpose of voting on such proposals; and

Each share of Series B Preferred Stock redeemed in any Redemption shall be redeemed in consideration for the right to receive an amount equal to $0.01 in cash for each one whole share of Series B Preferred Stock as of the applicable Redemption Time.

iii. Issuance of Series B Preferred Stock Dividend

Effective December 5, 2022, the Company issued a stock dividend to be distributed as follows to stockholders of record as of close of business on December 5, 2022: (i) 0.016 shares of Series B Preferred Stock for each outstanding share of common stock; and (ii) 1.744 shares of Series B Preferred Stock for each outstanding share of Series A Preferred Stock. Effective February 3, 2023, the Company redeemed 190,786 shares of Series B Preferred stock in exchange for $0.01 per share.

iv. Share issuances

During the year ended December 31, 2022, the Company issued 7,801,831 common shares valued at $1,156 gross and ($2,265) net of the $3,421 floor price adjustments upon the conversion of 6,214 shares of Series A Preferred Stock.

During the year ended December 31, 2021, the Company recorded a total of $2,475 in share issuance costs and issued:

(a) 295,537 common shares valued at $2,972 upon the exercise of common stock purchase warrants and stock options and the receipt of $2,765 in cash;

(b) Units consisting of 2,417,824 common shares and 2,417,824 common share purchase warrants for $5 per unit; valued at $12,125 in exchange for $12,125 in cash, and 482,250 common shares and 482,250 common share purchase units valued at $2,384 in consideration for services. The attached warrants are exercisable for $10 each with an original expiration date of April 15, 2023, subsequently amended to September 13, 2021 (Note 14(b) iii);

(c) 628,192 common shares valued at $2,880 upon conversion of debt and payment of accounts payable; and

(d) 20,190 common shares valued at $82 upon the conversion of 200 Series A Preferred shares.

15. Share-based payments

Share based payments in the legal form of stock options ("options") and/or warrants have been granted to members of the executive management, members of the board of directors, employees, and external consultants.

15. Share-based payments (cont.)

2021 Equity Incentive Plan

Our 2021 Equity Incentive Plan became effective on December 20, 2021. It was approved by shareholders in connection with the Recapitalization Share Exchange. Our 2021 Plan authorizes the award of stock options, Restricted Stock Awards ("RSAs"), Stock Appreciation Rights ("SARs"), Restricted Stock Units ("RSUs"), cash awards, performance awards and stock bonus awards. We have initially reserved 1,211,374 shares of our common stock under the 2021 Plan. The number of shares reserved for issuance under our 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors.

On November 24, 2021, the Board of Directors approved an equity-settled stock option plan which provides employees, officers, and directors an option to purchase a total of 869,828 common shares of the Company at prices of between $5.19 and $10.17. Employee warrants were granted with 25% vesting upon grant and the 75% balance vesting over 36 months until November 24, 2024, provided they remain within the Company's employment. Director warrants were granted with a vesting period of 48 months. Vested warrants are exercisable over a fixed period from the grant date up to and including November 23, 2026. During the year ended December 31, 2022, a total of 388,017 of these stock options were forfeited.

Additional Executive Plan

Effective September 15, 2019, the Company established an option compensation plan to grant the CEO a right to subscribe a total of two percent of the then outstanding shares of the Company on a fully diluted basis upon completion of twenty-four months of continuous employment. A total of 156,025 options were granted effective September 15, 2021, and became fully vested on that date. The options have been valued at $1,004 with the Black-Scholes model using an expected volatility of 97.88%; expected life of 5 years; risk free interest rate of (0.46%); an expected dividend yield of 0%; and an exercise price of $8.75. Vested warrants are exercisable for a fixed period from September 15, 2021, until November 23, 2026. During the year ended December 31, 2022, 156,025 options were forfeited.

Warrant plan #7

On December 18, 2020, the Board of Directors approved an equity-settled stock option plan which provides an employee and a member of the executive management of the Group with the option to purchase 67,791 common shares of the Company at market price on the date of grant. Warrants were granted with monthly vesting over 36 months until September 1, 2022, respectively October 1, 2023, provided they remain within the Company's employment. During the year ended December 31, 2021, the vesting terms were accelerated and upon the Company's listing on Nasdaq the options of the member of executive management became fully vested. Accordingly, a total of 28,191 options exercisable at $13.30 per share became completely vested as of December 20, 2021. Vested options are exercisable over a fixed period of 10 years from the grant date.

Warrant plan #6

In October 2019, the Board of Directors approved an equity-settled stock option plan which provides board of directors and members of the executive management of the Company the option to purchase 112,764 common shares of the Company at market price on the date of grant. During 2020, a total of 27,017 of the options were forfeited on the termination of a member of executive management. Options were granted with a three-year vesting term, providing non-termination of employment. During the year ended December 31, 2021, the vesting terms were accelerated and upon the Company's listing on Nasdaq the balance of 70,477 of the options exercisable at $12.09 became fully vested as of December 20, 2021. Vested options are exercisable over a fixed period of 10 years from grant date.

15. Share-based payments (cont.)

Warrant plan #5

On February 24, 2017, the Board of Directors approved an equity-settled stock option plan which provides board of directors and members of the executive management of the Group with the option to purchase 13,924 common shares of the Company at market price on the date of grant. Warrants were granted with either immediate vesting, or monthly vesting over 36 months until July 1, 2019, provided the recipient remains within the Group's employment. Vested warrants are exercisable over a fixed period from grant date up to and including July 1, 2021.

Warrant plan #4

On February 18, 2016, the Board of Directors approved an equity-settled stock option plan, which provides key management personnel with the option to purchase 12,676 common shares of the Company at market price on the date of grant. Warrants were granted with monthly vesting over 36 months from July 1, 2016, until July 1, 2019, provided the recipient remains within the Group's employment. Vested warrants are exercisable over a fixed period from grant date up to and including July 1, 2021.

Warrant plan #3

On December 17, 2014, the Board of Directors approved an equity-settled stock option plan, which provides key management personnel with the option to purchase 570,000 common shares of the Company at market price on the date of grant. Warrants were granted with 50% immediately vesting upon grant, 25% vesting on December 17, 2015, and 25% vesting on July 3, 2016, provided the recipient remains within the Group's employment. Vested warrants are exercisable over a fixed period from grant date up to and including July 1, 2021.

Warrant plans #1 - #6 and 2021 Stock Option Plan

Effective July 1, 2021, a total of 45,805 previously issued and outstanding options expired unexercised.

All share-based payment warrants and stock option plans

During the years ended December 31, 2022 and 2021, the total charge to profit or loss amounted to $1,752 and $6,368, respectively of which $1,156 and $4,203, respectively, are recognized as general and administrative expenses and $596 is recognized as research and development expenses. As of December 31, 2022, total unrecognized compensation cost relating to unvested options granted was $1,003 and is expected to be realized over a period of 2.6 years. The Company will issue shares upon exercise of options from shares reserved under the plans.

The table below summarizes the number of options that were outstanding, their weighted average exercise price and contractual term as of December 31, 2022, as well as the movements during the period.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)
Balance on January 1, 2022	1,174,992	$ 6.8	4.91
Granted	46,000	1.2	—
Forfeited	(544,042)	7.3	—
Outstanding as of December 31, 2022	676,949	6.55	4.14
Options exercisable at December 31, 2022	380,119	6.46	4.24

15. Share-based payments (cont.)

A total of 544,042 stock options were forfeited, and no options expired or were exercised in the year ended December 31, 2022. The intrinsic value of all stock options outstanding at December 31, 2022 was $0. The weighted average exercise price for options outstanding at the end of 2022 is $6.55.

The weighted average grant date fair value per share of options granted in 2022 and 2021 was $1.19 and $10.25, respectively. The total fair value of options vested during the years December 31, 2022 and 2021, was $1,328 and $4,223, respectively. The estimate of the grant date fair value of each option issued is based on a Black-Scholes model. The assumptions used in our valuations are summarized as follows:

	For the Years ended December 31,	
	2022	**2021**
Expected volatility	105.85% - 120.22%	80.6% - 97.9%
Weighted average share price	$ 1.19	$ 6.63
Expected life (in years)	5	5 - 9.8
Expected dividend yield	0%	0%
Risk-free interest rate	3.05% - 4.09%	(0.45)% - (0.46)%

Expected Term — The expected term is based upon the historical exercise patterns of options.

Expected Volatility — Was determined based upon the expected term of the options which is based upon the historical exercise patterns of options.

Risk-Free Interest Rate — The risk-free interest rate is based on the 5 years government bond yield rate of Denmark at the date of grant maturities approximately equal to the options' expected term.

Dividend Rate — The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock — The quoted prices of the Company's common stock is used to estimate the fair value of the share-based awards at grant date.

16. License and Development Agreements

(a) License Agreement with Novartis for Dovitinib

We hold the exclusive worldwide rights to all therapeutic and/or diagnostic uses related to cancer in humans for dovitinib from Novartis pursuant to a license agreement. Pursuant to the agreement, we are solely responsible for the development of dovitinib during the term of the agreement.

On September 27, 2022, Allarity Therapeutics Europe Aps ("Allarity Europe"), a wholly-owned subsidiary of the Company, entered into a Second Amendment to License Agreement (the "Second Amendment") with Novartis Pharma AG, a company organized under the laws of Switzerland ("Novartis"), which amended the terms of the License Agreement dated April 6, 2018 (the "Original Agreement"), as amended by that certain First Amendment to License Agreement effective as of March 30, 2022 ("Amendment" and together with the Original Agreement, the "Agreement") and that certain Promissory Note dated April 6, 2018, which was re-issued by Allarity Therapeutics Denmark ApS, a subsidiary of Allarity Europe, in favor of Novartis on March 30, 2022, to modify the terms and timing of the Outstanding Milestone Payment (as defined in the Second Amendment), including an increase in such milestone payment by $500 (paid on or about December 25, 2022), in addition to the $5,000 which is included in accounts payable at September 30, 2022, and originally expensed in the year ended December 31, 2021. The Second Amendment became effective upon receipt by Novartis of the first portion of the Outstanding Milestone Payment ($1,000), which was paid on or about September 28, 2022. As of December 31, 2022, the Company has an outstanding milestone payment of $4 million due to Novartis recorded in accounts payable.

16. License and Development Agreements (cont.)

Under Clause 7.2 of the Original Agreement, the Company agreed to pay Novartis a milestone payment in one lump sum ("Third Milestone Payment") upon submission of the first NDA with the FDA for a Licensed Product in the United States (the "Third Milestone"). The Second Amendment restructured the terms of the Third Milestone Payment to an installment plan (with the final installment due in 2023), allowing the Company more time to make the Third Milestone Payment.

In addition, the Second Amendment amended (1) Clause 1.1 of the Agreement to include the definitions of Financing Transaction, Phase 1 Clinical Trial and Phase 1b/2 Clinical Trial, (2) Clause 2.1 of the Agreement to clarify that the Company would not be permitted to sublicense any rights granted to the Company prior to completion of a Phase II Clinical Trial without the prior written consent of Novartis, and (3) Clause 7.3 to provide for the acceleration of certain milestone payments in the event the Company enters into a Financing Transaction (as defined in the Second Amendment). If all milestones under the Second Amendment are achieved, the Company may be obligated to pay Novartis up to a maximum of $26,500.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Novartis in connection with the development of dovitinib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the dovitinib development program from us corresponding to: (i) upon enrollment of half of the patients required in a Phase 2 clinical trials in certain countries in accordance with agreed upon protocols; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA or any other Regulatory Authority in certain countries; (v) upon receipt of the first authorization by the FDA to market and sell a licensed product; and (vi) upon receipt of a MAA (including a respective pricing and reimbursement approval) for a licensed product in one or more specified European countries.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Novartis royalties based on annual incremental sales of product derived from dovitinib in an amount between 5% and 10% of annual sales of between $0 and $250 million, between 6% and 13% of annual sales between $250 million and $500 million, between 7% and 13% of annual sales between $500 million and $750 million, and between 13% and 15% of annual sales in excess of $750 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the 10 year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Novartis that is not cured within 30 days. Novartis also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 30 days or if we file for bankruptcy.

(b) License Agreement with Eisai for Stenoparib

We hold the exclusive worldwide rights to all preventative, therapeutic and/or diagnostic uses related to cancer in humans and by amendment to the agreement on December 11, 2020, viral infections in humans (including, but not limited to, coronaviruses) for stenoparib from Eisai, Inc. ("Eisai") pursuant to a license agreement. Pursuant to the license agreement, we are solely responsible for the development of stenoparib during the term of the agreement. The agreement also provides for a joint development committee consisting of six members, three appointed by us and three appointed by Eisai. One of our members of the joint development committee is designated chair of the committee and has the power to break any deadlock in decisions by the committee that must be made by a majority vote with each representative having one vote. The purpose of the committee is to implement and oversee development activities for stenoparib pursuant to the clinical development plan, serving as a forum for exchanging data, information and development strategy.

16. License and Development Agreements (cont.)

Effective July 12, 2022, the Company's July 6, 2017 Exclusive License Agreement with Eisai Inc. (the "Third Amendment"), the terms of the original exclusive license were further amended in order to (1) further postpone the due date of the Extension Payment and extend the deadline for the Company's successful completion of its first Phase 1b or Phase 2 clinical trial for Stenoparib (the "Product") beyond December 31, 2022; and (2) amend terms related to Eisai's right of termination of development.

In consideration of the extended timeframe, and the Company not achieving the minimum patient enrollment, by July 1, 2022, set out in the Second Amendment, the Company is obligated to pay Eisai an extension payment as follows:

(i) $100 within 10 days of the execution of the Third Amendment (paid during the period ended September 30, 2022); and

(ii) $900 on or before April 1, 2023 (recognized as a milestone expense in the year ended December 31, 2022, and recorded as an accrued development cost liability at December 31, 2022).

Once the extension payment is paid in full, the Company shall have until April 1, 2024, to complete enrollment in a further Phase 1b or Phase 2 Clinical Trial of the Product. If the Company has not achieved successful completion of a further Phase 1b or Phase 2 Clinical Trial of the Product prior to April 1, 2024, Eisai may terminate this Agreement in its entirety, in its sole discretion on at least 120 days prior written notice.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Eisai in connection with the development of stenoparib by us or our affiliates, or by a third-party Program Acquirer that assumes control of the stenoparib development program from us corresponding to: (i) successful completion of a Phase 2 clinical trial; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA; (v) submission of an NDA to the MHLW in Japan; (vi) upon receipt of authorization by the FDA to market and sell a licensed product; (vii) upon receipt of approval of an MAA by the EMA for a licensed product; and (viii) upon receipt of approval by the MHLW in Japan for a licensed product. If all milestones have been achieved, we may be obligated to pay Eisai up to a maximum of $94 million. In addition, we have agreed to pay Eisai a one-time sales milestone payment in the amount of $50 million the first time our annual sales of licensed product is $1 billion or more.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of product derived from stenoparib in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 10% of annual sales between $100 million and $250 million, between 7% and 11% of annual sales between $250 million and $500 million, and between 11% and 15% of annual sales in excess of $500 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the 15 year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be terminated sooner without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Eisai that is not cured within 90 days (30 days for a payment default). Eisai also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. By an amendment effective as of August 3, 2021, and executed by Eisai on August 23, 2021, Eisai also has the right to terminate the agreement if we do not complete a Phase 2 clinical trial before December 31, 2022, unless we elect to pay a $1,000 (one million dollar) extension payment ("Extension Payment"). Notwithstanding the foregoing, in the event we fail to enroll and dose at least 30 patients with the first dose of cancer drug in the ongoing Phase 2 Ovarian Cancer Clinical Trial by July 1, 2022, then the Extension Payment will be due and payable in fully by July 30, 2022. In addition, if we fail to achieve successful completion of first Phase 2 Clinical Trial prior to December 31, 2022, and do not elect to pay the Extension Payment then Eisai may terminate the agreement in its sole discretion pursuant to the terms of the amendment.

16. License and Development Agreements (cont.)

Option to Reacquire Rights to Stenoparib

For the period commencing with enrollment of the first five patients in a Phase 2 clinical trial pursuant to the clinical development plan and ending 90 days following successful completion of such Phase 2 clinical trial, Eisai has the option to reacquire our licensed rights to develop stenoparib for a purchase price equal to the fair market value of our rights, giving effect to the stage of development of stenoparib that we have completed under the agreement. We commenced a Phase 2 clinical trial April 15, 2019, and as of the date of these consolidated financial statements, Eisai has not indicated an intention to exercise its repurchase option.

(c) Development, Option and License Agreement with R-Pharm for IXEMPRA®

On March 1, 2019, the Company entered into an option to in-license the rights to any and all therapeutic and/or diagnostic uses in humans for IXEMPRA® in the European Union (Great Britain but excluding Switzerland and Lichtenstein) (the "Territory") from R-Pharm U.S. Operating, LLC ("R-Pharm"), pursuant to a Development, Option and License Agreement (the "Option"). By an amendment to the agreement dated August 4, 2022, for no consideration, the term of the option will expire on September 1, 2023, if not exercised by us before then. The agreement provides a right of extension, should we elect, for an additional $250 thousand. As a condition to the exercise of the Option, we are required to offer R-Pharm a right to re-acquire the licensed rights from us on terms to be mutually agreed upon, including the payment to us of the fair market value of the licensed rights. Pursuant to the Option, we are solely responsible for the development of IXEMPRA® during the term of the Option within the Territory. The agreement also provides for a joint development committee consisting of four members, two appointed by us and two appointed by R-Pharm. Decisions by the committee that must be made by a unanimous consent of the parties, with us having the tie breaking vote on matters involving our DRP Biomarker, patient selection in the mBC clinical trial and the commercialization plan and R-Pharm having the tie breaking vote on all other matters. The purpose of the committee is to implement and oversee development activities for IXEMPRA® pursuant to the clinical development plan, serves as a forum for exchanging data, information, and development strategy.

Development Milestone Payments

Pursuant to the agreement, once we have exercised the Option, we have agreed to make milestone payments to R-Pharm in connection with the development of IXEMPRA® by us or our affiliates, or by a third-party Program Acquirer that assumes control of the IXEMPRA® development program from us corresponding to: (i) upon receipt of regulatory approval for the Product for the treatment of the first indication in the first country in the Territory; and (ii) upon receipt of regulatory approval for the Product for the treatment of each additional indication in the first country in the Territory for each such additional indication. If all milestones have been achieved, and assuming only one additional indication in the second milestone is achieved, we may be obligated to pay R-Pharm up to a maximum of $12.5 million.

Royalty Payments

In addition to the milestone payments described above, once we have exercised the Option, we have agreed to pay R-Pharm royalties based on annual incremental sales of product derived from IXEMPRA® in an amount between 5% and 8% of annual sales of between $0 and $30 million, and between 8% and 12% of annual sales over $30 million.

After the Option is exercised, we would be obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the seven year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 90 days prior written notice, or upon written notice of a material breach of the agreement by R-Pharm that is not cured within 90 days (30 days for a payment default). R-Pharm also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy.

16. License and Development Agreements (cont.)

(d) Development costs and Out-License Agreement with Smerud

In June of 2020 (the "June 2020 Out-License Agreement"), as amended March 28, 2022 (the "Amended License Agreement"), the Company out-licensed its secondary LiPlaCis® and 2X-111 programs to Smerud Medical Research International, the Company's long-time CRO partner in Europe, for further Phase 2 clinical development of each program together with its DRP® companion diagnostic. Pursuant to the terms of the Amended License Agreement, Chosa ApS, a company organized under the laws of Denmark ("Chosa"), replaced us as the exclusive licensee to the LiPlaCis® technology. In addition, we also granted Chosa an exclusive, royalty-free, transferable and sublicensable license for (i) our DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® (a liposomal formulation of Cisplatin) for the research and development of LiPlaCis® products, and (ii) the use of any and all know-how and intellectual property rights owned by us for Chosa's use of our DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® (a liposomal formulation of Cisplatin) for the development and commercialization of LiPlaCis® products, as contemplated in the Amended License Agreement.

LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome

On March 28, 2022, concurrent with the entry into the Amended License Agreement, we entered into the LiPlaCis Support Agreement with Allarity Europe, Smerud, Chosa and LiPlasome (the "Support Agreement"). Pursuant to the terms of the Support Agreement, we agreed (i) to pay to LiPlasome a certain percentage of the Commercialization Proceeds received from Smerud by way of debt cancellation relating to prior work on LiPlaCis® by Smerud, which obligation was to be satisfied by the payment of USD $338 (2,273 thousand DKK) to LiPlasome upon execution of the Support Agreement, (ii) to equally share the milestone payments under the terms of the License Agreement, pursuant to which it was contemplated that upon the achievement of all the milestones, our pro rata share of the Milestone Payments would be up to $3.5 million, (iii) to amend and restate the Original License Agreement, and (iv) to terminate the 2020 Sublicense Agreement as contemplated by the parties pursuant to the terms of the Support Agreement.

Development costs

Under the terms of the June 2020 Sublicense agreement (the "2020 Sublicense Agreement") between the Company and Smerud Medical Research International AS (Norway) ("Smerud"), the Company is liable for development costs incurred by Smerud in the approximate amount of $1,264, which has been accrued as of December 31, 2021, as payable to Smerud. However, effective March 28, 2022, the Company terminated its LiPlasome rights through the following agreements:

A Letter Agreement between Chosa Oncology Ltd. (England), Chosa ApS (Denmark) (collectively "Chosa"), Smerud, and the Company, which references the following agreements:

Development costs

a. The 2022 Amended and Restated License Agreement between LiPlasome Pharma Aps (Denmark) ("LiPlasome"), Chosa, and the Company's subsidiary Allarity Therapeutics ApS, which amended the original February 15, 2016 LiPlasome License Agreement (as amended January 27, 2021), whereby Chosa replaced the Company as licensee of LiPlasome in exchange for Smerud's cancellation of the Company's $1,309 liability to Smerud and the Company's agreement to pay $338 to LiPlasome. Consequently, in 2022, the Company recorded a balance due to LiPlasome of $338 in accrued liabilities (paid on April 1, 2022) and recorded other income of $971 which was recognized as a gain on sale of IP.

b. The LiPlacis Support Agreement between Allarity Therapeutics Europe, Smerud, Chosa and LiPlasome. Terms of the Support Agreement provide that each of Smerud and the Company agreed that the 2022 Sublicense Agreement is terminated in its entirety.

16. License and Development Agreements (cont.)

(e) Oncoheroes

Effective January 2, 2022, the Company entered into an Exclusive License Agreement with Oncoheroes Biosciences Inc. (the "Oncoheroes Agreement") to grant Oncoheroes an exclusive royalty-bearing global license to both dovitinib and stenoparib in pediatric cancers. Oncoheroes will take responsibility for pediatric cancer clinical development activities for both clinical-stage therapeutics. The Company will support Oncoheroes' pediatric clinical trials by providing clinical-grade drug inventory at cost and by facilitating DRP® companion diagnostic screening of pediatric patients for each drug. Under the licenses, Oncoheroes will receive commercialization rights for pediatric cancers, subject to the Company's first buy-back option for each program, and the Company will receive an upfront license fee and regulatory milestones for each program, specifically one for dovitinib and one for stenoparib, as follows:

i. A one-time upfront payment of $250 and $100 for stenoparib and dovitinib respectively, within 5 business days after January 2, 2022 ($350 received as of April 4, 2022) and recorded in other income as a gain on sale of IP; and

ii. two milestone payments of $1 million each due and payable upon receipt of regulatory approval of a product in the United States, and of a product in Europe, respectively.

Pursuant to the Oncoheroes Agreement the Company is also entitled to tiered royalties on aggregate net product sales ("Sales") of between 7% and 12% on net sales of products as follows: 7% on Sales less than $100 million; 10% on Sales of greater than $100 million and less than $200 million; and 12% on Sales greater than $200 million.

(f) Lantern Pharma, Inc. – Irofulven Agreement

On July 23, 2021, we entered into an Asset Purchase Agreement with Lantern Pharma, Inc. relating to our inventory of Irofulven active pharmaceutical ingredients, our clinical research data relating to Irofulven developed by us during the drug development program under the May 2015 Drug License and Development Agreement for Irofulven and terminated our obligation to further advance the development of Irofulven under the May 2015 agreement. Under the Asset Purchase Agreement, Lantern Pharma agreed to pay us $1 million on closing of the transaction, and additional amounts:

(i) when the inventory of Irofulven API is recertified with a longer shelf life;

(ii) upon the initiation of treatment of the first patient in an investigator-led "compassionate use" ERCC2/3 mutation subgroup study using Irofulven in certain agreed upon investigators;

(iii) upon the initiation of treatment of the first patient within twenty-four months after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma; and

(iv) upon the initiation of treatment of the second patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma.

In addition to the sale of our inventory of Irofulven API and Data to Lantern Pharma, we also granted Lantern Pharma a non-exclusive, worldwide license to use our putative Irofulven DRP® companion diagnostic to advance the development and commercialization of Irofulven and other Illudins (sesquiterpenes with anti-tumor properties produced by some mushrooms). We have also agreed not to engage in any drug development program for Illudins or any of its analogues or any use thereof for a period of five years.

Effective March 18, 2022, pursuant to clause (i) the inventory was recertified with a longer shelf life and as of March 31, 2022, and we received $459 which was recorded in other income as a gain on sale of IP.

17. Tax

The reconciliation of the statutory rate to the effective tax rate is as follows:

Reconciliation of effective tax rate:	**2022**	**2021**
Tax computed on the loss before tax at a tax rate of 21.0% for the years ended December 31, 2022 and 2021	$ (3,692)	$ (5,568)
Foreign rate differential	(260)	(210)
Non-deductible expenses, share-based payments	—	523
Non-deductible expenses, other	1	905
Tax value of derivative warrants	(3,597)	(438)
Special tax deduction on research and development expenses	(754)	(464)
Loss offset to research and development incentive	609	682
Other adjustments	1	60
Adjustment of tax concerning previous years	(871)	134
Change in valuation allowance	7,044	4,322
Transaction costs	—	187
Effective tax rate	$ (1,521)	$ 133

The components of net loss before income taxes were as follows:

	Year ended December 31,	
	2022	**2021**
Denmark	$ (25,336)	$ (21,250)
Sweden	(3)	(11)
United States	7,760	(5,254)
	$ (17,579)	$ (26,515)

The components of the provision for income taxes from operations were as follows:

	Year ended December 31,	
	2022	**2021**
Current:		
Denmark	$ —	$ —
Sweden	—	44
United States	—	69
Total	—	113
Deferred:		
Denmark	(1,521)	20
Sweden	—	—
United States	—	—
Total	(1,521)	20
	$ (1,521)	$ 133

17. Tax (cont.)

Deferred tax comprises:	**2022**	**2021**
Property, plant and equipment	$ 20	$ 21
Intangible assets	(1,160)	(5,198)
Stock compensation	1,152	815
Other accruals	(44)	(47)
Net operating losses	12,981	9,095
Total deferred tax	12,949	4,686
Valuation allowance	(13,298)	(6,647)
Net deferred tax liabilities	$ (349)	$ (1,961)

Tax on profit/loss for the year:	**2022**	**2021**
Current income tax (benefit) expense	$ —	$ 88
Change in deferred tax	(1,521)	20
Adjustment of tax concerning previous years	—	25
Tax (benefit) expense	$ (1,521)	$ 133

Tax losses carried forward of approximately $59.6 million can be carried forward indefinitely. Deferred tax has been provided corresponding to the statutory tax rate applied.

The statute of limitations for re-assessment of tax returns in Denmark is three years and five years for transfer pricing. As of December 31, 2022, the tax years that remain subject to examination by the major tax jurisdictions, under the statute of limitations, are from the year ended December 31, 2017, forward. The Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities.

18. Related parties

During the year ended December 31, 2022, a Director of the Company was paid $269 in fees as a consultant. During the year ended December 31, 2021, a member of the Company's Board of Directors participated in the June 2021 rights offering and purchased a total of 11,336 shares for $84 and a consultant was paid a total of $93 in fees.

19. Basic and diluted net loss per share

Basic and diluted net loss per share attributable to common shareholders was as follows:

	Years Ended December 31,	
	2022	**2021**
Numerator:		
Net loss attributable to common shareholders	$ (21,052)	$ (26,648)
Denominator:		
Weighted average common shares outstanding – basic and diluted	9,527,111	6,358,988
Net loss per share attributable to common shareholders – basic and diluted	$ (2.21)	$ (4.19)

The Company's potentially dilutive securities, which include warrants and shares issuable upon conversion of convertible debt, have been excluded from the computation of diluted net loss per share attributable to common shareholders as the effect would be to reduce the net loss per share attributable to common shareholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

19. Basic and diluted net loss per share (cont.)

	As of December 31,	
	2022	2021
Warrants and stock options	2,695,907	3,193,950
Series A Convertible Preferred stock	7,406,057	1,997,982
Convertible debt*	9,071,430	—
	19,173,394	5,191,932

* Estimated based on $2,667 at $0.1825 per share.

20. Financial Instruments

The following tables present information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of December 31, 2022, Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	$ —	$ —	$ (374)	$ (374)
	$ —	$ —	$ (374)	$ (374)

	Fair Value Measurements as of December 31, 2021, Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Investment	$ 350	$ —	$ —	$ 350
Liabilities:				
Warrant liability	$ —	$ —	$ (11,273)	$ (11,273)
Series A Convertible Preferred Stock Redemption Feature	—	—	(7,181)	(7,181)
	$ —	$ —	$ (18,454)	$ (18,454)

Methods used to estimate the fair values of our financial instruments, not disclosed elsewhere in these consolidated financial statements, are as follows:

When available, our marketable securities are valued using quoted prices for identical instruments in active markets. If we are unable to value our marketable securities using quoted prices for identical instruments in active markets, we value our investments using broker reports that utilize quoted market prices for comparable instruments. Accordingly, our investment is considered a Level 1 financial asset. We have no financial assets or liabilities measured using Level 2 inputs. Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable.

The Company recognizes its derivative liabilities as level 3 and values its derivatives using the methods discussed below. While the Company believes that its valuation methods are appropriate and consistent with other market participants, it recognizes that the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date. The primary assumptions that would significantly affect the fair values using terms in the notes that are subject to volatility and market price of the underlying common stock of the Company.

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company's policy is to recognize transfers into and out of levels within the fair value hierarchy at the date the actual event or change in circumstances that caused the transfer occurs. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. There were no transfers between level 1 or level 2 during the years ended December 31, 2022 or 2021.

20. Financial Instruments (cont.)

During the years ended December 31, 2022 and 2021, the Company used Monte Carlo simulation models to measure the fair value of the Series A Preferred Stock redemption feature at $0 and $7,181, respectively. During the year ended December 31, 2022, the Company utilized the reset strike options Type 2 model by Espen Garder Haug and Black-Scholes Merton models to measure the fair value of the warrant liability at $374. On December 31, 2021, the Company used the Black-Scholes Merton model to measure the fair value of the warrant liability at $11,273. All changes in fair value were recorded in the Consolidated Statements of Operation and Comprehensive Loss during the corresponding period. Fluctuations in the Company's stock price are a primary driver for the changes in the derivative valuations during each reporting period. During the years ended December 31, 2022 and 2021, the Company's stock price decreased from its initial valuation. As the stock price decreases for each of the related derivative instruments, the value to the holder of the instrument generally decreases. Stock price is one of the significant unobservable inputs used in the fair value measurement of each of the Company's derivative instruments.

21. Commitments and Contingencies

License Agreement with 2-BBB Medicines B.V. for Stenoparib ("2X-111")

On March 27, 2017, we in-licensed the exclusive worldwide rights to the central nervous system ("CNS") and/or cerebrocardiovascular drug application, including the (preventive) treatment of peripheral effects of agents causing CNS disease or symptoms, including cancer, for 2X-111 from 2-BBB Medicines B.V. ("2-BBB") pursuant to a license agreement. Upon execution of the agreement, we paid 2-BBB a one-time, non-refundable, non-creditable payment of $500. Pursuant to the agreement, we are solely responsible for the development of 2X-111 during the term of the agreement.

Development and Sales Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to 2-BBB in connection with the development of 2X-111 by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the 2X-111 development program from us corresponding to: (i) upon enrollment of the first ten patients required in a Phase 2 clinical trial; (ii) upon the successful completion of a Phase 2 clinical trial; (iii) upon dosing of the first patient in the first Phase 3 clinical trial; (iv) upon submission of the first NDA with the FDA; (v) submission of an MAA to the EMA in the European Union; (vi) upon submission of an NDA in the first of either China or India; (vii) upon receipt of the first authorization by the FDA to market and sell a licensed product; (viii) upon receipt of a MAA for a licensed product in the European Union; and (ix) upon receipt of regulatory approval in the first of either China or India. If all development milestones have been achieved, we may be obligated to pay 2-BBB up to a maximum of $27.75 million which could increase to $55.5 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans. In addition to the development milestones described above, we have agreed to make a mid-level seven figure one-time payment upon our sales of a licensed product reaching $500 million annually and a low eight figure payment upon the first and second time our sales of a licensed product reaches $1 Billion annual. If all sales milestones have been achieved, we would be obligated to pay 2-BBB up to a maximum of $22.5 million which could increase to $45 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans.

21. Commitments and Contingencies (cont.)

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay 2-BBB royalties based on annual incremental sales of product derived from 2X-111 in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 13% of annual sales between $100 million and $250 million, and between 7% and 13% of annual sales in excess of $250 million. We are obligated to pay royalties under the agreement on a product-by-product and country-by-country basis, from the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) the 2-BBB intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual property arose from activities under the clinical development plan), or (b) the 10th anniversary of the date of first commercial sale of such product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by 2-BBB that is not cured within 90 days. 2-BBB also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. 2-BBB also has the right to terminate the agreement in the event we challenge a 2-BBB patent and we have the right to terminate the agreement upon 30 days' notice for specified safety reasons.

22. Subsequent Events

(a) Redemption of Series B Preferred Stock

Upon conclusion of the 2023 Annual Meeting of Stockholders on February 3, 2023, all of the 190,786 shares of Series B Preferred Stock outstanding were automatically redeemed, with the holders of the Series B Preferred Stock only having a right to receive the purchase price for the redemption, which was $0.01 per share of Series B Preferred Stock.

(b) Series A Preferred Stock Conversions

Subsequent to December 31, 2022, pursuant to the exercise of conversion by the 3i, we issued 14,102,155 shares of Common Stock to the 3i upon the conversion of 2,936 shares of Series A Preferred Stock based on a conversion price ranging from $0.18 to $0.26. No proceeds were received by the Company upon such conversion. As of the date of these financial statements, we had 10,650 shares of Series A Preferred Stock issued and outstanding. As of the date of this report, we have no shares of common stock available for issuance.

(c) Modification to Conversion Price of Series A Preferred Stock

On January 23, 2023, the Company and 3i, LP amended the letter agreement entered into on December 9, 2022, to provide that the modification of the term Conversion Price (as defined therein) will be in effect until terminated by the Company and 3i, LP.

(d) Request for documents from the SEC

In January 2023, the Company received a letter to produce documents from the SEC and that stated that the staff of the SEC is conducting an investigation known as "In the Matter of Allarity Therapeutics, Inc." to determine if violations of the federal securities laws have occurred. The documents requested appear to focus on disclosures relating to submissions, communications and meetings with the FDA regarding our NDA for Dovitinib or Dovitinib-DRP. The SEC letter also stated that investigation is a fact-finding inquiry and does not mean that that the SEC has concluded that the Company or anyone else has violated the laws. We do not know when the SEC's investigation will be concluded or what action, if any, might be taken in the future by the SEC or its staff as a result of the matters that are the subject to its investigation or what impact, if any, the cost of continuing to respond to inquiries might have on our financial position or results of operations.

(e) Establishment and sale of Series C Preferred Stock

On February 24, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock (the "Series C COD") with the Delaware Secretary of State designating 50,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock with a stated value of $27.00 per share. On February 28, 2023, the Company filed a Certificate of Amendment to the Series C COD (the "COD Amendment") to clarify the terms of conversion price and floor price based on definitions provided in the Series C COD (the COD Amendment, together with the Series C COD, the "COD"). Each share of Series C Preferred Stock has 620 votes and is subject to certain redemption rights and voting limitations.

On February 28, 2023, the Company entered into a Securities Purchase Agreement (the "SPA") with 3i, L.P. for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock ("Series C Preferred Stock") at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million (the "Offering"). The 50,000 shares of Series C Preferred Stock (the "Shares") are convertible into shares of the Company's common stock, subject to the terms of the COD. The conversion price for the Series C Preferred Stock is initially equal the lower of: (i) $0.182, which is the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day (as defined in the COD) immediately preceding the Original Issuance Date (as defined in the COD); and (ii) the lower of: (x) the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Conversion Date or such other date of determination; and (y) the average of the official closing prices of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) for the five Trading Days immediately preceding the Conversion Date (as defined in the COD) or such other date of determination, subject to adjustment (the "Conversion Price"). In no event will the Conversion Price be less than $0.0370 (the "Floor Price"). In the event that the Conversion Price on a Conversion Date would have been less than the applicable Floor Price if not for the immediately preceding sentence, then on any such Conversion Date the Company will pay the Holder an amount in cash, to be delivered by wire transfer out of funds legally and immediately available therefor pursuant to wire instructions delivered to the Company by the Holder in writing, equal to the product obtained by multiplying (A) the higher of (I) the highest price that the Common Stock trades at on the Trading Day immediately preceding such Conversion Date and (II) the applicable Conversion Price and (B) the difference obtained by subtracting (I) the number of shares of Common Stock delivered (or to be delivered) to the Holder on the applicable Share Delivery Date with respect to such conversion of Series C Preferred Stock from (II) the quotient obtained by dividing (x) the applicable Conversion Amount that the Holder has elected to be the subject of the applicable conversion of Series C Preferred Stock, by (y) the applicable Conversion Price without giving effect to clause (x) of such definition. The Offering closed on February 28, 2023.

In connection with the Offering, concurrently with the SPA, the Company entered into a registration rights agreement with 3i (the "RRA") pursuant to which the Company is required to file a registration statement with the Securities and Exchange Commission (the "SEC") to register for resale the shares of Common Stock that are issued upon the potential conversion of the Shares. Under the terms of the RRA, if the Company fails to file an Initial Registration Statement (as defined in the RRA) on or prior to its Filing Date (as defined in the RRA), or fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments, in cash and as partial liquidated damages and not as a penalty, equal to 2.0% of 3i's subscription amount of the Shares pursuant to the SPA. In addition, if we fail to pay any partial liquidated damages in full within seven days after the date payment, we will have to pay interest at a rate of 18.0% per annum, accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The Company has also agreed to pay all fees and expenses incident to the performance of the RRA, except for any broker or similar commissions. In connection with the Offering, the Company and 3i entered into a limited waiver agreement (the "Waiver") pursuant to which 3i confirmed that the sale and issuance of the Shares will not give rise to any, or trigger any, rights of termination, defaults, amendment, anti-dilution or similar adjustments, acceleration or cancellation under agreements with 3i.

(f) Special Meeting of Stockholders

Pursuant to a proxy statement filed with the SEC on or about March 6, 2023 (the "Proxy Statement"), the Company will be holding a Special Meeting of Stockholders (the "Special Meeting") virtually online on March 20, 2023, or as otherwise set forth in the Company's notice and proxy statement for the Special Meeting. Stockholders of record of our outstanding shares of Common Stock and Series C Preferred Stock on March 3, 2023 (the "Record Date") will be entitled to notice of, and to vote at, the Special Meeting and any adjournments, continuations or postponements thereof that may take place At the Special Meeting, the stockholders of Common Stock and Series C Preferred Stock will be voting on the following proposals: (1) to approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares from 30,500,000 to 750,500,000, and to increase the number of our common stock from 30,000,000 to 750,000,000, in substantially the form attached to the Proxy Statement as Appendix A (the "Share Increase Proposal"); and (2) to approve an amendment to our Certificate of Incorporation, as amended, in substantially the form attached to the Proxy Statement as Appendix B, to, at the discretion of the Board of Directors of the Company (the "Board"), effect a reverse stock split with respect to the Company's issued and outstanding common stock, par value $0.0001 per share, at a ratio between 1-for-20 and 1-for-35 (the "Range"), with the ratio within such Range to be determined at the discretion of the Board (the "Reverse Stock Split Proposal") and included in a public announcement. Under the terms of the Series C Preferred Stock, the holders thereof may only vote on Proposal 1 (Share Increase Proposal) and Proposal 2 (Reverse Stock Split Proposal) and for no other matters. Each holder of one share of Series C Preferred Stock is entitled to 620 votes representing 31,000,000 votes in the aggregate assuming 50,000 shares of Series C Preferred Stock is outstanding.

Exhibit 4(vi)

DESCRIPTION OF OUR CAPITAL STOCK

The following description of the material terms of our capital stock. We urge you to read the applicable provisions of Delaware General Corporation Law ("DGCL", our Certificate of Incorporation, as amended, Certificate of Designation for Series A Convertible Preferred Stock, Certificate of Designation for Series B Preferred Stock, Certificate of Designation for Series C Convertible Redeemable Series C Preferred Stock, and bylaws carefully and in their entirety because they describe your rights as a holder of shares of our capital stock.

General

Our purpose is to engage in any lawful act or activity for which corporations may now or hereafter be organized under the DGCL. Our Certificate of Incorporation, as amended, authorizes capital stock consisting of 30,000,000 shares of common stock, par value $0.0001 per share, and 500,000 shares of preferred stock, par value $0.0001 per share, of which 20,000 shares of preferred stock has been designated Series A Convertible Preferred Stock ("Series A Preferred Stock"), 200,000 shares of preferred stock has been designated as Series B Preferred Stock ("Series B Preferred Stock"), and 50,000 shares of preferred stock has been designated as Series C Convertible Redeemable Preferred Stock ("Series C Preferred Stock").

On December 20, 2021, 20,000 shares of preferred stock, designated Series A Preferred Stock, were sold and issued to 3i, LP, along with a common stock purchase warrant for 2,018,958 shares of common stock.

On November 22, 2022, the Board of Directors declared a dividend of Series B Preferred Stock to the stockholders of record of common stock and Series A Preferred Stock as of December 5, 2022 (the "Record Date"). On the Record Date, each share of common stock outstanding received 0.016 of a share of Series B Preferred Stock and each share of Series A Preferred Stock outstanding received 1.744 shares of Series B Preferred Stock. We issued an aggregate of 190,786.42 shares of Series B Preferred Stock, which were redeemed on February 3, 2023.

On February 28, 2023, we entered into a Securities Purchase Agreement (the "SPA") with 3i, LP for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock, par value of $0.0001 per share (the "Series C Preferred Stock"), at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million. The 50,000 shares of Series C Preferred Stock (the are convertible into shares of the Company's common stock, $0.0001 per share subject to the terms of the Series C COD (as defined below).

As of March 3, 2023, we had 30,000,000 shares of common stock, 10,650 shares of Series A Preferred Stock, and 50,000 shares of Series C Preferred Stock issued and outstanding.

Common Stock

Holders of our common stock, or Common Stock, are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders, including the election or removal of directors, except for any directors who are elected exclusively by the holders of a class of our preferred stock that entitles that class of stock to elect one or more directors. The holders of our common stock do not have cumulative voting rights in the election of directors.

Upon our liquidation, dissolution or winding up and after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of our common stock (and the holders of any preferred stock that may then be outstanding, to the extent required by our Certificate of Incorporation, including any certificate of designation with respect to any series of preferred stock) will be entitled to receive pro rata our remaining assets available for distribution, unless holders of a majority of the outstanding shares of common stock approve a different treatment of the shares. Holders of our common stock do not have preemptive, subscription, redemption or conversion rights. Our common stock will not be subject to further calls or assessment by us. There will be no redemption or sinking fund provisions applicable to our common stock. All shares of our common stock that will be outstanding at the effective time will be fully paid and non-assessable. The rights, powers, preferences and privileges of holders of our common stock will be subject to those of the holders of our Series A Preferred Stock and any other shares of preferred stock we may authorize and issue in the future.

Preferred Stock

Our Certificate of Incorporation authorizes our Board of Directors to establish one or more series of preferred stock (including convertible preferred stock). Unless required under the Certificate of Incorporation, or by law or Nasdaq, the authorized shares of preferred stock will be available for issuance without further action by stockholders. Our Board of Directors may determine, with respect to any series of preferred stock, the powers including preferences and relative participations, optional or other special rights, and the qualifications, limitations or restrictions thereof, of that series, including, without limitation:

- the designation of the series;
- the number of shares of the series, which our Board of Directors may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of our affairs;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of ours or any other corporation, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible and all other terms and conditions upon which the conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series; and
- the voting rights, if any, of the holders of the series.

We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our common stock might believe to be in their best interests or in which the holders of our common stock might receive a premium for your common stock over the market price of the common stock. Additionally, the issuance of preferred stock may adversely affect the rights of holders of our common stock by restricting dividends on our common stock, diluting the voting power of our common stock or subordinating the liquidation rights of our common stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our common stock.

Series A Convertible Preferred Stock

On December 8, 2021, the Board adopted resolutions to create a series of twenty thousand (20,000) shares of preferred stock, par value $0.0001, designated as “Series A Convertible Preferred Stock.” On December 14, 2021, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock setting forth the rights, preferences, privileges and restrictions for 20,000 shares of Series A Convertible Preferred Stock (the “Series A COD”).

Except to the extent that the holders of at least a majority of the outstanding Series A Preferred Stock (the "Required Holders") expressly consent to the creation of Parity Stock (as defined below) or Senior Preferred Stock (as defined below), all shares of capital stock are junior in rank to all Series A Preferred Stock with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company (such junior stock is referred to herein collectively as "Junior Stock"). The rights of all such shares of capital stock of the Company will be subject to the rights, powers, preferences and privileges of the Series A Preferred Stock. Without limiting any other provision of the Series A COD, without the prior express consent of the Required Holders, voting separate as a single class, the Company will not hereafter authorize or issue any additional or other shares of capital stock that is (i) of senior rank to the Series A Preferred Stock in respect of the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company (collectively, the "Senior Preferred Stock"), (ii) of pari passu rank to the Series A Preferred Stock in respect of the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company (collectively, the "Parity Stock") or (iii) any Junior Stock having a maturity date or any other date requiring redemption or repayment of such shares of Junior Stock that is prior to the first anniversary of the Initial Issuance Date. In the event of the merger or consolidation of the Company with or into another corporation, the Series A Preferred Stock will maintain their relative rights, powers, designations, privileges and preferences provided for herein and no such merger or consolidation will result inconsistent therewith.

The Series A Preferred Stock has a liquidation preference equal to an amount per Series A Preferred Stock equal to the sum of (i) the Black Scholes Value (as defined in the Warrants, which was sold concurrent with the Series A Preferred Stock) with respect to the outstanding portion of all Warrants held by such holder (without regard to any limitations on the exercise thereof) as of the date of such event and (ii) the greater of (A) 125% of the Conversion Amount of such Series A Preferred Stock on the date of such payment and (B) the amount per share such holder would receive if such holder converted such Series A Preferred Stock into common stock immediately prior to the date of such payment, and will be entitled to convert into shares of common stock at an initial fixed conversion price of $9.9061 per share, subject to a beneficial ownership limitation of 9.99%.

Under the terms of the Series A COD, the initial fixed conversion price of the Series A Preferred Stock is $9.9061, subject to adjustment. In the event that (i) the average of the VWAP of the Company's shares for each of the five (5) trading days immediately preceding the date of delivery is less than the fixed conversion price of $9.9061 (a "Price Failure"), or (ii) the sum of (x) the aggregate daily dollar trading volume (as reported on Bloomberg) of our common stock on Nasdaq during the ten (10) trading day period ending on the trading day immediately preceding such date of determination, divided by (y) ten (10), is less than $1,500,000 (a "Volume Maximum Failure"), each share of Series A Preferred Stock is entitled to convert at a price equal to 90% of the sum of the two (2) lowest VWAPs during the ten (10) trading day period immediately preceding the date of delivery divided by two (2) (the "90% Conversion Price"), but not less than the Floor Price (as defined in the Series A COD), or, at the time of such Price Failure or Volume Maximum Failure, the sum of the average daily U.S. Dollar volume for our common stock during the ten (10) days previous to conversion divided by ten (10) is less than $2 million then each share of Series A Preferred Stock is entitled to convert at the lower of the fixed conversion price or a price equal to 80% of the sum of the two (2) lowest VWAPs during the ten (10) trading day period immediately preceding delivery divided by two (2) (the "80% Conversion Price"), but not less than the Floor Price (such 80% Conversion Price or 90% Conversion Price, as the case may be, the "Alternate Conversion Price").

Simultaneously with the closing of our Recapitalization Share Exchange, we closed on the PIPE Financing pursuant to the SPA. On December 20, 2021, we issued 20,000 shares of Series A Preferred Stock at $1,000 per share and a common stock purchase warrant to purchase 2,018,958 shares of common stock at an initial exercise price of $9.9061 to 3i, LP for an aggregate purchase price of $20 million. Each share of Series A Preferred Stock has a right to convert into shares of our common stock at an initial fixed conversion price of $9.9061. However, in the event of certain triggering events, each share of Series A Preferred Stock is entitled to convert at a price equal to 90% of the sum of the two (2) lowest VWAPs during the ten (10) trading day period immediately preceding delivery divided by two (2), but not less than the Floor Price, or if thirty (30) days after our common stock commences trading on Nasdaq the average daily U.S. Dollar volume for the ten (10) days previous to conversion divided by ten (10) is less than $2,000,000, then each share of Series A Preferred Stock is entitled to convert at the lower of the fixed conversion price or a price equal to 80% of the sum of the two (2) lowest VWAPs during the ten (10) trading day period immediately preceding delivery divided by two (2), but not less than the Floor Price.

In addition, the Series A COD and the PIPE Warrant provides for an adjustment to the conversion price and exercise of the PIPE Warrant in the event of a "new issuance" of our common stock, or common stock equivalents, at a price less than the applicable conversion price of the Series A Preferred Stock or exercise price of the PIPE Warrant. The adjustment is a "full ratchet" adjustment in the conversion price of the Series A Preferred Stock and the exercise price of the PIPE Warrant equal to the lower of the new issuance price or the then existing conversion price of the Series A Preferred Stock or exercise price of PIPE Warrant, with few exceptions. Furthermore, if we fail to maintain an adequate number of authorized and unissued shares of our common stock in reserve and we are unable to deliver shares or our common stock upon conversion of the Series A Preferred Stock, we may be required to redeem the shares we were unable to deliver at a price equal to the highest closing price of our common stock during the time between the failure to deliver shares of our common stock and the redemption date.

If certain defined "triggering events" defined in the Series A COD occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Series A Preferred Stock into common stock when a conversion right is exercised, failure to issue our common stock when the PIPE Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, certain defaults on our debts or contractual obligations, or upon a "bankruptcy triggering event" (as defined in the Series A COD), then we may be required to pay a dividend that is added to the stated value on the Series A Preferred Stock in the amount of 18% per annum, but paid quarterly in cash, so long as the triggering event is continuing, or to redeem the Series A Preferred Stock for cash in an amount of 125% of the stated value of the Series A Preferred Stock and in the event that we experience a "Change of Control" (as defined in the Series A COD) we may also be required to redeem the Shares at a premium of 125% of their stated value. In addition, if thirty days after our common stock commences trading on Nasdaq the average daily dollar volume for the ten (10) days previous to conversion divided by ten (10) is less than $2,500,000, then the Series A Preferred Stock shall be entitled to a one-time dividend equal to an 8% increase in the stated value of the Preferred Share, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per Preferred Share. This dividend was paid during the first quarter of 2022.

On November 22, 2022, the Company amended Section 12 of the Series A COD of Series A Preferred Stock to provide for voting rights. Subject to a 9.99% beneficial ownership limitation, the holders of Series A Preferred Stock shall have the right to vote on all matters presented to the stockholders for approval together with the shares of common stock, voting together as a single class, on an "as converted" basis using the "Conversion Price" (initially $9.9061 per share before any adjustment) (rounded down to the nearest whole number and using the record date for determining the stockholders of the Company eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in the Company's Certificate of Incorporation or the Series A COD of Series A Preferred Stock. The voting rights described above expired on February 28, 2023, and thereafter holders of preferred stock shall not have voting rights except as required by law (including without limitation, the DGCL). Accordingly, holders of Series A Preferred Stock have no voting rights, except as required by law and as expressly provided in the Series A COD.

Furthermore, on December 9, 2022, the Company and 3i, LP, the holder of outstanding shares of Series A Preferred Stock, entered into a letter agreement which provided that pursuant to Section 8(g) of the Series A COD, the parties agreed that the Conversion Price (as defined in such Series A COD) was modified to mean the lower of: (i) the Closing Sale Price (as defined in Series A COD) on the trading date immediately preceding the Conversion Date (as defined in the Series A COD) and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Series A COD) through and inclusive of January 19, 2023 (the "Termination Date"). In January 2023, pursuant to a subsequent letter agreement the Termination Date was extended indefinitely until agreed upon by the Company and 3i, LP.

Series B Preferred Stock

On November 22, 2022, the Board of Directors established the Series B Preferred Stock, par value $0.0001 per share. On November 22, 2022, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock setting forth the rights, preferences, privileges and restrictions for 200,000 shares of Series B Preferred Stock. The holders of Series B Preferred Stock are not entitled to receive dividends of any kind. Each outstanding share of Series B Preferred Stock has 400 votes per share. The Series B Preferred Stock ranks senior to the common stock, but junior to the Series A Preferred Stock, as to any distribution of assets upon a liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily All shares of Series B Preferred Stock that are not present in person or by proxy through the presence of such holder's shares of common stock or Series A Preferred Stock, in person or by proxy, at any meeting of stockholders held to vote on the proposals relating to reverse stock split, the share increase proposal and the adjournment proposal as of immediately prior to the opening of the polls at such meeting (the "Initial Redemption Time") will be automatically be redeemed by the Company at the Initial Redemption Time without further action on the part of the Company or the holder thereof (the "Initial Redemption"). Any outstanding shares of Series B Preferred Stock that have not been redeemed pursuant to an Initial Redemption will be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board of Directors in its sole discretion, automatically and effective on such time and date specified by the Board of Directors in its sole discretion or (ii) automatically upon the approval by the Company's stockholders of the reverse stock split proposal and the share increase proposal at any meeting of stockholders held for the purpose of voting on such proposals. Each share of Series B Preferred Stock redeemed in any Redemption will be redeemed in consideration for the right to receive an amount equal to $0.10 in cash for each ten whole shares of Series B Preferred Stock as of the applicable Redemption Time. Each share of Series B Preferred Stock has 400 votes per share and is entitled to vote with the Common Stock and Series A Preferred Stock, together as a single class, on the certain proposals. The power to vote, or not to vote, the shares of Series B Preferred Stock is vested solely and exclusively in the Board of Directors, or its authorized proxy. Upon conclusion of the 2023 Annual Meeting of Stockholders on February 3, 2023, all outstanding shares of Series B Preferred Stock were redeemed with the holders of such Series B Preferred Stock only entitled to right to receive payment for the redeemed shares, based on $0.01 per share of Series B Preferred Stock.

Series C Preferred Stock

Pursuant to the approval and authorization of the Board of Directors, the Company established the Series C Preferred Stock. On February 24, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock (the "COD") with the Delaware Secretary of State designating 50,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock with a stated value of $27.00 per share (the "Stated Value"). On February 28, 2023, the Company filed a certificate of amendment to the Series C COD (the "COD Amendment") to clarify the terms of conversion price and floor price based on definitions provided in the Series C COD (the COD Amendment, together with the COD, the "Series C COD"). Defined terms not defined below have the meaning set forth in the Series C COD.

The Series C COD provides that the Series C Preferred Stock will have no voting rights other than the exclusive right to vote with respect to the Amendment and the Reverse Stock Split, and shall not be entitled to vote on any other matter except to the extent required under the General Corporation Law of the State of Delaware, and the right to cast 620 votes per share of Series C Preferred Stock on the Amendment and Reverse Stock Split proposals. Under the terms of the Series C COD, the holders of Series C Preferred Stock will be entitled to receive dividends, based on the Stated Value, at a rate of five percent (5%) per annum, which shall accrue and be compounded daily, commencing on the Original Issue Date until the date that the Preferred Stock is converted to Common Stock. In addition, upon any liquidation, dissolution or winding-up of the Company, prior and in preference to the Common Stock, holders of Series C Preferred Stock shall be entitled to receive out of the assets available for distribution to stockholders an amount in cash equal to 105% of the aggregate Stated Value of all shares of Series C Preferred Stock held by such holder.

The conversion price for the Series C Preferred Stock shall initially equal the lower of: (i) $0.182, which is the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Original Issuance Date; and (ii) the lower of: (x) the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Conversion Date or such other date of determination; and (y) the average of the official closing prices of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) for the five (5) Trading Days immediately preceding the Conversion Date or such other date of determination, subject to adjustment herein (the "Conversion Price"). In no event shall the Conversion Price be less than $0.0370 (the "Floor Price"). In the event that the Conversion Price on a Conversion Date would have been less than the applicable Floor Price if not for the immediately preceding sentence, then on any such Conversion Date the Company shall pay the Holder an amount in cash, to be delivered by wire transfer out of funds legally and immediately available therefor pursuant to wire instructions delivered to the Company by the Holder in writing, equal to the product obtained by multiplying (A) the higher of (I) the highest price that the Common Stock trades at on the Trading Day immediately preceding such Conversion Date and (II) the applicable Conversion Price and (B) the difference obtained by subtracting (I) the number of shares of Common Stock delivered (or to be delivered) to the Holder on the applicable Share Delivery Date with respect to such conversion of Series C Preferred Stock from (II) the quotient obtained by dividing (x) the applicable Conversion Amount that the Holder has elected to be the subject of the applicable conversion of Series C Preferred Stock, by (y) the applicable Conversion Price without giving effect to clause (x) of such definition.

Each holder of Series C Preferred Stock shall have the right to cause the Company to redeem in cash all or part of such holder's shares of Series C Preferred Stock at a price per share equal to 110% of the Stated Value (i) after the earlier of (1) the receipt of Authorized Stockholder Approval and (2) the date that is 60 days following the original issue date and (ii) before the date that is 365 days after the original issue date. Upon receipt of a written notice to the Company by each holder (each, a "Redemption Notice") setting forth the number of shares of Series C Preferred Stock that such holder wishes to redeem, the Company shall redeem such shares of Series C Preferred Stock in accordance with the Redemption Notice no later than 5 days after the date on which the Redemption Notice is delivered to the Company.

Dividends

The DGCL permits a corporation to declare and pay dividends out of "surplus" or, if there is no "surplus," out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. "Surplus" is defined as the excess of the net assets of the corporation over the amount determined to be the capital of the corporation by the Board of Directors. The capital of the corporation is typically calculated to be (and cannot be less than) the aggregate par value of all issued shares of capital stock. Net assets equals the fair value of the total assets minus total liabilities. The DGCL also provides that dividends may not be paid out of net profits if, after the payment of the dividend, capital is less than the capital represented by the outstanding stock of all classes having a preference upon the distribution of assets.

Declaration and payment of any dividend will be subject to the discretion of our Board of Directors. The time and amount of dividends will be dependent upon our financial condition, operations, cash requirements and availability, debt repayment obligations, capital expenditure needs and restrictions in our debt instruments, industry trends, the provisions of Delaware law affecting the payment of distributions to shareholders and any other factors our Board of Directors may consider relevant.

On November 22, 2022, the Board of Directors declared a dividend of Series B Preferred Stock to the stockholders of record of common stock and Series A Preferred Stock as of the Record Date. On the Record Date, each share of common stock outstanding received 0.016 of a share of Series B Preferred Stock and each share of Series A Preferred Stock outstanding received 1.744 shares of Series B Preferred Stock.

We have no current plans to pay dividends on our common stock. Any decision to declare and pay dividends in the future will be made at the sole discretion of our Board of Directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our Board of Directors may deem relevant. Because we will be a holding company and will have no direct operations, we will only be able to pay dividends from funds we receive from our operating subsidiaries. In addition, our ability to pay dividends may be limited by the agreements governing any indebtedness that we or our subsidiaries incur in the future.

PIPE Warrant

Concurrently with the issuance of our Series A Preferred Stock, we issued warrants to purchase 2,018,958 shares of our common stock at an exercise price of $9.9061 per share, subject to adjustments, PIPE Warrant. The terms of the PIPE Warrant are as follows:

- The PIPE Warrant has a term of three years and expire on December 20, 2024;
- The exercise of the PIPE warrant is subject to a beneficial ownership limitation of 9.99%;

- The exercise price and the number of shares issuable upon the exercise of the PIPE Warrant are subject to adjustment, as follows:

    - In the event of a stock dividend, stock split or stock combination recapitalization or other similar transaction involving the Company's common stock the exercise price will be multiplied by a fraction of which the numerator shall be the number of shares of common stock outstanding immediately before such event and of which the denominator shall be the number of shares of common stock outstanding immediately after such event;

    - If the Company sells or issues any shares of common stock, options, or convertible securities at an exercise price less than a price equal to the PIPE Warrant exercise price in effect immediately prior to such sale (a "Dilutive Issuance"), then immediately after such Dilutive Issuance, the exercise price then in effect shall be reduced to an amount equal to the new issuance price;

    - Simultaneously with any adjustment to the exercise price, the number of shares that may be purchased upon exercise of the PIPE Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate exercise price payable for the adjusted number of shares shall be the same as the aggregate exercise price in effect immediately prior to such adjustment (without regard to any limitations on exercise) and;

    - Voluntary adjustment reducing the exercise price for the Company to any amount and for any period deemed appropriate by the Board of Directors of the Company with the prior written consent of the Required Holders.

In the event of either the Company consolidating or merging with or into another entity (the "Fundamental Transaction"), the sale or assignment of substantially all of the Company's subsidiaries, or a Triggering Event (as defined in the Certificate of Designations), the holder is entitled to require the Company to pay the holder an amount in cash equal to the Black-Scholes value of the PIPE Warrant on or prior to the later of the second trading after the date of request for payment and the date of consummation of the Fundamental Transaction; or at any time after the occurrence of the Triggering Event.

Waiver with 3i, LP

In connection with the sale of the shares of Series C Preferred Stock, the Company and 3i, LP entered into a limited waiver agreement pursuant to which 3i, LP confirmed that the sale and issuance of the 50,000 shares of Series C Preferred Stock, will not give rise to any, or trigger any, rights of termination, defaults, amendment, anti-dilution or similar adjustments, acceleration or cancellation under the existing agreements with 3i, LP.

Secured Promissory Notes-3i, LP

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement with 3i, LP for a bridge loan to extend the Company's cash runaway beyond December 31, 2022, in order to provide the Company with more time to complete the process of amending its Certificate of Incorporation to increase it authorized share capital and proposed reverse stock split to facilitate additional capital investments (the "Bridge Loan"). Under the Secured Note Purchase Agreement, the Company has authorized the sale and issuance of three secured promissory notes, the first note in an aggregate principal amount of $350,000 to be issued at closing (which loan was received in November 2022); the second note in the principal amount of $1,666,640 to be issued at closing and which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Series A COD, that began to accrue on July 14, 2022; and the third note in an aggregate principal amount of $650,000 which was funded on December 30, 2022. Each note matures on January 1, 2024, carries an interest rate of at 5% per annum, and is secured by all of the Company's assets pursuant to the Security Agreement. In addition, 3i LP may exchange such promissory note for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of such promissory note. In addition, each promissory note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing.

Annual Stockholder Meetings

Our bylaws will provide that annual stockholder meetings will be held at a date, time and place, if any, as exclusively selected by our Board of Directors. To the extent permitted under applicable law, we may conduct meetings by remote communications, including by webcast.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our shareholders will have appraisal rights in connection with a reorganization or consolidation we may undertake in the future. Pursuant to the DGCL, shareholders who properly request and perfect appraisal rights in connection with such reorganization or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Shareholders' Derivative Actions

Under the DGCL, any of our shareholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action; provided that the stockholder bringing the action is a holder of our shares at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law.

Anti-Takeover Provisions

Our Certificate of Incorporation and our by-laws could make it more difficult for a third-party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue shares of preferred stock, which may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third-party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation, by-laws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Certificate of Incorporation and bylaws and Delaware law, as applicable, among other things:

- provide for a classified board of directors;
- provide the board of directors with the ability to alter the by-laws without stockholder approval;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Exclusive Forum

Our Certificate of Incorporation provides that unless we consent to the selection of an alternative forum, any (1) derivative action or proceeding brought on our behalf, (2) action asserting a claim of breach of a fiduciary duty owed by any director, officer, stockholder or employee to us or our shareholders, (3) action asserting a claim arising pursuant to any provision of the DGCL or Certificate of Incorporation or bylaws or (4) action asserting a claim governed by the internal affairs doctrine or otherwise related to our internal affairs shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, another state or federal court located within the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares our capital stock shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. In addition, the provisions described above will not apply to suits brought to enforce a duty or liability arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. We intend for this provision to apply to any complaints asserting a cause of action under the Securities Act despite the fact that Section 22 of the Securities Act creates concurrent jurisdiction for the federal and state courts over all actions brought to enforce any duty or liability created by the Securities Act or the rules and regulations promulgated thereunder. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act where the state courts have concurrent jurisdiction and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors to corporations and their shareholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. Our Certificate of Incorporation includes a provision that eliminates the personal liability of directors for monetary damages for any breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL. The effect of these provisions is to eliminate our rights and the rights of our shareholders, through shareholders' derivative suits on our behalf, to recover monetary damages from a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, exculpation does not apply to any director if the director has acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends or redemptions or derived an improper benefit from his or her actions as a director.

Our bylaws provide that we must indemnify and advance expenses to our directors and officers to the fullest extent authorized by the DGCL. We are also expressly authorized to carry directors' and officers' liability insurance providing indemnification for our directors, officers and certain employees for some liabilities. We believe that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability, advancement and indemnification provisions in our Certificate of Incorporation and bylaws may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duty.

These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our shareholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royal Street, Canton, MA 02021.

Exchange Listing

Our common stock is currently listed on The Nasdaq Global Market under the symbol "ALLR."

Exhibit 10.32

ALLARITY THERAPEUTICS, INC
22 School Street, 2nd Floor
Boston, MA 02108

December 8, 2022

3i, LP
140 Broadway Floor 38
New York, NY 10005

Re: Conversion Price Voluntary Adjustment Notice

Dear Sirs:

Reference is made to (a) that certain Securities Purchase Agreement dated as of May 20, 2021 (the "**Purchase Agreement**") between the Company and the purchaser identified therein, which is the same as the address listed above (the "**Investor**"), (b) Series A Convertible Preferred Stock of the Company issued to the Investor (the "**Series A**"), (c) and the other transaction documents, as modified from time to time, referred to collectively, as the "**Transaction Documents**". Capitalized terms used but not defined herein shall have the meanings given to them in the Purchase Agreement, or if not defined therein, in the Series A, or if not defined therein, in the applicable Transaction Document, in each case as of the date hereof.

This letter agreement (this "**Letter Agreement**") confirms our recent discussions about, among other matters, certain modifications to the Series A.

1. Pursuant to Section 8 (g) of the Certificate of Designations for the Series A Preferred Stock, the Company hereby reduces the Conversion Price to the lower of: (i) the Closing Sale Price on the trading date immediately preceding the Conversion Date and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days of December 8, 2022, through and inclusive of January 19, 2023. Any conversion which occurs shall be voluntary at the election of the Holder, which shall evidence its election as to the Series A being converted in writing on a conversion notice setting forth the then Minimum Price.

This Letter Agreement is a Transaction Document and is limited as written. As of the date first written above, each reference in the Purchase Agreement or any other applicable Transaction Document to "**this Agreement**," "**hereunder**," "**hereof**," "**herein**," or words of like import, and each reference in the other Transaction Documents to such Purchase Agreement or other Transaction Documents (including, without limitation, by means of words like "**thereunder**," "**thereof**" and words of like import), shall refer to the Purchase Agreement as modified thereby, and this Letter Agreement and the Purchase Agreement shall be read together and construed as a single agreement. The execution, delivery and effectiveness of this Letter Agreement shall not, except as expressly provided herein, (A) waive or modify any right, power or remedy under, or any other provision of, any Transaction Document or (B) commit or otherwise obligate any Purchaser to enter into or consider entering into any other amendment, waiver or modification of any Transaction Document.

All communications and notices hereunder shall be given as provided in the Transaction Documents. This Letter Agreement (a) shall be governed by and construed in accordance with the law of the State of New York, (b) is for the exclusive benefit of the parties hereto and the other Purchasers and beneficiaries of the Purchaser Agreement and, together with the other Transaction Documents, constitutes the entire agreement of such parties, superseding all prior agreements among them, with respect to the subject matter hereof, (c) may be modified, waived or assigned only in writing and only to the extent such modification, waiver or assignment would be permitted under the Transaction Documents (and any attempt to assign this Letter Agreement without such writing shall be null and void), (d) is a negotiated document, entered into freely among the parties upon advice of their own counsel, and it should not be construed against any of its drafters and (e) shall survive the satisfaction or discharge of the amounts owing under the Transaction Documents. The fact that any term or provision of this Letter Agreement is held invalid, illegal or unenforceable as to any person in any situation in any jurisdiction shall not affect the validity, enforceability or legality of the remaining terms or provisions hereof or the validity, enforceability or legality of such offending term or provision in any other situation or jurisdiction or as applied to any person.

This Letter Agreement is expressly conditioned on the following conditions precedent:

(1) The Company's Board of Directors shall have approved this Letter Agreement and all undertakings thereto in all respects and shall provide written evidence of the same to the Investor by December 8, 2022: and

(2) The Company shall have verified and confirmed with its transfer agent that there are no impediments to the issuance of shares as a result of this Letter Agreement.

Kindly confirm your agreement with the above by signing in the space indicated below and by PDFing a partially executed copy of this letter to the undersigned, and which may be executed in identical counterparts, each of which shall be deemed an original but all of which shall constitute one and the same agreement.

Very truly yours,

ALLARITY THERAPEUTICS, INC.

By: /s/ James G. Cullem
James G. Cullem, Chief Executive Officer

AGREED AND ACCEPTED:

3i, LP

By: /s/ Maier J Tarlow
Name: Maier J Tarlow
Title: Manager On Behalf Of The GP

Exhibit 10.35

ALLARITY THERAPEUTICS, INC
22 School Street, 2nd Floor
Boston, MA 02108

January 23, 2023

3i, LP
140 Broadway Floor 38
New York, NY 10005

Re: Amendment to the Conversion Price Voluntary Adjustment Notice dated 12.8.22

Dear Sirs:

Reference is made to that certain Letter Agreement dated December 8, 2022 ("**Letter Agreement**"), regarding certain modifications to Series A. Capitalized terms used herein but not defined shall have the meanings ascribed to them in Letter Agreement, a copy of which is attached.

The parties agree that Section 1 of the Letter Agreement is amended in its entirety to read as follows:

1. Pursuant to Section 8 (g) of the Certificate of Designations for the Series A Preferred Stock, the Company hereby reduces the Conversion Price to the lower of: (i) the Closing Sale Price on the trading date immediately preceding the Conversion Date and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days beginning on December 8, 2022, until terminated upon written agreement by the Company and the Required Holders. Any conversion which occurs shall be voluntary at the election of the Holder, which shall evidence its election as to the Series A being converted in writing on a conversion notice setting forth the then Minimum Price.

This Amendment was approved by the Company's Board of Directors on January 19, 2023. All terms of the Letter Agreement not amended hereby remain in full force and effect.

Kindly confirm your agreement with the above by signing in the space indicated below and by PDFing a partially executed copy of this letter to the undersigned, and which may be executed in identical counterparts, each of which shall be deemed an original but all of which shall constitute one and the same agreement.

Very truly yours,
ALLARITY THERAPEUTICS, INC.

By: /s/ James G. Cullem
James G. Cullem, Chief Executive Officer

AGREED AND ACCEPTED:
3i, LP

By: /s/ Maier J Tarlow
Name: Maier J Tarlow
Title: Manager On Behalf Of The GP

Exhibit 21.1

Subsidiaries

Name	Jurisdiction of Incorporation
Allarity Acquisition Subsidiary Inc.	Delaware
Allarity Therapeutics Europe ApS (formerly Oncology Venture Product Development ApS)*	Denmark
Allarity Therapeutics Denmark ApS (formerly OV-SPV2 ApS)*	Denmark
Medical Prognosis Institute, Inc.*(1)	Arizona
Oncology Venture US Inc.*(1)	Delaware

* wholly-owned subsidiary of Allarity Acquisition Subsidiary, Inc

(1) In the process of being dissolved because inactive.

Exhibit 31.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James G. Cullem, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allarity Therapeutics, Inc (the "Registrant").

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 10, 2023

By: /s/ James G. Cullem
Name: James G. Cullem
Title: Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joan Y. Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allarity Therapeutics, Inc. (the "Registrant").

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 10, 2023

By: /s/ Joan Y. Brown
Name: Joan Y. Brown
Title: Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Allarity Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacities and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 10, 2023

By: /s/ James G. Cullem
Name: James G. Cullem
Title: Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Allarity Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacities and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 10, 2023

By: /s/ Joan Y. Brown
Name: Joan Y. Brown
Title: Chief Financial Officer