UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-38244

Genprex, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**90-0772347**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1601 Trinity Street, Bldg B, #3.312.09 **Austin, Texas**	
(Address of principal executive offices)	**78712** **(Zip Code)**

Registrant's telephone number, including area code: (877) 774-4679

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 $0.001 per share	GNPX	The Nasdaq Capital Market

Securities registered pursuant to 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 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 registrant 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. Yes ☐ No ☒

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2020 was approximately $114 million, computed by reference to the closing price of the registrant's common stock on June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter) of $3.14 per share, as reported by The Nasdaq Capital Market.

As of March 15, 2021, there were 43,276,764 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant's 2021 annual meeting of stockholders, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2020.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. Any statements in this Annual Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future management and organizational structure are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to:

- Market conditions;
- Our capital position;
- Our ability to compete with larger better financed pharmaceutical companies;
- Our uncertainty of developing marketable products;
- Our ability to develop and commercialize our products;
- Our ability to obtain regulatory approvals;
- Our ability and third parties' ability to maintain and protect intellectual property rights;
- Our ability to raise additional future financing and possible lack of financial and other resources;
- The success of our clinical trials through all phases of clinical development;
- Any delays in regulatory review and approval of our current and future product candidates;
- Our dependence on third-party manufacturers to supply or manufacture our products;
- Our ability to control product development costs;
- Our ability to attract and retain key employees;
- Our ability to compete effectively;
- Our ability to enter into new strategic collaborations, licensing or other arrangements;
- Changes in government regulation affecting product candidates could increase our development costs;
- Our involvement in patent and other intellectual property litigation could be expensive and could divert management's attention;
- The possibility that there may be no market acceptance for our products; and
- Changes in third-party reimbursement policies which could adversely affect potential future sales of any of our products that are approved for marketing.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements, which speak only as of the date of this Annual Report. Except as required by law, we assume no obligation and expressly disclaim any duty to update any forward-looking statement to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements contained in this Annual Report. All forward-looking statements are expressly qualified in their entirety by the cautionary statements contained in this section.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to Our Financial Position and Need for Additional Capital

- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.
- We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.
- We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.

Risks Related to Development and Commercialization of Our Current and Future Product Candidates

- Our success depends greatly on the success of our development of REQORSA for the treatment of NSCLC, and our other product candidates, including GPX-002 for the treatment of diabetes.
- Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our current and future product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our current and future product candidates.
- Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.
- The accelerated approval pathway for our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.
- If we are unable to secure contract manufacturers with capabilities to produce the products that we require, we could experience delays in conducting our planned clinical trials.
- REQORSA, GPX-002 and any other product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates, and the approval may be for a narrower indication than we seek. Furthermore, even if we obtain regulatory approval of our current and future product candidates, the products may not gain market acceptance among physicians, patients, hospitals, treatment centers, third-party payors and others in the medical community.
- REQORSA, GPX-002 and other future product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- Our business may be adversely affected by the ongoing coronavirus pandemic.

Risks Related to Regulatory Approval and Marketing of Our Current and Future Product Candidates and Other Legal Compliance Matters

- If the FDA does not find the manufacturing facilities of our current or future contract manufacturers acceptable for commercial production, we may not be able to commercialize REQORSA, GPX-002 or any of our future product candidates.
- We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, contract research organizations, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- Coverage and reimbursement may be limited or unavailable in certain market segments for REQORSA, GPX-002 and our future product candidates, if approved, which could make it difficult for us to sell REQORSA, GPX-002 and our future product candidates profitably.
- Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.
- We are subject to a variety of risks associated with international operations which could materially adversely affect our business.

Risks Related to Our Dependence on Third Parties

- We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our current product candidates and our financial condition and operating results.
- We rely, in part, and expect to continue to rely, in part, on third parties to conduct, supervise and monitor our clinical trials, and to distribute, manufacture and perform release testing for our current and future product candidates and other key materials. If such third parties perform in an unsatisfactory manner or do not carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for our product candidates which may harm our business.
- We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

Risks Related to Our Intellectual Property

- If we fail to comply with obligations pursuant to our license agreements, we could lose intellectual property and other rights that are important to our business.
- If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.
- Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property. In addition, we may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- We may not be able to protect our intellectual property rights throughout the world.

Risks Related to Employee Matters and Managing Growth

- We have no sales, marketing or distribution experience, and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

General Risk Factors

- The market price of our common stock may be highly volatile, and you may lose all or part of your investment.
- If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired.
- We have no intention of declaring dividends in the foreseeable future.
- Our charter documents contain an exclusive forum provision with respect to certain actions which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable and discourage lawsuits against us or our current or former directors or officers and/or stockholders in such capacity.

PART I

Item 1. Business.

Overview

We are a clinical stage gene therapy company focused on developing life-changing treatments for cancer and diabetes. Our lead cancer drug candidate, REQORSA™ Immunogene therapy drug (sometimes referred to as GPX-001), is being developed to treat non-small cell lung cancer ("NSCLC"). The active agent in REQORSA is a TUSC2 gene expressing plasmid that is encapsulated in a DOTAP cholesterol nanoparticle. TUSC2 is a tumor suppressor gene which has both tumor killing (via apoptosis) and immunomodulatory effects. We utilize our novel proprietary ONCOPREX® Nanoparticle Delivery System to deliver the TUSC2 gene expressing plasmid to cancer cells. The TUSC2 gene is one of a series of genes whose therapeutic use is covered by our exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson").

We are planning to initiate our Acclaim-1 and Acclaim-2 clinical trials in 2021. Acclaim-1 is a Phase 1/2 clinical trial using a combination of REQORSA with AstraZeneca PLC's Tagrisso® in patients with late-stage NSCLC with mutated epidermal growth factor receptors ("EGFRs") whose disease progressed after treatment with Tagrisso. In January 2020, we received Food and Drug Administration ("FDA") Fast Track Designation for the Acclaim-1 patient population. Acclaim-2 is a Phase 1/2 clinical trial using a combination of REQORSA with Merck & Co.'s Keytruda® in late-stage NSCLC patients who are low expressors (1% to 49%) of the protein programmed death-ligand 1 ("PD-L1").

In diabetes, we are developing a gene therapy that is exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh") for the treatment of Type 1 and Type 2 diabetes. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. Our diabetes product candidate is currently being evaluated in preclinical studies.

Oncology Platform

Utilizing our non-viral ONCOPREX Nanoparticle Delivery System, we are developing cancer treatments that are designed to administer cancer fighting genes. We encapsulate the gene-expressing plasmids using ONCOPREX lipid nanoparticles, and administer them intravenously, where they are then taken up by tumor cells and express proteins that are missing or found in low quantities in the tumor cells. With our lead drug candidate, REQORSA, there is a multimodal mechanism of action whereby REQORSA interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and modulates the immune response against cancer cells. REQORSA has also been shown to block mechanisms that create drug resistance.

We believe that our ONCOPREX Nanoparticle Delivery System could allow delivery of a number of cancer-fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer. We believe that REQORSA's combination of pan-kinase inhibition, direct induction of apoptosis, anti-cancer immune modulation and complementary action with targeted drugs and immunotherapies is unique, and positions REQORSA to provide treatment for patients with NSCLC and possibly other cancers, who are not benefitting from current therapies.

Diabetes Gene Therapy

Our diabetes gene therapy, also referred to as GPX-002, was developed by lead researcher Dr. George Gittes, at the Rangos Research Center at the University of Pittsburgh Medical Center ("UPMC") Children's Hospital. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. The therapy utilizes a procedure in which an adeno-associated virus vector delivers Pdx1 and MafA genes to the pancreas.

Recent Developments

License Amendment with MD Anderson

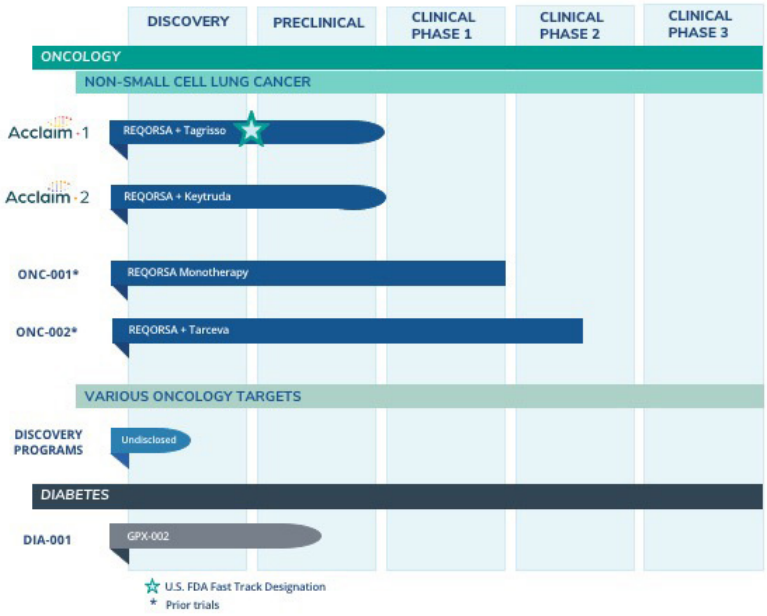
On March 3, 2021, we entered into an amendment (the "MD License Amendment") to the Patent and Technology License Agreement dated May 4, 2020 with MD Anderson. The MD License Amendment grants us a worldwide, exclusive, sublicensable license to an additional portfolio of six patents and one patent application and related technology for methods for treating cancer by administration of a TUSC2 therapy in conjunction with EGFR inhibitors or other anti-cancer therapies in patients predicted to be responsive to TUSC2 therapy. Pursuant to the MD License Amendment, we agreed to (i) pay annual maintenance fees ranging from the mid five figures to the low six figures, (ii) total milestone payments of $6,150,000, (iii) a one-time fee in the mid five figures and (iv) certain patent related expenses.

Financings

On February 11, 2021, we sold an aggregate of 4,000,000 shares of our common stock for a purchase price of $6.25 per share in a registered direct offering. We received net proceeds of approximately $23.2 million after deducting estimated offering expenses.

Our Pipeline

Our technologies are designed to administer disease-fighting genes to provide new treatment options for large patient populations with cancer and diabetes who currently have limited treatment options. We are developing our lead product candidate REQORSA to be administered with targeted therapies and with immunotherapies for NSCLC. We continue to conduct preclinical research to explore how REQORSA may be administered with targeted therapies and immunotherapies in other solid tumors and are researching how other cancer fighting genes can be applied using our ONCOPREX Nanoparticle Delivery System. We also are developing our pre-clinical diabetes candidate, GPX-002. The following table summarizes our product development pipeline.



Introduction – Cancer

Cancer and Genetic Mutations. Cancer results from genetic mutations. Mutations that lead to cancer are usually present in two major classes of genes: oncogenes, which are involved in functions such as signal transduction and transcription; and tumor suppressor genes, which play a role in governing cell proliferation by regulating transcription. Transduction is the process by which chemical and physical signals are transmitted through cells. Transcription is the process by which a cell's DNA sequence is copied to make RNA molecules, which then play a role in protein expression. In normal cells, mutations in oncogenes are discovered and targeted for elimination by tumor suppressor genes. In cancer cells, the oncogene mutations may overwhelm the natural tumor suppression processes, or those tumor suppression processes may be impaired or absent. Functional alterations due to mutations in oncogenes or tumor suppressor genes may result in the abnormal and uncontrolled growth patterns characteristic of cancer. These genetic alterations facilitate such malignant growth by affecting signal transduction pathways and transcription, thus inhibiting normal growth signaling in the cell, circumventing the natural process of apoptosis, evading the immune system's response to cancer, and inducing angiogenesis, which is the formation of new blood vessels that supply cancer cells.

The most common genetic alterations present in NSCLC are in tumor suppressor genes, against which few targeted small molecule drugs, historically considered the backbone of traditional medicine, have been developed.

Another genetic condition associated with lung cancer is the overexpression of EGFRs and mutations of kinases. Kinases are enzymes that play an important role in signal transduction through the modification of proteins by adding or taking away phosphate groups, a process called dephosphorylation, to change the proteins' function. When two EGFR transmembrane proteins are brought to proximity on the cell membrane surface, or dimerize, either through a ligand, or binding molecule, that binds to the extracellular receptor, or through some other process, the intracellular protein-kinase domains can autophosphorylate, and activate downstream processes, including cell signaling pathways that can lead to either cell cycle arrest or cell growth and proliferation. EGFRs and kinases can act similarly to a switch that turns "on" and "off" when phosphate groups are either added or taken away. Mutated kinases can have a malfunctioning on/off switch, causing the switch to be stuck in the "on" position or failing to turn the switch "off," leading to the loss of cell control.

Cancer and the Immune System. Cancer can also spread when the body's natural immune functions are impaired, including by the cancer cells themselves. PD-1, or Programmed Death-1, is a receptor expressed on the surface of activated T cells, which are part of the body's immune system. PD-L1 is a protein/receptor expressed on the surface of cancer and other cells. The binding of PD-1 to PD-L1 has been speculated to contribute to cancer cells' ability to evade the body's immune response. PD-1 and similar molecules are called immune checkpoints because they can impede the normal immune response, for example by blocking the T cells from attacking the cancer cells. In many cancers, PD-L1 receptors are up-regulated. Substantial research is now being performed in the emerging field of immuno-oncology to discover drugs or antibodies that could block PD-L1 and similar receptors. It is believed that blocking the PD-1/PD-L1 interaction pathway and other similar checkpoints, such as cytotoxic T-lymphocyte-associated protein 4, or CTLA-4, with drugs called checkpoint inhibitors can prevent cancer cells from inactivating T cells.

Current Treatment of NSCLC. Chemotherapy is the standard treatment for the majority of NSCLC patients, as it is for many other cancer patients. Because it is a non-selective systemic treatment, rather than a targeted approach to treating cancer, chemotherapy also kills healthy cells and has a number of other side effects.

A subset of NSCLC patients carry one or both of two EGFR mutations, referred to as exon 19 deletion and exon 21 substitution, which make their tumors sensitive to tyrosine kinase inhibitors ("EGFR TKIs"). Because EGFR is frequently overexpressed in lung tumors, it has become a favored therapeutic target for pharmaceutical companies. Several pharmacological and biological approaches, including EGFR TKIs, have been developed specifically to block activated EGFR for cancer therapy. The class of drugs functioning as protein kinase inhibitors ("KIs") comprises the majority of targeted therapies for lung cancer, accounting for most sales and use. Of the KIs, the EGFR TKI drugs are the most common, with drugs targeting EGFR kinases leading the sector growth. Several EGFR TKI therapies are marketed commercially including, but not limited to, Tagrisso, Tarceva, Iressa and Gilotrif.

Approximately 7% of NSCLC patients of North American and European descent and approximately 30% to 50% of NSCLC patients of Asian descent have activating EGFR mutations. This means that the majority of NSCLC patients do not have activating EGFR mutations and are therefore "EGFR negative" and not optimal candidates for EGFR TKIs.

However, while EGFR TKIs are most effective in patients who have an activating EGFR mutation and are therefore described as "EGFR positive," they are significantly less effective in overall NSCLC populations and are generally not effective in patients without an activating EGFR mutation.

In addition, even among those patients who are EGFR positive and benefit from EGFR TKI therapy, nearly all eventually become resistant to and ultimately no longer respond to EGFR TKI therapy, resulting in eventual disease progression. For example, according to the FLAURA study, sponsored by AstraZeneca, the median time to tumor progression for lung cancer patients on Tagrisso is approximately 18 months. Furthermore, clinical trials have shown that combining EGFR TKIs with conventional chemotherapy does not increase survival for lung cancer patients.

Epidemiology of Non-Small Cell Lung Cancer. According to the World Health Organization in 2019, lung cancer was the leading cause of cancer deaths worldwide, causing more deaths than colorectal, breast, liver or stomach cancers. In the United States, according to the American Cancer Society, it is estimated that in 2021 there will be more than 235,000 new cases of lung cancer and more than 131,000 deaths from this disease. The American Society of Clinical Oncology reports that NSCLC represents 84% of all lung cancers and has a 24% five-year survival rate. However, according to the National Cancer Institute, 57% of lung cancer diagnoses are distant, or have metastasized, and the five-year relative survival rate for Stage 4 (metastatic) NSCLC is approximately 5%. With limited benefit from current therapies, we believe there is a significant unmet medical need for new treatments for NSCLC in the United States and globally, and we believe REQORSA may be suitable for a majority of NSCLC patients.

REQORSA™

Our REQORSA™ immunogene therapy is designed to (i) interrupt cell signaling pathways that cause replication and proliferation of cancer cells, (ii) to target and kill cancer cells via receptor pathways, and (iii) to stimulate the natural immune responses against cancer. REQORSA is an immunogene therapy in that it combines features of gene therapy and immunotherapy. It up-regulates TUSC2 expression in the cell, and also increases the anti-tumor immune cell population and down-regulates PD-L1 receptors, thereby potentially boosting the immune response to cancer.

REQORSA consists of the TUSC2 gene expressing plasmid encapsulated in a non-viral nanoparticle made from lipid molecules (our ONCOPREX Nanoparticle Delivery System) with a positive electrical charge. REQORSA is injected intravenously and specifically targets cancer cells. Cancer cells have elevated metabolism compared to healthy cells and as a result, are negatively charged compared to healthy cells, which are positively charged, or charged neutral. REQORSA is designed to deliver the functioning TUSC2 gene to cancer cells while minimizing their uptake by normal tissue. Tumor biopsy studies conducted at MD Anderson show that, in three patients, the uptake of TUSC2 in tumor cells after REQORSA treatment was 10 to 33 times the uptake in normal cells. We believe that REQORSA, unlike other gene therapies, which either need to be delivered directly into tumors or require cells to be removed from the body, re-engineered and then reinserted into the body, is the first systemic gene therapy to be used for cancer in humans.

REQORSA has been shown to have a multimodal mechanism of action whereby it interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for programmed cell death (apoptosis) in cancer cells, and modulates the immune response against cancer cells. REQORSA also has been shown to block mechanisms that create drug resistance.

REQORSA is a pan-kinase inhibitor shown to simultaneously inhibit the EGFR and Protein kinase B, also known as AKT, oncogenic kinase pathways *in vitro* and *in vivo*. Once the cancer cell takes up the nanoparticles containing the TUSC2 expressing plasmid, it is reprogrammed to die. Resistance to targeted drugs and checkpoint inhibitors develop through activation of alternate bypass pathways. For example, when PD-1 is blocked, the TIM-3 checkpoint is up-regulated. We believe that REQORSA's multimodal activity will block emerging bypass pathways, thereby potentially reducing the probability that drug resistance develops.

Many approved cancer therapeutics target only single molecules or a single specific genetic abnormality related to driving the proliferation and survival of cancer cells. In contrast, REQORSA is designed to work by targeting several molecules within the cancer cell to interrupt cell signaling pathways that cause replication and proliferation of cancer cells, to target and kill cancer cells, to block mechanisms that create drug resistance and to stimulate the natural immune response.

Our preclinical and clinical data indicates that REQORSA is well tolerated and may be effective alone or in combination with targeted small molecule therapies. Preclinical data indicates that REQORSA may also be effective with immunotherapies, and in a three-drug combination with immunotherapy and chemotherapy. By facilitating the action of both drugs, we believe there may be an expanded population of patients who may benefit from these advanced therapy regimens.

TUSC2, the Active Agent in REQORSA™

TUSC2, is a multifunctional gene that plays a vital role in cancer suppression and normal cell regulation. Key TUSC2 anti-cancer mechanisms of action include the inactivation of multiple oncogenic kinases, the induction of apoptosis, the control of cell signaling and inflammation, and modulation of the immune system to fight cancer. REQORSA has also been shown to block mechanisms that create drug resistance. Our data indicates that REQORSA in combination with both EGFR TKIs and with immunotherapies achieve results more favorable than results achieved with either REQORSA or such other therapies alone, and may make those drugs effective for patients who would not otherwise benefit from them.

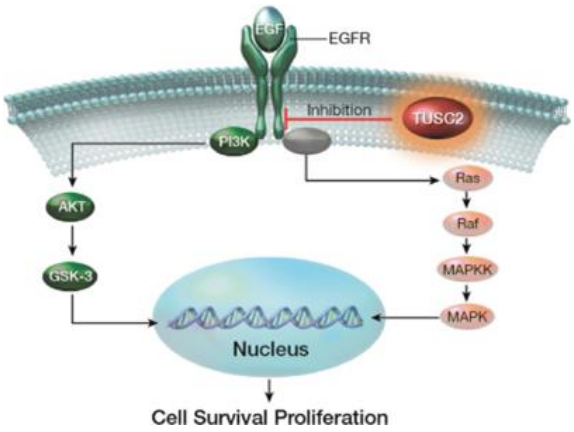
Normal TUSC2 function is inactivated at the early onset of cancer development, making TUSC2 a potential target for all stages of cancer, including metastatic disease. The TUSC2 protein is reduced or absent in approximately 85% of lung cancers. In patients with NSCLC, the loss of TUSC2 expression has been associated with significantly worse overall survival than when TUSC2 expression is not impaired.

Studies show TUSC2 protein functions as a key mediator in the Apaf1-mediated mitochondrial apoptosis pathway by recruiting and directing cytoplasmic Apaf1 protein to a critical cellular location and activating it *in situ* and by up-regulating activity of other proapoptotic effectors. Normal TUSC2 function mediates apoptosis in cancer cells through interaction with Apaf1 and down-regulates multiple tyrosine kinases including EGFR, AKT, platelet-derived growth factor receptor ("PDGFR"), c-Kit, and c-Abl. TUSC2 mediates apoptosis in cancer cells but not normal cells through its interaction with Apaf1 and down-regulates tyrosine kinases including EGFR, PDGFR, c-Kit, and c-Abl.

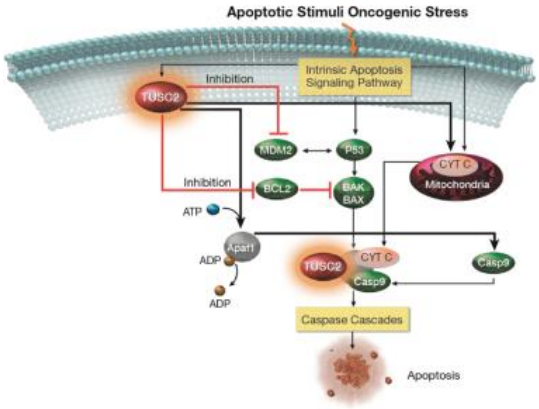
In normal cells, the proteins involved in the PI3K/AKT pathway (also called the mTOR pathway), in which PI3K, a kinase, generates messenger molecules required to translocate AKT, another protein kinase, to the cell’s plasma membrane where it is phosphorylated and activated, play an important role in cellular function and cellular trafficking. These proteins are often found to be aberrantly active in cancers, causing cells to lose their ability to control cell growth, proliferation, and differentiation. Thus, mutations in PI3K (overexpression) and its upstream receptors, EGFR, have been associated with many forms of cancers.

Similarly, proteins in the Ras/MAPK pathway, which is a signal transduction pathway that transduces signals to the cell nucleus where specific genes are activated for cell growth, division and differentiation, play a critical role in cellular responses to various stress stimuli, including osmotic stress, DNA damage, and proinflammatory factors. As shown in the figures below, the TUSC2 protein, a potent pan-kinase inhibitor, blocks multiple cell signaling pathways downstream of the receptor (EGFR in the figures), leading to cell cycle interruption and thereby preventing cancer cell proliferation and survival.

Under stress conditions, such as oncogenic stress, cells go through a regulated process of programmed cell death, also known as apoptosis, in order to control cell development and replication. The TUSC2 protein interacts via various apoptotic signaling pathways to stimulate programmed cell death via the release of caspases, enzymes that play a significant role in apoptosis.



Pan-Kinase Inhibition by TUSC2



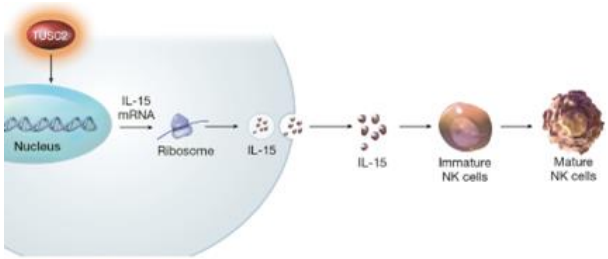
Stimulation of Apoptotic Signaling by TUSC2

Our clinical and preclinical data indicates that the combination of REQORSA, with EGFR TKIs, may increase anti-tumor activity in cancers with or without the EGFR mutations and in cancers that have become resistant to EGFR TKI therapy, thus expanding the number of patients who could benefit from those drugs.

TUSC2 and the Immune Response. In addition to its pro-apoptotic cytotoxicity and tyrosine kinase inhibitory activity, TUSC2 enhances the immune response to cancer. Data from preclinical studies at MD Anderson has shown a therapeutic benefit from the combination of TUSC2 and anti-PD-1 antibody and a key role for TUSC2 in regulating immune cell subpopulations including cytokines, natural killer ("NK") cells, and T lymphocytes. In addition, TUSC2 has been found to down-regulate PD-L1 receptors on the surface of cancer cells. By inducing tumor cell apoptosis TUSC2 increases antigen release and presentation, thus promoting an enhanced antitumor response in the presence of other immune regulators.

NK cells, an important part of the innate immune system, have developed several mechanisms to distinguish healthy cells from target cells. These mechanisms allow NK cells to kill cells that are deemed dangerous to the host, including cancer cells. However, one of the consequences of malignant transformation is the ability of the cancer cell to evade the immune system. Cancer cells do so via the up-regulation and interplay of receptors, including checkpoint inhibitors such as PD-1 and PD-L1.

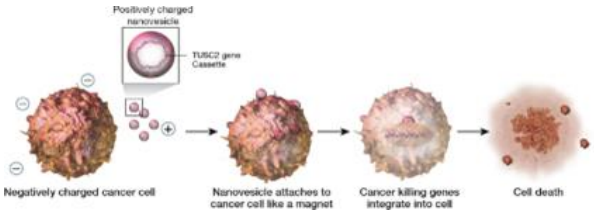
As shown in the illustration below, TUSC2 has been found to stimulate the release of interleukin-15, or IL-15, resulting in up-regulation of mature NK cells that circulate and target cancer cells.



Modulation by TUSC2 of the Immune Response to Cancer

ONCOPREX® Nanoparticle Delivery System

Our immunogene therapy platform consists of anti-cancer genes expressing DNA plasmids contained in non-viral lipid nanoparticles delivered intravenously. REQORSA, our lead drug candidate, utilizes the ONCOPREX® Nanoparticle Delivery System to encapsulate the TUSC2 gene in positively charged nanoparticles that bind to actively replicating (and therefore negatively charged) cancer cells, and then enter the cancer cell through selective endocytosis, a process by which cells take in substances from outside the cell by engulfing them in a vesicle. The nanoparticles in our system differ significantly from liposomes historically used for drug delivery in that they are true particles encapsulating the therapeutic payload within a bilamellar lipid coat.



Operation of the ONCOPREX Nanoparticle Delivery System

The particle size is small enough to allow REQORSA to cross tight barriers in the lung, but large enough to avoid accumulation or clearance in the liver, spleen and kidney. The cationic (positive) charge of the nanoparticles target cancer cells, and direct nanoparticle fusion avoids target cell endocytosis. A Phase 1 clinical trial showed that intravenous REQORSA therapy selectively and preferentially targeted primary and metastatic tumor cells, resulting in anticancer activity. The nanoparticles are non-immunogenic, allowing repetitive therapeutic dosing and providing extended half-life in the circulation.

The ONCOPREX Nanoparticle Delivery System is based on a non-viral delivery system. Most gene therapies rely on viral based delivery systems. The benefit of the viral system is that viruses are skilled at penetrating cells. However, viruses can also affect more than one type of cell and it is possible that the virus may infect additional cells, not just the targeted cells containing mutated genes. If this happens, healthy cells may be damaged causing other illness or diseases, such as cancer. With REQORSA, once it is taken up into a cancer cell, the TUSC2 gene is expressed into a protein that is capable of restoring certain defective functions arising in the cancer cell. REQORSA has been designed using the ONCOPREX Nanoparticle Delivery System to deliver the functioning TUSC2 gene to cancer cells while minimizing their uptake by normal tissue. Tumor biopsy studies conducted at MD Anderson showed that, in three patients, the uptake of TUSC2 in tumor cells after REQORSA treatment was 10 to 33 times the uptake in normal cells.

REQORSA Origins

TUSC2 was discovered through a lung cancer research consortium from MD Anderson and The University of Texas Southwestern Medical Center along with the National Cancer Institute. The TUSC2 discovery teams included Jack A. Roth, MD, FACS, chairman of our Scientific and Medical Advisory Board.

Our technology discoveries and research and development programs have been the subjects of numerous peer-reviewed publications and have been supported by Small Business Innovation Research ("SBIR") grants and grants from the National Institutes of Health, the United States Department of Treasury, and the State of Texas. We hold a worldwide, exclusive license from MD Anderson to patents covering the therapeutic use of TUSC2 and other genes that have been shown to have cancer fighting properties, as well as a number of related technologies, including 27 issued patents and 17 pending patent applications. The rights we have obtained pursuant to our license agreement with MD Anderson are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government.

REQORSA Development Rationale and Strategy

Our goal is to utilize our novel immunogene platform to provide large patient populations suffering from devastating illness with more effective treatments.

REQORSA, our lead product candidate, is being developed as a potential treatment for NSCLC. Clinical and preclinical data indicates that REQORSA, when combined with EGFR TKIs such as Tagrisso, Tarceva and Iressa, provides a synergistic effect that could also benefit the larger population of NSCLC patients who are EGFR negative (which means they are not expected to benefit from EGFR TKI drugs alone). Further, our data shows that REQORSA may re-sensitize EGFR positive patients who become resistant to, and therefore no longer benefit from, EGFR TKIs alone. Thus, REQORSA may both significantly expand the benefit of EGFR TKIs to the majority of patients who do not have EGFR activating mutations, and also extend the usefulness and benefit of EGFR TKIs for the population of NSCLC patients who are EGFR positive, but whose tumors progress on EGFR TKIs. Preclinical and clinical data support our belief that REQORSA may provide medical benefit in several subpopulations of NSCLC patients for which there is an unmet medical need, and also served as the basis for the receipt from the FDA in January 2020 of a Fast Track Designation. In granting our Fast Track Designation, the FDA found that REQORSA may provide a benefit over existing therapies for patients whose tumors progress on Tagrisso. The FDA Fast Track Designation is for use of the combination of REQORSA with TKI Tagrisso for the treatment of NSCLC patients with EGFR mutations whose tumors progressed after treatment with Tagrisso.

Pre-clinical data also has shown that REQORSA enhances the immune response to cancer. Data from preclinical studies at MD Anderson has shown a therapeutic benefit from the combination of TUSC2 and anti-PD-1 antibody and a key role for TUSC2 in regulating immune cell subpopulations including cytokines, NK cells, and T lymphocytes. In addition, TUSC2 has been found to down-regulate PD-L1 receptors on the surface of cancer cells.

Pre-clinical studies by MD Anderson researchers have included combining REQORSA with:

- the EGFR TKI gefitinib (marketed as Iressa® by AstraZeneca Pharmaceuticals) in animals and in human NSCLC cells;
- third generation EGFR TKIs such as osimertinib (marketed as Tagrisso® by AstraZeneca Pharmaceuticals);
- MK2206 in animals (MK2206 is an inhibitor of AKT kinases, which affect cell signaling pathways downstream from tyrosine kinases);
- an anti-PD-1 antibody equivalent to the checkpoint inhibitor pembrolizumab (marketed as Keytruda® by Merck & Co.) in animals;
- an anti-PD-1 antibody equivalent to the checkpoint inhibitor nivolumab (marketed as Opdivo® by Bristol-Myers Squibb Company) in animals; and
- an anti-CTLA4 antibody equivalent to ipilimumab (marketed as Yervoy® by Bristol-Myers Squibb Company) in animals.

The manufacturers of the marketed drugs were not involved in any of our clinical or preclinical studies. In studies involving marketed drugs, the drugs were administered concurrently with REQORSA without being modified in any way, and the antibodies used in our preclinical studies that did not use the marketed drugs were the non-humanized equivalent to marketed drugs.

Data from these clinical and preclinical studies indicates that combining REQORSA with these other therapies yields results more favorable than either these therapies or REQORSA alone, with minimal side effects relative to other lung cancer drugs, thereby potentially making REQORSA a therapy complementary to these cancer treatments.

Our Fast Track Designation, clinical and preclinical data have provided the basis for the Company’s development strategy for REQORSA and its use in treating NSCLC. Accordingly, we are planning to initiate, our Acclaim-1 and Acclaim-2 clinical trials in late-stage NSCLC in 2021.

Acclaim-1

In January 2020, we received Fast Track Designation from the FDA for use of REQORSA in combination with TKI Tagrisso for the treatment of NSCLC patients with EGFR mutations whose tumors progressed after treatment with Tagrisso. Given the poor prognosis for these patients and our FDA Fast Track Designation, we are prioritizing this drug combination and patient population and plan to initiate a Phase 1/2 clinical trial in 2021.

The Acclaim-1 trial is a Phase 1/2 Open-Label, Dose-Escalation and Clinical Response Study of REQORSA in Combination with Tagrisso in patients with advanced, EGFR-mutant, metastatic non-small-cell lung cancer who have progressed after treatment with Tagrisso. We anticipate enrolling patients at approximately 15 clinical sites and estimate that the Phase 1 portion of the Acclaim-1 trial will enroll up to 18 patients and that the Phase 2 portion will enroll approximately 74 patients (a 1:1 ratio of REQORSA and Tagrisso combination therapy versus Tagrisso monotherapy). Patients will be treated until a second progression event or unacceptable toxicity is experienced. Patients must have histologically confirmed unresectable stage III or IV EGFR-positive NSCLC (any histology) with:

- radiological progression on Tagrisso (third generation EGFR-TKI); and
- an ECOG performance status of 0 to 1.

The primary endpoint of the Phase 1 portion is dose limiting toxicity ("DLT"), defined as ≥Grade 3 prolonged non-hematological or ≥Grade 4 prolonged hematological toxicity occurring during the first cycle of therapy and considered to be possibly, probably, or definitely related to REQORSA and Tagrisso combination therapy. The primary endpoint of the Phase 2 portion of the trial is progression-free survival which is defined as time from randomization after first progression on Tagrisso, to first event (second progression) or death. Patients will be followed for up to 12 months following administration of their last dose of Tagrisso. We have received centralized institutional review board ("IRB") approval for Acclaim-1.

Acclaim-2

In 2019, preclinical data was presented by MD Anderson collaborators relating to the combination of TUSC2, the active agent in REQORSA, with Keytruda showing that TUSC2 combined with the checkpoint blockade mechanism of action of Keytruda was more effective than Keytruda alone in increasing the survival of mice with human immune cells (humanized mice) that had metastatic lung cancer. MD Anderson also presented preclinical data in 2019 for the combination of TUSC2, Keytruda and chemotherapy for the treatment of some of the most resistant metastatic lung cancers. This study found that the addition of TUSC2 demonstrates synergy with Keytruda and chemotherapy, and thus, may improve on first-line standard of care for lung cancer. In May 2020, we entered into a worldwide, exclusive license agreement with The Board of Regents of the University of Texas System on behalf of MD Anderson for the use of TUSC2 in combination with immunotherapies, including Keytruda, and also for the use of TUSC2 in a three-drug combination of TUSC2, immunotherapy and chemotherapy.

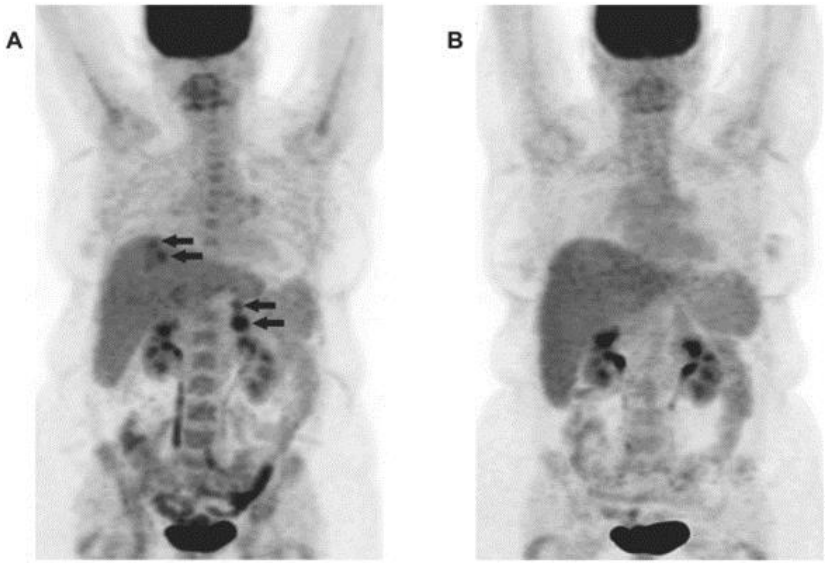
The Acclaim-2 trial is a Phase 1/2 clinical trial combining REQORSA with Keytruda in patients whose disease has progressed on Keytruda in NSCLC patients who are low expressors (1% to 49%) of PD-L1. We plan to initiate the Acclaim-2 trial in 2021.

ONC-001: REQORSA™ Phase 1 Monotherapy Trial (completed)

In 2012, MD Anderson researchers completed a Phase 1 clinical trial of REQORSA as a monotherapy (the “REQORSA Monotherapy Trial”). The primary objective of the REQORSA Monotherapy Trial was to assess the toxicity of REQORSA administered intravenously and to determine the maximum tolerated dose ("MTD") and recommended Phase 2 dose of REQORSA alone. Secondary objectives were to assess the expression of TUSC2 following intravenous delivery of REQORSA in tumor biopsies and also to assess the anticancer activity of REQORSA. This trial showed that REQORSA was well tolerated and established the MTD and the therapeutic dosage for REQORSA at 0.06 mg/kg administered every 21 days. Although this trial was not designed to show changes in outcomes, a halt in cancer growth was observed in a number of patients, and tumor regressions occurred in primary lung tumors and metastatic cancers in the liver, pancreas, and lymph nodes. In addition, pre- and post-treatment patient biopsies demonstrated that intravenous REQORSA selectively and preferentially targeted patients’ cancer cells, and suggested that clinical anti-cancer activity was mediated by TUSC2.

In the Phase 1 Monotherapy Trial, REQORSA was injected intravenously in stage IV (metastatic) lung cancer patients who had received traditional platinum combination chemotherapy but still showed tumor progression at the time of entry into the study. 31 subjects were treated at six dose levels. Seventy percent of subjects had received two or more prior chemotherapy regimens. The only serious adverse events, defined as grade 3, 4 or 5 events under the Common Terminology Criteria for Adverse Events published by the U.S. Department of Health and Human Services, were grade 3 fever (experienced by three patients) and grade 3 hypotension (experienced by 1 patient). The only dose-limiting toxicities were two episodes of transient grade 3 hypophosphatemia (abnormally low levels of phosphate in the blood) resulting in an MTD of 0.06 mg/kg. Twenty-three subjects received two or more doses, of whom five subjects, or 22% of the 23 subjects, achieved disease control for periods ranging from 2.6 months to 10.8 months. The median disease control period for these subjects was 5.0 months (95% CI: 2.0-7.6), while the other 18 subjects' cancer progressed during the Phase 1 Monotherapy Trial. Disease control for cancer therapies is defined under the Response Evaluation Criteria in Solid Tumors ("RECIST") as Complete Response (CR) + Partial Response (PR) + Stable Disease (SD)>8weeks). Median survival for all subjects in the Phase 1 Monotherapy Trial was 8.3 months (95% CI 6.0-10.5 months) and mean survival time was 13.2 months (95%CI 8.9-7.5 months) with a range of two to 23+ months.

Two subjects had reductions in primary tumor size of 14% and 26%. One subject with stable disease, a 54-year-old female with a large cell neuroendocrine carcinoma who received 12 cycles of REQORSA therapy, had evidence of a durable metabolic response, which is a lasting reduction of metabolic activity in the tumor, as shown by positron emission tomography ("PET") imaging. The response was documented with PET scans performed after the second, fourth and sixth doses, all showing decreased metabolic activity in the tumor with no changes in size or number of metastases by computed tomography ("CT") imaging. The illustration below is of the PET scan of this subject performed after the fourth dose. This subject had received six prior chemotherapy regimens. Prior to entry in the Phase 1 Monotherapy Trial, two hepatic metastases were progressing on gemcitabine. The subject also had a metastasis in the head of the pancreas and a peripancreatic lymph node, shown by the arrows in the illustration below. Illustration A shows the pretreatment PET scan. The dose of Fluorodeoxyglucose (18F) was 8.8mCi. Illustration B shows the post treatment PET scan performed 20 days following the fourth dose of REQORSA. The dose of Fluorodeoxyglucose (18F) was 9.0mCi. All scans were performed within a 60 to 90 minute window after injection.



Metabolic Tumor Response in a Metastatic Lung Cancer Subject

This subject survived after subsequent therapy more than seven years after the final treatment with REQORSA, to our knowledge, without evidence of cancer progression in the responding sites.

ONC-002: Phase 1/2 - Trial Combining REQORSA with Tarceva (Phase 1 portion completed; Phase 2 portion no longer enrolling in favor of conducting Acclaim-1)

Phase 1 Portion: The Phase 1 Monotherapy Trial showed that REQORSA is well tolerated, that high levels of TUSC2 expression are detected in the tumor post-treatment, and that there is evidence of tumor growth suppression. Based on the results from the Phase 1 Monotherapy Trial and substantial preclinical evidence that REQORSA is complementary with EGFR TKIs, we began a Phase 1/2 trial (the "Phase 1/2 Combination Tarceva Trial") at MD Anderson combining REQORSA with Tarceva in patients with Stage IV (metastatic) or recurrent NSCLC that is not potentially curable by radiotherapy or surgery, whether or not they have received prior chemotherapy, and whether or not they have an activating EGFR mutation. Enrollment in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial commenced in 2014 at MD Anderson with Dr. Charles Lu as the Principal Investigator.

In the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial, 18 subjects were treated with the following dose levels:

Dose Level	Drug Doses
1	Tarceva (100 mg/day) + REQORSA (0.045mg/kg)
2	Tarceva (100 mg/day) + REQORSA (0.06mg/kg)
3	Tarceva (150 mg/day) + REQORSA (0.045mg/kg)
4	Tarceva (150 mg/day) + REQORSA (0.06mg/kg)

As in the Phase 1 Monotherapy Trial, subjects received a pre-treatment regimen of oral and intravenous dexamethasone and diphenhydramine to reduce fever, along with an infusion of REQORSA every three weeks. Subjects received oral Tarceva daily during each three-week cycle during the treatment period.

The Phase 1 portion of the Phase 1/2 Combination Tarceva Trial was also a dose escalation study with the primary purpose of determining the MTD. DLT were defined as grade 3, 4, or 5 events during the first cycle of treatment that were considered to be treatment related. At dose level 1, one subject had grade 3 adverse events of fatigue, muscle weakness, and hyponatremia (low sodium level) considered to be related to the study treatment (Tarceva). Therefore, three additional subjects were treated at this dose level (six subjects total), none of whom suffered a DLT. At dose level 2, there were no DLTs. At dose level 3, one subject had a grade 3 rash considered to be related to the study treatment (Tarceva); therefore, an additional three subjects were treated at this dose level (six subjects total). No additional subjects suffered a DLT. At dose level 4, there were no DLTs; thus dose level 4 was determined to be the MTD.

Once the MTD for the study treatment combination was determined in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial to be Dose Level 4, accrual proceeded with the Phase 2 portion of the study. Since the eligibility criteria, drug administration details (other than dose) and evaluation details were identical for the Phase 1 portion and the Phase 2 portion, three subjects in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial who were treated at the MTD were included in the Phase 2 portion of the study.

Four patients in the Phase 1 portion of the study had stable disease ranging from 12 weeks to 36 weeks. The following observations from our preclinical studies and from the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial provided the rationale for proceeding with the Phase 2 portion of the study:

- TUSC2 inhibits a variety of tyrosine kinases including EGFR, PDGFR, c-kit, and c-abl;
- expression of TUSC2 in NSCLC cells combined with EGFR TKIs is complementary *in vitro* and *in vivo*;
- intravenous administration of a nanoparticle encapsulated TUSC2 expression plasmid effectively delivers TUSC2 to distant tumor sites and mediates an anti-tumor effect in orthotopic human lung cancer xenograft models; and
- when the TUSC2-nanoparticle is combined with an EGFR TKI, the suppression of tumor growth in mouse xenograft models is synergistic.

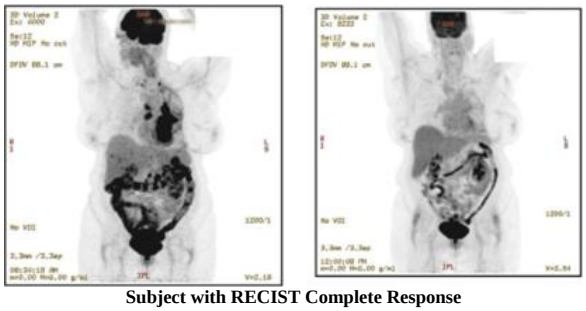
Phase 2 Portion: The Phase 2 portion of the Phase 1/2 Combination Tarceva Trial was designed to include subjects treated with the combination of REQORSA and Tarceva at the MTD with the primary goal of measuring the response rate, and secondary endpoints of stable disease, time to progression and overall survival. The response rate for cancer therapies is defined under the RECIST as Complete Response (CR) + Partial Response (PR); disease control rate is defined under the RECIST criteria as Complete Response (CR) + Partial Response (PR) + Stable Disease (SD) > 8 weeks.

Enrollment criteria for the Phase 2 portion were identical to those in the first phase. The first subject enrolled in the Phase 2 portion began Tarceva on Day 8, and subsequently every other enrolled subject began Tarceva on Day 8. The rationale for delaying Tarceva was to allow exploratory analyses of potential differential effects of REQORSA alone and in combination with Tarceva on downstream pathway activation and potential biomarkers of Tarceva resistance. Subjects received three-week cycles of REQORSA in combination with Tarceva until the occurrence of progressive disease (PD), unacceptable toxicity, withdrawal of consent, or study treatment discontinuation for other reasons, whichever occurred first.

Of the 39 patients allowed in the protocol for the Phase 2 portion of the trial, 10 were enrolled (three of whom were also subjects of the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial) and nine were evaluable for response under the trial protocol, because they received two or more cycles of treatment. None of the 10 subjects treated in the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial suffered a DLT. Interim results from the Phase 2 portion for the 9 evaluable patients show that:

- One patient had a response rate for a study response rate of 11%; this response was a CR;
- Four patients had tumor regression;
- The median response duration for all patients (the median time between when response is first noted to the time when cancer progression is observed) was three months; and
- Disease control rate for the nine patients was 78%.

The patient with the CR, a 58-year-old female, upon enrollment in the study had metastatic NSCLC status following 6 cycles of pemetrexed and carboplatin and two cycles of maintenance pemetrexed with cancer progression. The patient's tumor has EGFR exon 18 and 20 missense mutations, which are not sensitive to Tarceva. As shown in the illustrations below, this patient had disappearance of both the lung primary tumor and the lung, liver and lymph node metastases.



Subject with RECIST Complete Response

We are no longer enrolling the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial in favor of conducting Acclaim-1.

The response rate and disease control rate in the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial substantially exceeds the response rate of 7% (with no CRs) and disease control rate of 58% reported for a clinical trial of the EGFR TKI afatinib (marketed as Gilotrif® by Boehringer Ingelheim Pharmaceuticals, Inc.) in a study referred to as the LUX-Lung 1 clinical trial. A total of 585 patients were enrolled in that Phase 2b/3 clinical trial, whose primary endpoint was overall survival and whose secondary endpoints were progression-free survival, RECIST response, quality of life and safety. The LUX-Lung 1 clinical trial was a randomized, double blinded Phase 2b/3 clinical trial treating subjects with Stage IIIB or IV adenocarcinoma, a type of NSCLC. The Phase 2 portion of our Phase 1/2 trial was not blinded, and was designed to treat NSCLC subjects regardless of EGFR status.

The following table sets forth interim data from the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial for subjects with and without EGFR mutations.

REQORSA + TARCEVA COMBINATION

PHASE 2 PRELIMINARY DATA IN SUBJECTS WITH OR WITHOUT EGFR MUTATIONS

PATIENT EGFR STATUS	RESPONSE	PRIOR THERAPY	LINE OF THERAPY
Positive (exon 18+20)	Complete Response	Chemo	3
Negative	24% regression Target Lesion	Chemo / anti-PD1	2
Negative	30% regression one Target Lesion 18% regression all Target Lesion	Chemo / anti-PD1	6
Positive (exon 21) / T790M Negative	Tumor Regression Metabolic response *PET Scan*	Tarceva *Multiple cycles*	3
Positive (exon 21)	Stable Disease	Tarceva	2
Negative	Stable Disease	Chemo	2
Negative	Stable Disease	Chemo	4

- *Combination therapy (re)sensitizes lung cancer cells and/or overcomes resistance to targeted therapies and other classes of drugs (i.e. anti-PD1 inhibitor). Slowed tumor progression in 7 out of 9 patients – 78% disease control rate (DCR; RECIST criteria).*
- *9 out of 10 patients evaluable to date, all but one received prior treatments. One subject withdrew consent.*
- *Genprex does not intend to reopen enrollment in this Phase1/2 trial.*

Preclinical Studies of REQORSA supporting our conduct of Acclaim-1

REQORSA and Tyrosine Kinases. Investigators at MD Anderson conducted preclinical research showing that REQORSA alone blocked the activation of the c-Abl tyrosine kinase. A number of other studies at MD Anderson have shown the complementary effects of REQORSA combined with a variety of targeted kinase inhibitory agents, both marketed and in various stages of clinical development, including Tarceva, Iressa, Tagrisso, MK2206, and others. Researchers investigated the use of REQORSA combined with commercially available EGFR TKI drugs Tarceva and Iressa, and conducted preclinical *in vitro* and *in vivo* studies combining REQORSA with these drugs in a variety of human lung cancer cell lines, including cancers with activating EGFR mutations and EGFR mutation negative cancers. Lung cancers known to have intrinsic and acquired resistance to Tarceva therapy were also studied, as were Kras-related and other cancers. Notably, studies in xenograft animal models showed that REQORSA and either Tarceva or Iressa showed synergistic anti-cancer effects, superior to either agent used alone, in both EGFR mutation negative cancers (generally not candidates for Tarceva) and in EGFR mutation positive cancers (optimal candidates for Tarceva), including cancers known to be resistant to Tarceva therapy. The addition of REQORSA to either Tarceva or Iressa overcame drug-induced resistance by simultaneously inactivating EGFR and AKT signaling pathways and by inducing apoptosis in Tarceva- or Iressa-resistant cancers with EGFR mutations and with EGFR mutation-negative cancers.

In one study, MD Anderson researchers tested the combination of Tarceva and REQORSA against five human NSCLC cell lines: H1299, H322, A549, H460, and H1975, the latter of which has the L858R and T790M EGFR mutations and is highly resistant to Tarceva. The results showed that the combination of REQORSA and Tarceva significantly reduced NSCLC colony formation beyond the effect of Tarceva, REQORSA or controls alone ($p<0.01$ at both 1 and 2.3 uM concentrations for all cell lines). The cooperative interaction between Tarceva and REQORSA was confirmed *in vivo* using a lung colony formation metastases model in nu/nu mice with A549 human lung cancer cells injected in the tail vein. Mice were treated with the combination of REQORSA and Tarceva and various controls including empty nanovesicles, Tarceva alone, REQORSA alone, and other controls.

The greatest reduction in lung colonies occurred in the REQORSA with Tarceva combination (90% reduction) which was reduced compared to all control groups ($p<0.0005$). In terms of total tumor nodules, the cooperative effect is greater than 0.9999. This means that there is less than a 1 in 10,000 chance that the low dose Tarceva with TUSC2 combination does not have a cooperative effect and greater than 9,999 in 10,000 chance that the cooperative effect exists. P-value is the probability that the difference between two data sets was due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In general, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. The FDA's evidentiary standard of efficacy generally relies on a p-value of less than or equal to 0.05.

REQORSA and TUSC2 deficient and Tarceva or Iressa resistant cell lines. MD Anderson researchers also tested REQORSA in TUSC2-deficient and Tarceva- or Iressa-resistant NSCLC cell lines. Treatment of the NSCLC EGFR mutation negative cell lines H1299, H322, H358 and H460 cancer cell line showed that the REQORSA combination significantly sensitized ($p<0.001$) response of the cancer cell lines to both Tarceva or Iressa treatment and synergistically induced apoptosis *in vitro*. The findings were confirmed *in vivo* in an H322 orthotopic lung cancer mouse model. These studies included the Kras mutant cell line H460, which is significant because patients with Kras mutant tumors are generally unresponsive to Tarceva or Iressa. Synergistic induction of apoptosis was observed with the combination of REQORSA and concentrations of Tarceva or Iressa similar to steady-state serum concentrations achievable with oral dosing. The combination of REQORSA and either Tarceva or Iressa induced similar levels of tumor cell growth inhibition, apoptosis induction, and inactivation of oncogenic protein kinases.

Data from these and other MD Anderson studies suggest a combination of REQORSA with Iressa or Tarceva can promote synergistic tumor cell killing and overcome drug-induced resistance by simultaneously inactivating the EGFR and the AKT signaling pathways and by inducing apoptosis in resistant cells with nonmutated EGFR. These data suggest that NSCLC patients with an activating EGFR mutation, whose cancer progresses on Tarceva, may potentially benefit from REQORSA with Tarceva combination therapy. These data also suggest that NSCLC patients without an activating EGFR mutation (generally unresponsive to Tarceva) may potentially benefit from REQORSA with Tarceva combination therapy.

TUSC2 and Tumor Sensitivity. In another study, MD Anderson researchers analyzed the effects of TUSC2 re-expression on the sensitivity of tumor cells to the AKT inhibitor MK2206 *in vitro* and in mice. The AKT pathway is an important intracellular, converging positive regulator of apoptosis. AKT stimulates apoptosis and is frequently dysregulated in cancers, and this has been associated with reduced sensitivity to anti-tumor drugs. The study showed that the combination of TUSC2 transfection with MK2206 treatment suppressed tumor cell viability *in vitro* and effectively inhibited xenograft tumor growth *in vivo* more effectively than either agent alone.

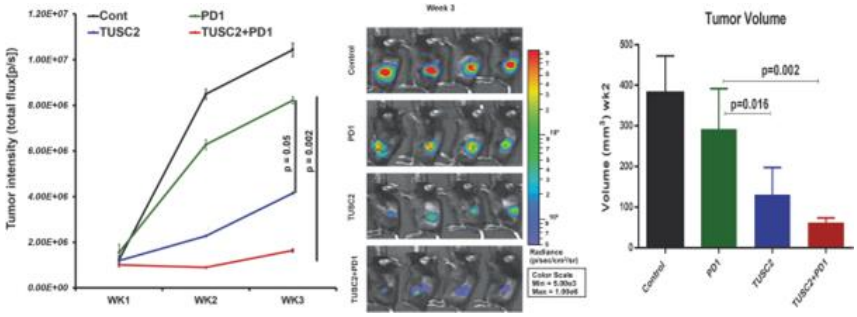
Preclinical Studies of TUSC2 in the Immune Response to Cancer supporting our conduct of Acclaim-2

Previous research has shown that TUSC2 regulates cytokine expression *in vitro*. Cytokines are proteins that stimulate inflammation as part of the immune response. Stable expression of TUSC2 in H1299 NSCLC cells altered expression of a wide spectrum of cytokines including IL2, IL7, IL8 and 10, GM-CSF and PDGF-beta. TUSC2 is a positive regulator of innate immunity via regulation of IL-15 expression. IL-15 induces NK cell differentiation.

The systemic effect of the TUSC2 and anti-PD1 antibody combination was examined in two immunocompetent, syngeneic mouse models of Kras and p53 mutant lung cancer. C57BL/6 mice were subcutaneously injected with murine adenocarcinoma lung carcinoma CMT/167-luc cells (KrasG12V mutation). CMT/167 cells do not express TUSC2. Tumors from untreated mice, isotype antibody control, or those treated with anti-PD1 were used as controls. 344SQ (KrasG12D allele and a knock-in Trp53R172HÄG allele) adenocarcinomas which metastasize to the lung in 126S2 mice were also used. When tumors reached 50-100 mm3, mice were either injected intravenously with DOTAP:cholesterol (DC)-TUSC2 complex alone (at a dose of 25 “g of plasmid DNA and 10 nmol DC, every 48 hours for three injections), or (DC)-TUSC2 complex combined with anti-PD1 antibody (250 “g for four injections) alone or combined with anti-CTLA4 (100ug for three injections). Tumor growth and development was monitored by scoring ex-vivo luminescence using the IVIS Imaging System 200 Series. All tumor measurements were blinded to treatment and results were analyzed independently by biostatisticians.

Preclinical Study Showing that the TUSC2 and Anti-PD1 Combination Cooperatively Inhibits Growth of CMT/167 Lung Adenocarcinomas

Mouse experiments showed combined treatment with TUSC2 and anti-PD1 antibody superior to anti-PD1 alone in five independent experiments in two different tumor models. Results of a representative experiment are shown in the graph below. By week three the reduction in tumor image intensity by the combination of TUSC2 and anti-PD1 and TUSC2, anti-PD1, plus anti-CTLA4 was greater than the reduction with TUSC2 alone, anti-PD1 combined with anti-CTLA4, or the isotype control. Spleens and blood were collected for immunological analysis profiling by multicolor flow cytometry. Immune profiling panels were designed to evaluate response and major changes of specific regulatory innate and adaptive immune cells to TUSC2 or anti-PD1 treatment in peripheral blood and spleen.



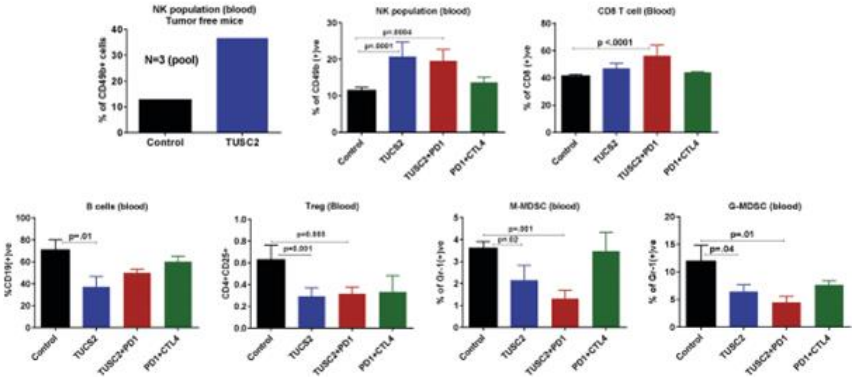
Preclinical Study Showing Effect of TUSC2 Anti-PD1 Combo on T Lymphocytes

Preclinical Study Showing the Effect of the TUSC2 and Anti-PD1 Combination on T Lymphocytes

The population of NK cells, cytotoxic lymphocytes critical to innate immune function, was assessed in peripheral blood mononuclear cells ("PBMCs") in tumor bearing mice treated with anti-PD1, TUSC2 alone and the combination. As shown in the graph below, the NK cell population increased strongly in the TUSC2 alone and TUSC2+PD1 groups which correlated with tumor regression. Anti-PD1 alone had no effect on NK cell proliferation.

Tumor free mice without mutations that lead to metastasis were injected intravenously with TUSC2 which caused a threefold up-regulation of NK cells in the peripheral blood of TUSC2 injected mice as compared with non-injected mice. CD8 T cells, which are cytotoxic T cells ("CTL") for tumor killing, act as a prognostic marker of tumor regression. Increased numbers of CTL were found in the TUSC2 and TUSC2+PD1 groups as compared with that of the control group which directly correlated with the anti-tumor effect, as shown in the graph below. Lower levels of CD62L expression on T lymphocytes in TUSC2 treated mice suggests that TUSC2 regulates T cell activation. Moreover, TUSC2 induced down-regulation of regulatory T cells (Treg, CD4+CD25+). TUSC2 was shown to down-regulate checkpoint markers such as PD-1, CTLA-4, Tim-3, and LAG-3.

Effect of TUSC2 alone or in combination with anti-PD1 on immune cell populations in peripheral blood. Multi-color flow cytometry showed that TUSC2 significantly upregulated NK and cytotoxic T cells, and downregulated regulatory T cells, myeloid-derived suppressor cells (MDSCs), and B lymphocytes in tumor-bearing mice. The plot at the upper left shows that TUSC2 upregulated NK cells by 3-fold in tumor-free mice. All analyses were done 2 weeks after tumor cell implantation.



Effect of TUSC2 with Anti-PD1 on Immune Cell Populations in Peripheral Blood (Large)

Preclinical Study Showing that TUSC2 Immunogene Therapy is Synergistic with Anti-PD1 in Lung Cancer Syngeneic Mouse Models

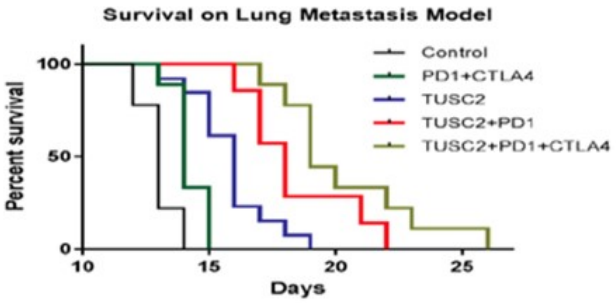
Based on the prolonged responses that were observed in TUSC2 clinical trials, which suggest that TUSC2 may modulate the immune response, and on the fact that checkpoint blockade immunotherapy against PD1 and PD-L1 has yielded durable antitumor activity in a subset of NSCLC patients, MD Anderson researchers conducted a preclinical study to investigate the immune response to TUSC2 in immune cell populations and the synergistic antitumor effect of TUSC2 in combination with anti-PD1 checkpoint blockade in syngeneic mouse NSCLC models.

Two Kras-mutant syngeneic mouse models were used to explore the effect of TUSC2+anti-PD1 (+/- anti-CTLA-4) on immune cells infiltration into the tumor micro-environment. Activating Kras mutations are the most common driver mutations in lung adenocarcinomas. Lung cancer with mutant Kras has a poor prognosis, is often resistant to conventional therapy, and readily becomes resistant to targeted therapies with kinase inhibitors. Studies by researchers not at MD Anderson have found that PD1 expression was highly associated with the presence of Kras mutations and that PD-L1 expression was elevated in premalignant Kras-mutant cells, suggesting that Kras mutation may affect the function of the PD1/PD-L1 immune checkpoint pathway.

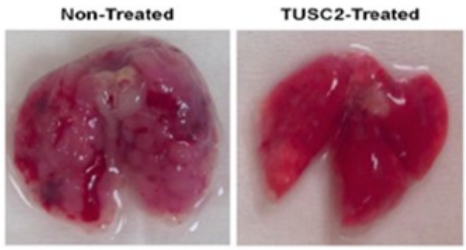
The first syngeneic mouse model used a murine lung carcinoma cell line CMT/167-luc with a Kras G12V mutation and a low level of TUSC2 expression, implanted subcutaneously in C57BL/6 mice. The second syngeneic mouse model optimized an aggressive experimental metastatic lung cancer model using 129SvE mice injected with SQ344 lung cancer cells, which contained KrasG12D allele. The SQ344 tumor model was found to be less sensitive to anti-PD1 single agent treatment.

The image below shows the results of this preclinical study, in which anti-PD-1, TUSC2 and anti-CTLA-4 treatments were administered in the SQ344 metastatic lung tumor mouse model. The graph on the left shows the survival of the mice with the lung tumor cells treated with (a) no treatment, (b) a combination of anti-PD-1 and anti-CTLA-4, (c) TUSC2 alone, (d) a combination of TUSC2 and anti-PD-1, and (e) a combination of TUSC2, anti-PD-1 and anti-CTLA-4. The image on the right shows samples of untreated lung tissue and lung tissue treated with TUSC2.

REQORSA IS SYNERGISTIC WITH ANTI-PD1 IN A SYNGENEIC MOUSE MODEL OF LUNG CANCER



TUSC2+anti-PD1 exhibit greater antitumor activity than either agent alone or control.



TUSC2+anti-PD1 combination significantly prolonged survival in a lung metastasis model refractory to checkpoint blockade alone.

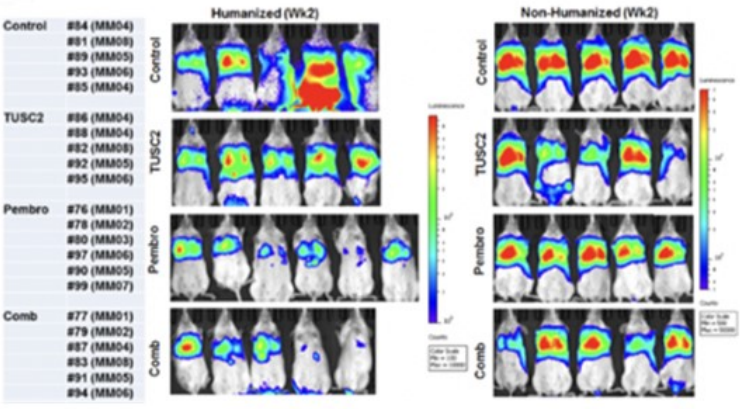
Preclinical Studies Showing that TUSC 2 Immunogene Therapy is Synergistic with Anti-PD1 in Lung Cancer Humanized Mouse Models

The results of a preclinical study combining anti-PD1 with TUSC2 immunogene therapy showed strong antitumor immune responses of anti-PD-1 against PDX (patient derived xenograft) tumors developed in humanized mice. In addition, TUSC2 plus anti-PD1 plus a chemotherapy combination resulted in metastasis regression significantly greater than either TUSC2 immunogene therapy alone or anti-PD1 plus chemotherapy.

REQORSA IS SYNERGISTIC WITH ANTI-PD1 IN A HUMANIZED MOUSE MODEL OF LUNG CANCER

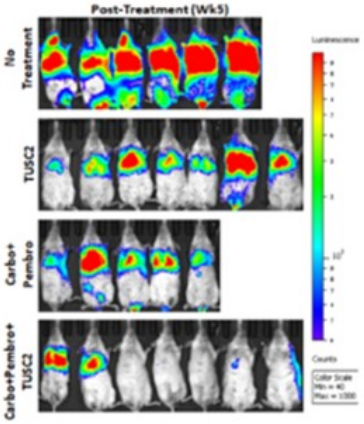
REQORSA + Keytruda

Strong antitumor immune responses of anti-PD1 were found against PDX tumors developed in humanized mice.



REQORSA + Keytruda + Chemo

REQORSA+anti-PD1+chemo combination resulted in metastasis regression significantly greater than either REQORSA alone or anti-PD1+chemo.



Discovery Programs

ONCOPREX® Nanoparticle Delivery System as a platform. We believe that the ONCOPREX Nanoparticle Delivery System may be applicable to delivery of a range of therapeutic and prophylactic plasmid DNA and RNA interference constructs and show efficacy in cancers beyond NSCLC. The manufacturing methods we have developed for REQORSA have been optimized and we believe they may be useful for a wide array of disease treatments. Clinical data from the use of REQORSA has shown that the ONCOPREX Nanoparticle Delivery System is well tolerated in humans and can be delivered at high therapeutic doses.

Rights to other Tumor Suppressor Genes. We have licensed rights to a group of candidate tumor suppressor genes, including 101F6, NPRL2, CACNA2D2, PL6, BLU, RASSF1, HYAL 1 and HYAL2, in addition to tumor suppressor gene, TUSC2, all of which are located in a sub-region of human chromosome 3 known as 3p21.3. Using a number of techniques, MD Anderson researchers and their collaborators have identified these genes as potentially having cancer-fighting characteristics. MD Anderson researchers have subsequently conducted a number of preclinical studies on certain of these genes, particularly 101F6 and NPRL2, as well as TUSC2, both alone and in combination with other compounds, in order to assess their actual effects on NSCLC. Under our Sponsored Research Agreement with MD Anderson, we plan to continue to support continuing research into the cancer-fighting properties of these and other genes in the 3p21.3 sub-region.

Researchers at MD Anderson have collaborated with other researchers to identify other genes, such as those in the 3p21.3 chromosomal region, that may act as tumor suppressors or have other cancer fighting functions. We hold rights to certain of these genes under license agreements with MD Anderson. Data from preclinical studies performed by MD Anderson researchers and others suggest that TUSC2, the active agent in REQORSA, could be effective against other types of cancer, including glioblastoma, head and neck, breast (including triple-negative breast cancer), renal cell (kidney), thyroid, and soft tissue sarcoma, as well as NSCLC. Therefore, the ONCOPREX Nanoparticle Delivery System may allow delivery of a number of cancer fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer.

Introduction – Diabetes

Diabetes Mellitus. Diabetes mellitus refers to a group of metabolic diseases that affect how the body produces and uses blood sugar (glucose). Glucose is vital to health because it is an important source of energy for the cells that make up the body’s muscles and tissues. It is also the brain's main source of fuel. Chronic diabetes conditions include Type 1 diabetes and Type 2 diabetes, both of which lead to excess sugar in the blood and can cause serious health problems. Left untreated, high blood sugar levels can damage eyes, kidneys, nerves, and the heart, and can also lead to coma and death.

Epidemiology of Diabetes. According to the U.S. Center for Disease Control, 34.2 million Americans, or approximately 10.5% of the population, have diabetes. It is also believed that more than 88 million Americans have prediabetes, which represents approximately 35% of the U.S. population. The prevalence of this chronic disease is continuing to rise.

The Role of Alpha Cells and Beta Cells. The two most abundant endocrine cell types in the pancreas, the beta and the alpha cells, are essential for the maintenance of blood glucose homeostasis whereby levels of glucose are maintained by the body within a narrow range. While the beta cell produces insulin, the only blood glucose-lowering hormone of the body, the alpha cell releases glucagon, which elevates blood glucose. While the release products of the beta cell inhibit alpha cell function, the alpha cell releases factors that are stimulatory for beta cell function and increase glucose-stimulated insulin secretion.

In people with Type 1 diabetes, however, beta cells are destroyed by the immune system and no longer secrete insulin leading to an absolute deficit of insulin. Type 2 diabetes is due to "insulin resistance," an initial resistance of the body's cells to obey the direction from insulin. To overcome this resistance, the beta cells secrete more insulin, and glucose is eventually forced into the cells. Glucose is maintained within normal limits, but at the expense of increased insulin secretion by the beta cells. After many years of such increased secretion, the beta cells become "tired" from working overtime, and the fatigue process begins. This fatigue tends to be progressive, and in time the compensation of insulin resistance disappears. At that point, blood glucose levels start going up.

Current Treatments for Diabetes. Advances in new treatments have helped many people better manage the disease. However, despite patients' best attempts, managing diabetes remains a challenging, daily balancing act because insulin therapy simply cannot ideally mimic the body’s biological function.

Type 1 diabetes patients are treated with insulin, with most of the progress in therapy relating to enhanced delivery of the drug and improved methods for measuring blood glucose levels. A variety of drug release technologies have allowed for rapid-acting, intermediate-acting and long-acting insulin injections that provide drug anywhere from one to 24 hours. In addition, improvements in needles, continuous delivery ports, and inhalation technologies all have helped patients better manage their disease and may impact quality of life, but none of these advances are disease modifying.

Type 2 diabetes patients are advised to use diet and exercise to manage their condition. When these lifestyle changes alone do not control the disease, Type 2 diabetes patients may be prescribed a variety of medications that help alter how the body manages blood sugar levels. For example, biguanides such as Metformin®, reduce the amount of glucose produced in the liver. DPP-4 inhibitors, such as Januvia®, Onglyza®, and Tradjenta®, improve blood sugar levels and prevent them from dropping too low. Glucagon-like peptides, such as Byetta®, Trulicity® and Victoza®, change the way the body produces insulin. Drugs in the SGLT2 inhibitor class, such as Farxiga and Inokana, release more glucose into the urine. Finally, insulin injections may be needed if these oral medications, along with diet and exercise, do not lower blood sugar levels enough. These medications, including insulin replacement therapy, while offering improvements for Type 2 diabetes patients, do not affect the underlying cause of the disease.

GPX-002

We have licensed a pre-clinical gene therapy from the University of Pittsburgh to restore the function of beta cells that are destroyed by the immune system and overcome further destruction of insulin-producing cells. This technology, referred to us as GPX-002, infuses adeno-associated virus carrying Pdx1 and MafA gene expression cassettes through the pancreatic duct to reprogram alpha cells into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body’s immune system.

Preclinical Studies

GPX-002 has been tested *in vivo* in mice and nonhuman primates. In studies in non-obese diabetic mice, a model of Type 1 autoimmune diabetes, the gene therapy approach restored normal blood glucose levels for an extended period of time, typically around four months. According to the researchers, the duration of restored blood glucose levels in mice could potentially translate to decades in humans. If successful, this gene therapy could eliminate the need for insulin replacement therapy for diabetic patients.

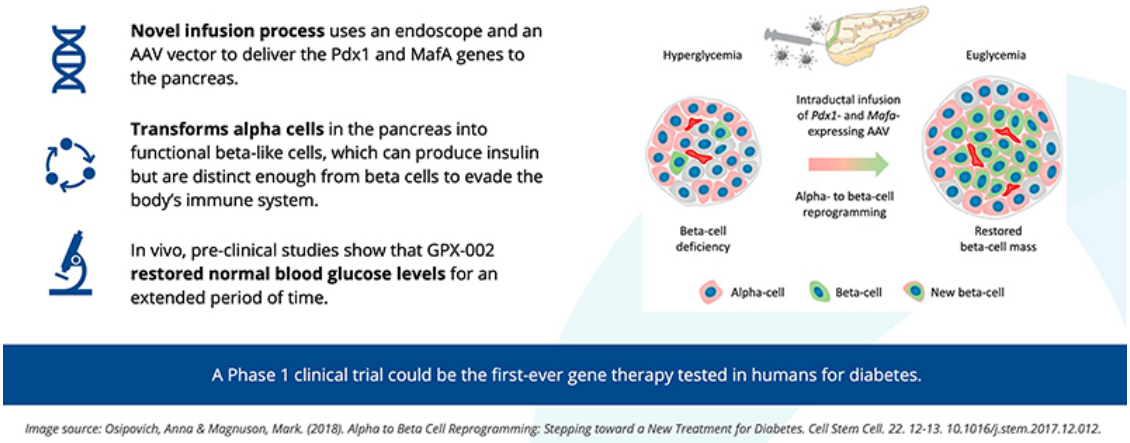


Image source: Osipovich, Anna & Magnuson, Mark. (2018). Alpha to Beta Cell Reprogramming: Stepping toward a New Treatment for Diabetes. Cell Stem Cell. 22. 12-13. 10.1016/j.stem.2017.12.012.

Process Development and Manufacturing

We have developed a robust manufacturing process for REQORSA through years of process development. REQORSA is an immunogene therapy with two main components. The active agent in REQORSA is a DNA plasmid encoding the TUSC2 protein. The plasmid is encapsulated by non-viral DOTAP cholesterol lipid nanoparticles. This system of encapsulating DNA plasmid in non-viral lipid nanoparticles is referred to by us as our ONCOPREX Nanoparticle Delivery System. Each of these two components is manufactured by separate third-party contract development and manufacturing organizations ("CDMOs") and then transported to another CDMO for final drug formulation. We do not currently have the internal infrastructure or facilities to manufacture REQORSA or any other product candidate for use in the conduct of our clinical trials or for commercial supply; however, our strategy could change in the future and we could choose to develop this infrastructure. Where other gene therapy agents need to be prepared individually for each patient or require viral vectors for gene delivery, REQORSA utilizes the ONCOPREX Nanoparticle Delivery System and has been shown to be scalable at current Good Manufacturing Practices ("cGMP") and stored for at least one year for later use. Successful tech transfer of REQORSA from MD Anderson, where it was previously manufactured, to a CDMO has been achieved as well as scale-up of our clinical grade manufacturing production in accordance with cGMP. The clinical grade production will be used to supply our Acclaim-1 and Acclaim-2 clinical trials. We manage our manufacturing arrangements with our CDMO vendors through various agreements.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek the broadest intellectual property protection possible for our products, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We hold a worldwide, exclusive license to 27 issued patents and 17 pending patent applications for technologies developed at MD Anderson and The University of Texas Southwestern Medical Center. These patents comprise various therapeutic, diagnostic, technical and processing claims relating to REQORSA, our ONCOPREX Nanoparticle Delivery System. We also hold a worldwide, exclusive license to an issued patent for diabetes technologies developed at the University of Pittsburgh.

We also have received trademark registrations for the trademarks GENPREX and ONCOPREX and have filed a trademark application for the drug name REQORSA.

Licenses and Research Collaborations

Agreements with MD Anderson

Our ONCOPREX and REQORSA technologies are exclusively licensed pursuant to a Patent and Technology License Agreement ("MD Anderson License Agreement") dated July 20, 1994 with MD Anderson, as amended on September 1, 1996, August 11, 1997, July 31, 1994 and October 4, 2001, between MD Anderson and Introgen Therapeutics, Inc. (f/k/a Intron Therapeutics, Inc.) ("Introgen").

Pursuant to the MD Anderson License Agreement, we have rights to patents covering use of various genes, including the TUSC2 gene, for treatment of cancer, as well as know-how and related intellectual property.

The exclusive licenses under the MD Anderson License Agreement, will continue until the expiration of all patents covered by such agreement. Upon the expiration of the exclusive licenses, we will have a non-exclusive, fully paid-up right and license to use and otherwise exploit the technology rights licensed under the agreement. MD Anderson may terminate the agreement for, among other things, a breach of the agreement by us which remains uncured.

Pursuant to a Technology Sublicense Agreement dated March 7, 2007 ("Sublicense Agreement"), Introgen sublicensed its rights under the MD Anderson License Agreement to Introgen Research Institute, Inc. ("IRI") a company formed and owned by Rodney Varner, our current President, CEO and Chairman of the board of directors.

Pursuant to an Assignment and Collaboration Agreement dated April 13, 2009 ("IRI Collaboration Agreement") IRI assigned its rights under the Sublicense Agreement to us, and we granted to IRI a non-exclusive, royalty-free license to use and practice the licensed technology for non-commercial research purposes. As consideration for this assignment, we agreed to assume all of IRI's obligations to MD Anderson under the MD Anderson License Agreement, including ongoing patent related expenses and royalty obligations.

The IRI Collaboration Agreement was amended by an Amended Collaboration and Assignment Agreement dated July 1, 2011 ("2011 IRI Collaboration Agreement"). The 2011 Collaboration Agreement provided that IRI would provide additional licensing opportunities and services to us, in return for monthly payments and our obligation to pay to IRI a royalty of 1% on sales of products licensed to us under the MD Anderson License Agreement. In 2012, IRI's obligation to provide those opportunities and services, and our obligation to make monthly payments to IRI, were terminated; however, we are required to pay a 1% royalty to IRI upon sales of products licensed to us under the MD Anderson License Agreement which royalty obligation continues for 21 years after the later of the termination of the MD Anderson License Agreement and the termination of the sublicense assigned by IRI to us.

Pursuant to a Technology Sublicense Agreement dated June 1, 2011, we granted to IRI a non-exclusive sublicense, for non-commercial purposes, to the rights under the Sublicense Agreement.

At the time that we entered into the 2011 IRI Collaboration Agreement, Mr. Varner was not an officer or director of Genprex, but he was deemed to be an "affiliate" of the Company due to his beneficial ownership of approximately 39% of our issued and outstanding shares. At the time we acquired the ONCOPREX and REQORSA technologies under the 2009 IRI Collaboration Agreement, they were the subject of the Phase 1 Monotherapy Trial. We completed the Phase 1 Monotherapy Trial and did substantial process development, manufacturing and regulatory work necessary to bring the technologies into a Phase 1/2 combination trial.

Pursuant to the MD Anderson License Agreement, the Sublicense Agreement and the 2009 IRI Collaboration Agreement, we are obligated to pay all fees, patent related expenses, royalties, and other amounts that become due with respect to the licensed patents, patent application and other technologies. We are also obligated to pay to MD Anderson royalties of 1.5% of net sales of the licensed products, as well as 1.5% of advance payments received by us (excluding amounts paid to us in reimbursement of development or other costs) from third parties pursuant to sublicense, marketing, distribution or franchise arrangements. Under the 2011 IRI Collaboration Agreement, we are obligated to pay to IRI a royalty of 1.0% of net sales of licensed products and 1.0% of certain other payments received by us. This royalty obligation continues for 21 years after the later of the termination of the MD Anderson License Agreement and the termination of the Sublicense Agreement. We have no other payment obligations to IRI under the 2009 IRI Collaboration Agreement or the 2011 IRI Collaboration Agreement. We were not required to make any up-front payments to MD Anderson or IRI when we entered into the MD Anderson License Agreement, the Sublicense Agreement or the 2009 IRI Collaboration Agreement.

On May 4, 2020 (the "MD Effective Date"), we entered into a Patent and Technology License Agreement with MD Anderson, as amended on March 3, 2021 (collectively, the "2020 License Agreement"). Pursuant to the 2020 License Agreement, MD Anderson granted us a worldwide, exclusive, sublicensable, royalty-bearing license to certain licensed intellectual property and technology, including, without limitation, use of chemotherapy in combination with TUSC2 therapy and methods for treating cancer by administration of a TUSC2 in conjunction with EGFR inhibitors or other anti-cancer therapies in patients that are expected to be responsive to TUSC2 therapy (collectively, the "Licensed IP"), to manufacture, use, commercialize, seller, offer for sale and import licensed products related to the treatment of cancer using TUSC2 therapy in combination with certain immunotherapies (the "Licensed Products"). In consideration for our use of the Licensed IP, we are required to make certain payments to MD Anderson, including, without limitation, an upfront license fee as well as a fee paid to amend the agreement, annual maintenance fees ranging from the low five figures to low six figures, milestone payments aggregating up to a maximum of $6,150,000, low single digit royalty payments to low double digits royalty payments with lower net sales being subject to lower royalty payments, and minimum annual royalties after the first sale in a low six figure amount. In addition, we shall be required to reimburse MD Anderson for certain patent expenses. The 2020 License Agreement shall expire on the later to occur of (a) the expiration of all patents issued under the Licensed IP and the cancellation, withdrawal, or express abandonment of all patent applications under the Licensed IP, or (b) 30 years after the MD Effective Date, unless earlier terminated pursuant to the terms thereof. In 2015 and 2017, we entered into two option agreements with MD Anderson, paying MD Anderson $35,000 and $37,803, respectively, for the rights to negotiate exclusive rights to additional licensed intellectual property and technology from MD Anderson.

License Agreement with P53, Inc.

On February 26, 2010, IRI and P53, Inc. entered into a Technology License Agreement ("P53 License Agreement") pursuant to which IRI granted to P53, Inc. ("P53") a worldwide, exclusive license under certain patents related to the ONCOPREX Nanoparticle Delivery System that we are now using for the delivery of TUSC2, but only for P53's use in gene therapy products in which the sole active genes are P53 and MDA-7. As a result of the 2009 IRI Collaboration Agreement, we are the licensor under the P53 License Agreement.

The P53 License Agreement authorizes P53 to develop, make and have made, use, offer for sale, sell, import and otherwise distribute the licensed products. As consideration for the P53 License Agreement, P53 agreed to pay IRI one-half of all amounts invoiced by MD Anderson to IRI, up to a maximum of $15,000 to be paid by P53, for patent prosecution expenses incurred prior to the effective date of the P53 License Agreement, as well as two-thirds of IRI's ongoing patent prosecution expenses, in each case with respect to the licensed patents. Additionally, P53 agreed to pay all amounts that become due to IRI as a result of the P53 License Agreement or the sales, licensing, or other activities of P53 under the P53 License Agreement. Pursuant to the P53 License Agreement, P53 has granted to IRI a fully paid license with respect to improvements made by P53 to the technology licensed to P53 under the P53 License Agreement. The P53 License Agreement remains in effect until the expiration of the last of the patents licensed under the agreement. The last licensed patent under the P53 License Agreement will expire in April 2025. We may terminate the agreement for, among other things, P53's breach of the agreement or if P53 challenges the validity or enforceability of any of the licensed patents. P53 may terminate the agreement upon 90 days' written notice.

License Agreement with University of Pittsburgh - Of the Commonwealth System of Higher Education

On February 11, 2020, we entered into an exclusive license agreement (the "UP License Agreement") with the University of Pittsburgh - Of the Commonwealth System of Higher Education ("UP") pursuant to which UP granted us a worldwide, exclusive license to certain licensed technology, and a worldwide, non-exclusive license to use certain related know-how, all related to diabetes gene therapy. The UP License Agreement permits us to make, have made, use and sell certain licensed technology and to practice the patent rights in the field of diabetes therapy. We have agreed to sell the licensed technology to UP upon its request on terms and conditions as such products and/or processes are made available to our most favored customer. As consideration for the UP License Agreement, we agreed to pay UP an initial license fee, annual maintenance fees, running royalties minimum annual royalties beginning with the first commercial sale of the licensed technology pursuant to such agreement, a share of non-royalty sublicense income, and milestone payments in the aggregate amount of up to $3,975,000, as well as patent prosecution expenses incurred prior to and after the effective date of the UP License Agreement. The UP License Agreement shall remain in effect until the later of 20 years after the first commercial sale of the licensed technology or the expiration of the last Valid Claim (as defined in the UP License Agreement). UP may terminate the agreement if, among other things, (i) we fail to cure a default, (ii) if we fail to achieve the specified milestones within the specified time periods or (iii) our intentional practice of the licensed patent rights or know-how outside the field of diabetes therapy. We may terminate the UP License Agreement upon six months' prior written notice to UP and payment of all amounts accrued or due to UP through the effective date of termination.

Grants

We have received grants from the following entities: Texas Emerging Technology Fund, the SBIR program, the National Institutes of Health ("NIH"), and the United States Department of the Treasury. Our collaborators at University of Pittsburgh have also received grants from the NIH in connection with pre-clinical work on GPX-002.

Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. There is also a strong emphasis on intellectual property and proprietary products. We have domestic and international competitors including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Currently, there are a number of drugs approved and under development for treatment of lung cancer. Treatments competitive with our primary product candidates generally fall into the following categories: chemotherapies such as cisplatin, carboplatin, docetaxel and pemetrexed; targeted therapies such as Tarceva, Iressa, Gilotrif, and Tagrisso, and immunotherapies such as checkpoint inhibitors and CAR and CAR T cells, and oncolytic virus-based technology. Any such competing therapy may be more effective and/or cost-effective than ours.

Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the cancer indications that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any product candidates that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive. Any product candidates that we successfully develop and commercialize may compete with existing and new therapies that may become available in the future. The availability of reimbursement from government and other third-party payers will also significantly affect the pricing and competitiveness of our products.

Government Regulation

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical drug product candidates that we develop must be approved by the FDA before they may be legally marketed.

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act (“FDCA”) and implementing regulations and other federal, state and local statutes and regulations. In the case of biologics, the section of the FDCA that governs the approval of drugs via New Drug Applications (“NDAs”) does not apply to the approval of biologics. Rather, biologics, such as gene therapy products, are approved for marketing under provisions of the Public Health Service Act ("PHSA") via a Biologics License Application (“BLA”). However, the application process and requirements for approval of BLAs are very similar to those for NDAs. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Ethical, social, and legal concerns about gene therapy, genetic testing, and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our current and potential product candidates. It is impossible to predict whether legislative changes will be enacted, regulations, policies, or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

U.S. Biological Products Development Process

The process required by the FDA before a biological product, including our REQORSA product candidate, may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLPs"), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as Good Clinical Practices ("GCPs") and any additional requirements for the protection of human research patients and their health information, to establish the safety, purity, and potency of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced and tested to assess compliance with GMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Within the FDA, the Center for Biologics Evaluation and Research ("CBER") regulates gene therapy products. CBER works closely with the NIH and its Novel and Exception Technology and Research Advisory Committee ("NExTRAC") which makes recommendations to the NIH on gene therapy issues and engages in a public discussion of scientific, safety, ethical and societal issues related to proposed and ongoing gene therapy protocols. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols, including informed consent documents. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing patients involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy Investigational New Drugs ("INDs").

Before testing any product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of certain preclinical tests must comply with federal regulations and requirements, including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

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Clinical trials involve the administration of the product candidate to volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, patient selection and exclusion criteria, and the parameters to be used to monitor patient safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of clinical trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent, which must be signed by each clinical trial patient or his or her legal representative, and must monitor the clinical trial until completed. Clinical trials involving biological product candidates also must be reviewed by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The investigational product candidate is initially introduced into human patients and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product candidate may be inherently too toxic to be ethically administered to healthy volunteers, the initial human testing is often conducted in patients; gene therapy is usually administered to patients in Phase 1 trials. This is also true in situations where toxicity can only be judged in patients with disease. An evaluation for preliminary evidence of efficacy can be performed at this time.
- Phase 2. The investigational product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminarily the efficacy of the product candidate for specific targeted diseases, and to generate hypotheses for the dosage tolerance, optimal dosage, and dosing schedule.
- Phase 3. Clinical trials are undertaken to evaluate further dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including (1) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence. Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies. A single pivotal trial may be sufficient in rare instances to provide substantial evidence of effectiveness (generally subject to the requirement of additional post-approval studies).

In addition, the manufacturer of an investigational biologic in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational biologic.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors observe patients for potential gene therapy-related delayed adverse events with agents such as those we are developing for a period of up to 15 years, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of clinical trial patients.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for expedited reporting. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the sponsor, or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the 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 investigational product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at *www.clinicaltrials.gov*. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial.

Concurrently with clinical trials, companies usually complete additional animal studies and also develop additional information about the physical characteristics of the components of a product as well as finalize processes for manufacturing the components in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA, emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the components of a product candidate do not undergo unacceptable deterioration over their shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of an investigational biologic product, FDA approval of a BLA must be obtained before commercial marketing of the product may begin. The BLA must include results of product development, laboratory, and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will file the BLA and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes annual program fees on prescription drugs, including biologics. 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. No user fees are assessed on BLAs for products designated as orphan drugs, unless the application also includes a non-orphan indication.

Within 60 days following submission, the FDA reviews the BLA to determine if it is substantially complete before the agency files it. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information.

In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to an initial filing review before the FDA files it. Once the submission is filed, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel products or products that 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. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations when making decisions. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure the safe use of the product. If the FDA concludes that a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in substantial compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites, to assure that the clinical trials were conducted in compliance with GCP requirements. To assure GMP, GLP and GCP compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently from how we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing.

If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to assess further a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of original standard BLAs within 10 months of the 60-day filing date and 90% of original priority BLAs within six months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Expedited Development and Review Programs

The FDA has four programs in place intended to facilitate and expedite development and review of new drugs and biologics intended to address unmet medical needs in the treatment of serious or life-threatening conditions. These are Fast Track Designation, Breakthrough Therapy Designation, Accelerated Approval Program, and Priority Review Designation.

The Fast Track program is intended to expedite or facilitate the process for reviewing a new product if it is intended for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast Track Designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product can receive Breakthrough Therapy Designation if it 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 it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A Breakthrough Therapy Designation conveys all of the features of Fast Track Designation in addition to more intensive FDA guidance on an efficient development program, organizational commitment involving senior managers, and eligibility for priority review. Specifically, the FDA intends to expedite the development and review of a Breakthrough Therapy by, where appropriate, intensively involving senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review. Where appropriate, the FDA also intends to assign a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program. The FDA notes that a compressed drug development program still must generate adequate data to demonstrate that the drug or biologic meets the statutory standard for approval. Omitting components of the development program that are necessary for such a determination can significantly delay, or even preclude, marketing approval.

Breakthrough Therapy Designation indicates that preliminary clinical evidence demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapy. Breakthrough Therapy Designation intensifies FDA involvement to ensure an efficient drug development program and is an organizational commitment from the FDA to involve its senior managers. A sponsor receiving Breakthrough Therapy Designation has up to six months after receiving the Breakthrough Therapy Designation to request an Initial Comprehensive Multidisciplinary meeting to discuss the drug development program. This initial meeting is a Type B meeting, used to discuss the overarching, high-level plan for drug development. These discussions include topics such as planned clinical trials and endpoints, any resizing or adaptations to the trials, plans for expediting the manufacturing development strategy and studies that potentially could be completed after approval. When Breakthrough Therapy Designation has been granted, the FDA is encouraged to meet regularly with the sponsor and subsequent meetings are considered Type B meetings and are established based on the needs of the program.

The FDA may grant accelerated approval under its Accelerated Approval Program to a product candidate for a serious or life-threatening condition upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is contingent on a sponsor's agreement to conduct at least one adequate and well-controlled additional post-approval trial to verify and describe the product's clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track Designation, Breakthrough Therapy Designation, and Accelerated Approval do not change the standards for approval but may expedite the development process.

An application for a product candidate may be eligible to obtain Priority Review Designation if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. A Priority Review Designation means FDA's goal is to take action on the marketing application within six months (compared to ten months under standard review) of the 60-day filing date. Priority Review Designation does not change the standards for approval but may expedite the review process.

Post-Approval Requirements

Maintaining post-approval compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of products continues after approval, particularly with respect to GMP. We rely, and expect to continue to rely, on third parties for the production and distribution of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register the establishments where the approved products are made with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our current and potential product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA includes, among other provisions:

- A 12-year exclusivity period from the date of first licensure of the reference product, during which approval of a 351(k) application referencing that product may not be made effective;
- A four-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted; and
- An exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars.

The BPCIA also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA is complex and its interpretation and implementation by the FDA remains unpredictable. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Pediatric Information

Under the Pediatric Research Equity Act (“PREA”), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to a BLA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act (“BPCA”) provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Additional U.S. Regulation

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice ("DOJ"), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and similar state laws, each as amended.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, may affect our business. These and other laws govern our use, handling and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith is unlikely to have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Federal and State Fraud and Abuse Laws

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, CMS, other divisions of the U.S. Department of Health and Human Services, for instance, the Office of Inspector General, DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. These federal and state laws, which generally will not be applicable to us or our current and potential product candidates unless and until we obtain FDA marketing approval for any of our current and potential product candidates, include, among others, anti-kickback statutes, the False Claims Act and related stated state and federal laws, the Stark Law and related state and federal laws, transparency laws, privacy and regulation regarding providing drug samples, sales and marketing activities and our relationships with customers and payors as follows.

The federal Anti-Kickback Statute prohibits, among other things, individuals and entities from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, recommending, ordering, or arranging for the purchase, lease, recommendation or order of any health care item or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that 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. Further, the Affordable Care Act codified case law 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 federal civil False Claims Act.

HIPAA created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payers, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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.

Federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, or knowingly making, using, or causing to be made or used, a false statement to get a false claim paid. Several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company’s marketing of the product for unapproved, and thus non-reimbursable, uses.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and false claims laws, which apply to items and services, reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

We may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and their respective implementing regulations, including the final Omnibus Rule published in 2013, imposes requirements on certain types of entities, including mandatory contractual terms, relating to the privacy, security, and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to business associates, which are independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same requirements, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, annually report to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices, and/or require the tracking and reporting of gifts, compensation, and other remuneration to healthcare providers and entities.

Because of the breadth of these laws and the narrowness of the exceptions and safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, and results of operations. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to, without limitation, significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved products to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record keeping and control procedures. Any failure to comply with the regulations may result in significant criminal and civil penalties as well as damage to our credibility in the marketplace.

Coverage and Reimbursement

In many of the markets where we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to reimbursement programs with varying price control mechanisms. In the United States, significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain product approval. Often private payers follow the coverage and reimbursement decisions of the Medicare program, and it is difficult to predict how CMS may decide to cover and reimburse approved products, especially novel products, and those determinations are subject to change.

Moreover, the process for determining whether a third-party payer will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payer will pay for the drug product. Third-party payers may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payer not to cover our current and potential product candidates could reduce physician utilization of our products once approved. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payer's determination to provide coverage for a drug product does not assure that other payers will also provide coverage for the drug product. Coverage and reimbursement for new products can differ significantly from payer to payer. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately and will be a time-consuming process. Additionally, third-party reimbursement may not be available or may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Federal, state and local governments in the United States and foreign governments continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state 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. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of drug products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate systems under which products may be marketed only after a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of studies or analyses of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to set their own prices for medicines, but exert cost controls in other ways, including but not limited to, placing revenue caps on product sales, providing reimbursement for only a subset of eligible patients, mandating price negotiations after a set period of time, or mandating that prices not exceed an average basket of prices in other countries. The downward pressure on health care costs in general, particularly treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, European governments may periodically review and decrease prices based on factors, including, but not limited to, years-on-market, price in other countries, competitive entry, new clinical data, lack of supporting clinical data, or other factors.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, an emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Third-party payers are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. 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 or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Health Care Reform

In March 2010, the Affordable Care Act was enacted, which affected, and may further affect, health care financing and delivery by both governmental and private insurers, and therefore the pharmaceutical and biotechnology industry. The Affordable Care Act has affected and may continue to affect existing government healthcare programs and may result in the development of new programs.

Among the Affordable Care Act's provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our current and potential product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, now 70%, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011; and
- a licensure framework for follow on biologic products.

There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. In December 2018 a judge for the United States District Court for the Northern District of Texas ruled that the entire Affordable Care Act is unconstitutional. This ruling was appealed to the U.S. Court of Appeals for the Fifth Circuit, which held that the individual mandate is unconstitutional. This decision was appealed, and in November 2020, the United States Supreme Court held oral arguments. It is uncertain how the United States Supreme court will rule on this case or how healthcare measures of the Biden administration will impact the Affordable Care Act and our business. With respect to repeal or revision of the Affordable Care and its replacement with new or revised legislation, it is unclear when such legislation will be enacted, what it will provide and what impact it will have on the availability of healthcare and containing or lowering costs of healthcare.

The former Trump Administration proposed a number of initiatives to drive down prescription drug costs and health care spending. President Biden has indicated a desire to address prescription drug costs as well. However, it is unclear how any proposed or future initiatives may affect our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the fiscal year 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the 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. The Consolidated Appropriations Act, 2021 extended the suspension of the 2% Medicare sequester through March 31, 2021. Further, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We anticipate that the Affordable Care Act and other legislative reforms will result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

Environmental Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, may affect our business. These and other laws govern our use, handling and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith is unlikely to have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to influence otherwise a person working in an official capacity.

Other countries, including a number of EU member states, have laws of similar application, including anti-bribery or anti-corruption laws such as the UK Bribery Act. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, as well as requesting, agreeing to receive, or accepting bribes from any person. Under the UK Bribery Act, a company that carries on a business or part of a business in the United Kingdom may be held liable for bribes given, offered or promised to any person in any country by employees or other persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability under the UK Bribery Act is strict, but a defense of having in place adequate procedures designed to prevent bribery is available.

Government Regulation Outside of the United States

In addition to regulations in the United States, we 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 products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be subjected to different types of restrictions in different countries.

Whether or not we obtain FDA approval for a product, we must obtain the required approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application equivalent to an IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial authorization, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may start.

The requirements and process governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP, applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension, or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution in those countries.

Employees

As of March 15, 2021, we had 12 full-time employees. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

Corporate Information and Available Information.

We were incorporated in Delaware in April 2009. Our principal executive offices are located at 1601 Trinity Street, Bldg B, #3.312.09, Austin, TX 78712, and our telephone number is (877) 774-4679.

Our website address is *www.genprex.com*. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

We have proprietary rights to a number of trademarks, including GENPREX, ONCOPREX and REQORSA, that are used in this Annual Report on Form 10-K. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are generally referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

We qualify as an “emerging growth company” as the term is used in The Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and therefore, we may take advantage of certain exemptions from various public company reporting requirements, including:

- a requirement to only have two years of audited financial statements and only two years of related selected financial data and management’s discussion and analysis;
- exemption from the auditor attestation requirement on the effectiveness of our internal controls over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments.

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 $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1.0 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. We may choose to take advantage of some, but not all, of the available benefits of the JOBS Act. We have taken advantage of some of the reduced reporting requirements in this Annual Report on Form 10-K. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. In addition, the JOBS Act provides that an emerging growth company can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We are using the proceeds from our recent sales of securities to advance REQORSA through clinical development, as well as for other corporate purposes. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital to complete clinical development and commercialize REQORSA and for preclinical and clinical development and commercialization of our gene therapy for diabetes, GPX-002. If the FDA requires that we perform additional preclinical studies or clinical trials beyond what we currently anticipate, our expenses will further increase beyond what we currently expect and the anticipated timing of any potential approval of REQORSA and GPX-002 would likely be delayed. Furthermore, there can be no assurance that the costs to obtain regulatory approval of these product candidates will not increase.

We will continue to require substantial additional capital to continue our preclinical and clinical development and commercialization activities. Because successful development of our current and potential product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our current and future product candidates.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs, results and timing of our preclinical development and clinical trials for REQORSA and GPX-002;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the ability of third parties to deliver materials and provide services for us;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our current and future product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing drug candidates and new product approvals;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Although we expect that our existing cash, and marketable securities will be sufficient to fund our current operations and planned clinical trial activities into 2024, this period could be shortened if there are any significant increases in planned spending on current or additional development programs or more rapid progress of these development programs than anticipated. Furthermore, we believe that our existing capital will not be sufficient to enable us to complete the development and commercialization of REQORSA or GPX-002. Accordingly, we expect that we will need to raise additional funds in the future.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, some of which may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our existing capital stock. In addition, the issuance of additional shares by us may cause the market price of our shares to decline and result in dilution to our stockholders. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may be required to curtail or cease operations. Accordingly, our business may fail, in which case you would lose the entire amount of your investment in our securities.

We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. From our inception on April 1, 2009, to December 31, 2020, we incurred an accumulated deficit of approximately $58.4 million. We incurred net losses of approximately $17.9 million and approximately $10.7 million for the years ended December 31, 2020 and 2019, respectively.

To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our preclinical development activities and clinical trials. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our current and potential product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If REQORSA, GPX-002 or any of our other potential product candidates fails in clinical trials or does not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or if, or when, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.

We are a clinical stage company with a limited operating history. Our operations to date have been limited to conducting clinical and preclinical research. We have not yet obtained any regulatory approvals for any of our drug candidates. Consequently, any predictions made about our future success or viability may not be accurate. Our operating results are expected to significantly fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval (assuming that our data support approval) of our current and potential product candidates in clinical development, including our ability to receive approval from the FDA for REQORSA or GPX-002;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our clinical trials through all phases of clinical development;
- potential side effects of our current and potential product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop our current and future product candidates;
- our identification and development of additional drug candidates beyond REQORSA and GPX-002;
- competition from existing products or new products that continue to emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations ("CROs");
- our dependency on third-party manufacturers to manufacture our products and key ingredients;
- our ability to establish or maintain collaborations, licensing or other arrangements, particularly with MD Anderson and UP;
- our ability to defend against any challenges to our intellectual property including claims of patent infringement;
- our ability to enforce our intellectual property rights against potential competitors;
- our ability to secure additional intellectual property protection for our product candidates and associated technologies;
- our ability to attract and retain key personnel to manage our business effectively; and
- potential product liability claims.

Risks Related to Development and Commercialization of Our Current and Future Product Candidates

Our success depends greatly on the success of our development of REQORSA for the treatment of NSCLC, and our other product candidates, including GPX-002 for the treatment of diabetes.

At this time, we are actively pursuing the development of REQORSA for NSCLC, and GPX-002, a preclinical stage gene therapy for diabetes. We are dependent on the success of REQORSA in the near term. We cannot provide you any assurance that we will be able to successfully advance REQORSA or GPX-002 through the development process, or that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, or developing or validating product release assays in a timely manner, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. Immunotherapy, gene therapy and biopharmaceutical product development are highly speculative undertakings and involve a substantial degree of uncertainty. Because REQORSA, GPX-002 and our other potential product candidates are based upon novel technology, it is difficult to predict whether, either as stand-alone therapies or in combination with other drugs, they will show consistently favorable results and to predict the time and cost of their development and of subsequently obtaining regulatory approval. We believe only a few gene therapy products have been approved in the United States or Europe. We have found it difficult to enroll patients in our clinical studies in the past and may, in the future, find it difficult to enroll patients in our clinical studies, including our Acclaim-1 and Acclaim-2 clinical trials, which could delay or prevent clinical studies of REQORSA or other current and potential product candidates. We may encounter delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of FDA and other regulatory authorities. We may not be successful in our efforts to identify or discover additional product candidates, or to develop product candidates that we have identified.

In addition, the clinical trial requirements of the FDA, the European Commission, the European Medicines Agency ("EMA"), the competent authorities of the Member States of the European Union ("EU") and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. Even if we are successful in developing product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for these product candidates in either the United States or the EU, or how long it will take to commercialize any other products for which we receive marketing approval. In addition, any future marketing authorization granted by the European Commission may not be indicative of what the FDA may require for approval and vice versa.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our current and potential product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our current and potential product candidates.

Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our current and potential product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our current and potential product candidates, and the resulting publicity could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Concern about the environmental spread of our product, whether real or anticipated, could also hinder the commercialization of our products.

Prior to receiving REQORSA in our Acclaim-1 clinical trial, patients are required to undergo genetic screening to detect EGFR mutations and in the Acclaim-2 clinical trial genetic screening to detect PD-L1 as well as other mutations relevant to cancer. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. Genetic testing information is also subject to significant restrictions under both federal and state law. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities restricting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of the foregoing could decrease demand for REQORSA or our future product candidates.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites; ability to comply with the eligibility and exclusion criteria for participation in the clinical trial; and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

In addition, our ability to successfully initiate, enroll and complete clinical trials in any foreign country is subject to numerous risks of conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for REQORSA and future product candidates.

Delays in the commencement, enrollment and/or completion of our Acclaim-1 and Acclaim-2 clinical trials or any future clinical trials could increase our product development costs or delay or limit the regulatory approval of REQORSA or other product candidates. We do not know whether the Acclaim-1 or Acclaim-2 clinical trials or any future trials or studies of other future product candidates will begin on time or will be completed on schedule, if at all. The start or end of a clinical study is often delayed or halted due to regulatory requirements, changes in the proposed regulatory approval pathway for a drug candidate, manufacturing challenges, including delays or shortages in available drug product, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, which include the age and condition of the patients and the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and/or availability of other investigational treatment options for the relevant disease. We are planning to initiate our Acclaim-1 and Acclaim-2 clinical trials pursuant to an existing IND. Prior to commencing either of these clinical trials, we intend to file with the FDA amendments to our IND consisting of an updated chemistry, manufacturing and controls section, and the protocol for the respective clinical trial. We cannot be sure that issues will not arise in connection with the filing of these amendments that will result in the FDA imposing a clinical hold which could result in the delay of either or both of these clinical trials

The accelerated approval pathway for our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

Under the FDA's accelerated approval program, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. We may seek accelerated approval for one or more of our product candidates on the basis of progression free survival, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit.

For drugs granted accelerated approval, post-marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence and, in most cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If any of our competitors were to receive full regulatory approval for an indication for which we are seeking accelerated approval prior to our approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would be more difficult or may not occur. Moreover, the FDA may withdraw approval of our product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

If we are unable to secure contract manufacturers with capabilities to produce the products that we require, we could experience delays in conducting our planned clinical trials.

Manufacturing REQORSA involves several manufacturing steps. Historically, part of our manufacturing process was conducted in manufacturing facilities at MD Anderson. We recently transferred this portion of the process to CDMOs and also scaled-up clinical production in quantities we believe are sufficient for our Acclaim-1 and Acclaim-2 clinical trials. Although we have contracted with CDMOs to produce the products that we require, no assurance can be given that such CDMOs will be able to continue to produce the products that we require. In accordance with cGMP, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult and could be costly, which could result in our inability to manufacture our clinical product candidates and a delay in the development of our clinical product candidate. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur higher costs to manufacture our clinical product candidates.

A product candidate can fail at any stage of preclinical and clinical development.

The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with current or prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our current and future product candidates;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates and high fail rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our current and potential product candidates during clinical trials; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

REQORSA™ , GPX-002, and any other product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates, and the approval may be for a narrower indication than we seek.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Additionally, our partners, clients, other vendors, and/or other stakeholders may not agree with our interpretation(s) of data obtained from our clinical trials, which could potentially cause a variety of issues, including, but not limited to, delays, the necessity for additional studies and analyses, dependence on third-party validation, and/or other unforeseen challenges. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Later-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. For example, the small number of patients in our completed Phase 1 Monotherapy clinical trial of REQORSA and the Phase 1/2 Combination Tarceva trial may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we have observed encouraging clinical activity in the Phase 1 Monotherapy and Phase 1/2 Combination Tarceva trial, the primary objectives of the Phase 1 Monotherapy Trial and the Phase 1 portion of the Phase 1/2 Combination Tarceva trial were safety and MTD and not to demonstrate efficacy. The assessments of clinical activity from these clinical trials, some of which were not pre-specified, may not be predictive of the results of later clinical trials of REQORSA. Furthermore, safety events may be observed in later trials that alter the anticipated risk-benefit profiles of REQORSA or other product candidates.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

We do not know whether any clinical trials we or any of our potential future collaborators may conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If REQORSA or GPX-002 is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed. If we are unable to bring REQORSA, GPX-002 or other product candidates to market, or to acquire other products that are on the market or can be developed, our ability to create stockholder value will be limited.

Regulatory authorities also may approve a product candidate for more limited indications than requested, or they may impose significant limitations in the form of narrow indications. These regulatory authorities may require warnings or precautions with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims or allow the promotional claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.

Even if we obtain regulatory approval of our current and potential product candidates, the products may not gain market acceptance among physicians, patients, hospitals, treatment centers, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy and genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. Even with the requisite approvals, the commercial success of REQORSA, GPX-002 and any of our future product candidates will depend in part on the medical community, patients, and third-party payors accepting gene therapy products in general, and our current and future product candidates in particular, as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, hospitals, treatment centers, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our current and potential product candidates are approved;
- physicians, hospitals, treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment – both in absolute terms and in relation to alternative treatments;
- the availability of coverage, reimbursement and pricing by third-party payors and government authorities and the adequacy thereof;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- the willingness, ability and availability of healthcare providers that can comply with the transportation, handling, and temperature-controlled storage requirements associated with our product candidates;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts, which are subject to various limitations under applicable law.

Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

REQORSA™, GPX-002 and other future product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

In our Phase 1 clinical trial of REQORSA as a monotherapy, the only serious adverse events, defined as grade 3, 4 or 5 events under the Common Terminology Criteria for Adverse Events published by the U.S. Department of Health and Human Services, were grade 3 fever and grade 3 hypotension, and the only dose-limiting toxicities were two episodes of transient grade 3 hypophosphatemia (abnormally low levels of phosphate in the blood).

The Phase 1 portion of our Phase 1/2 Combination Tarceva Trial was a dose escalation study with the primary purpose of determining the MTD. Dose Limiting Toxicities were defined as grade 3, 4 or 5 events during the first cycle of treatment that were considered to be treatment related. At dose level 1, one subject had grade 3 adverse events of fatigue, muscle weakness and hyponatremia (low sodium level) and considered to be related to the study treatment (Tarceva). Therefore, three additional subjects were treated at this dose level (six subjects total), none of whom suffered a DLT. At dose level 2, there were no DLTs. At dose level 3, one subject had a grade 3 rash considered to be related to the study treatment (Tarceva); therefore, an additional three subjects were treated at this dose level (six subjects total). No additional subjects suffered a DLT at dose level 3. At dose level 4, there were no DLTs; thus, dose level 4 was determined to be the MTD.

Additional or unforeseen side effects from REQORSA, GPX-002 or any of our future product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. A showing that REQORSA, GPX-002 or any of our other future product candidates cause undesirable or unacceptable side effects could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings.

If REQORSA, GPX-002 or any of our future product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of our products or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenues from the sale of our products.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently carry product liability insurance relating to our clinical trials only. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA or other regulatory agency and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our CROs, contractors and consultants possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our CROs, contractors and consultants, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business. Furthermore, the loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data which could cause the development and commercialization of our current and potential product candidates to be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, contractors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our current and potential product candidates could be disrupted if the operations of our contract manufacturers are affected by a man-made or natural disaster or other business interruption. Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations.

We do not carry insurance for all categories of risk that our business may encounter. There can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect us from potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which may adversely affect our financial position and results of operations.

Our business may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus (COVID-19) evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

As a result of the continuing spread of the coronavirus, our business operations could be delayed or interrupted. For example, our clinical trials may be delayed as a result of the pandemic. Manufacturing and testing, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring, data analysis, and laboratory research activities may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance. Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials and to manufacture clinical product. If any third-party parties in the supply chain for materials used in the production of our product candidates or the third-party manufacturers of our product candidates themselves are adversely impacted by restrictions resulting from the coronavirus outbreak, our ability to manufacture our product candidates for our clinical trials and research and development activities related thereto may be disrupted. In particular, we utilize lipids in the manufacture of REQORSA. Lipids are also used in the production of various COVID-19 vaccines and this has resulted in increased demand for this material and may limit the available supply.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other 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 trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition from domestic and international competitors including major multinational pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and other public and private research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection and/or FDA or other regulatory approval or in discovering, developing and commercializing drugs for the indications that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

If our competitors market products that are more effective, safer or less expensive or reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in all technologies that are or may become competitive with ours. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Risks Related to Regulatory Approval and Marketing of Our Current and Future Product Candidates and Other Legal Compliance Matters

We cannot provide assurance that REQORSA, GPX-002 or any of our future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market them.

Our business currently depends largely on the successful development and commercialization of our product candidates, REQORSA and/or GPX-002. Our ability to generate revenue related to product sales will depend on the successful development and regulatory approval of REQORSA for the treatment of cancer and/or GPX-002 for diabetes. Even if we complete the necessary clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate. Further, even if we obtain regulatory approval, it may only apply to a narrower indication than we expect and our products will remain subject to regulatory scrutiny.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted any marketing applications for any of our current and potential product candidates.

BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete, and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to file the BLA or refuse to file it. We cannot be certain that any submissions will be filed and reviewed by the FDA. In addition, regulators in other jurisdictions have their own procedures for approval of product candidates.

The FDA or regulators in other jurisdictions could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be safe and effective;
- determine that the product candidate does not have an acceptable benefit-risk profile;
- determine in the case of a BLA seeking accelerated approval that the BLA does not provide evidence that the product candidate represents a meaningful advantage over available therapies;
- determine that the results on our primary endpoints are not clinically meaningful;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the approval of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may disagree regarding the formulation or the specifications of our product candidates;
- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status; or
- may change approval policies or adopt new regulations.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. Furthermore, regulatory approval for any of our future product candidates may be withdrawn after approval.

If we are unable to obtain approval from the FDA or other regulatory agencies for REQORSA or GPX-002, or if, subsequent to approval, we are unable to successfully commercialize REQORSA or GPX-002 or our other potential product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. For example, in January 2017, the FDA Oncology Center of Excellence, or the Center of Excellence, was created to leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices (including diagnostics). While the Center of Excellence is designed to help expedite the development of oncology and malignant hematology-related medical products and support an integrated approach in the clinical evaluation of drugs, biologics and devices for the treatment of cancer, the Center of Excellence may, at times, create confusion within the FDA and especially in the Center of Biologics and Research, which is the primary review division for REQORSA. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the NIH, are also subject to review by NExTRAC. In August 2018, the NIH Director issued a statement describing a proposal intended to streamline the federal framework for oversight of gene therapy. The proposal, which the NIH developed in conjunction with the FDA, included amending the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, or *NIH Guidelines*, to eliminate duplicative review and reporting requirements for human gene transfer protocols. The statement also described NIH's effort to refocus the role of the RAC to be closer to its original mandate – a transparent forum for science, safety, and ethics of emerging biotechnologies. Accordingly, the *NIH Guidelines* have been updated to reflect these changes. Additionally, before a clinical trial can begin at an NIH-funded institution, that institution's IRB, and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess the safety of the study. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for performing studies or for obtaining approval of any of our current and potential product candidates. The regulatory changes discussed herein as well as other existing and future regulatory developments may cause unexpected delays and challenges for companies seeking approval of gene therapy products, like REQORSA or GPX-002.

These regulatory review committees and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current and potential product candidates or lead to significant post-approval limitations or restrictions. As we advance our current and potential product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. Any delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient revenue to maintain our business.

Even if we obtain regulatory approval for our product candidates, our products will remain subject to regulatory oversight.

Our product candidates for which we obtain regulatory approval will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates also may be subject to the specific obligations imposed as a condition for marketing authorization by equivalent authorities in a foreign jurisdiction, particularly by the European Commission, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product.

For example, in the United States, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations and are subject to FDA oversight and post-marketing reporting obligations, in addition to other potentially applicable federal and state laws.

In the EU, any future advertising and promotion of our products will be subject to EU laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with health care professionals. These laws require that promotional materials and advertising for medicinal products are consistent with the product's Summary of Product Characteristics ("SmPC") as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comport with the SmPC is considered to constitute off-label promotion, which is prohibited in the EU. The applicable laws at EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment.

In addition, product manufacturers and their facilities may be subject to payment of application and program fees and are subject to continual review and periodic inspections by FDA and other regulatory authorities for compliance with cGMP, requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagree with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements for any product following approval, a regulatory authority may:

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market;
- refuse to permit the import or export of products;
- request and publicize a voluntary recall of the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

If the FDA does not find the manufacturing facilities of our current or future contract manufacturers acceptable for commercial production, we may not be able to commercialize REQORSA, GPX-002 or any of our future product candidates.

We do not have the internal infrastructure or facilities to manufacture REQORSA or any other product candidate for use in the conduct of our clinical trials or for commercial supply. However, our strategy could change in the future and we could choose to develop such infrastructure. Currently, we intend to continue to use CDMOs for the production of the active pharmaceutical ingredients and the formulation of drug product for the trials of REQORSA to be conducted or that will need to be conducted prior to seeking regulatory approval. Although we have produced a sufficient amount of REQORSA to initiate our Acclaim-1 and Acclaim-2 clinical trials, we do not have agreements for ongoing supply of REQORSA or any of our other potential product candidates, and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to complete clinical trials and commercialize REQORSA if it is approved. Additionally, the facilities used by our contract manufacturers to manufacture product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We are completely dependent on our third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture materials that conform to our specifications and the FDA's cGMP standards and other requirements of any governmental agency to whose jurisdiction we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks including:

- the possibility that we are unable to enter into manufacturing agreements with third parties to manufacture our product candidates;
- the possibility that our contract manufacturers may breach the terms of their manufacturing agreements with us; and
- the possibility of termination or nonrenewal of any manufacturing agreement we may enter into.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if our product candidates are approved for commercialization and our contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. The Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co-pay support, funding of independent charitable foundations and other programs that offer benefits for patients. Several investigations into these types of programs have resulted in significant civil and criminal settlements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws would increase significantly, and our costs associated with compliance with such laws would likely also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs and interactions with physicians and other health care providers. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain 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, including off-label uses of our products, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. 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 fines or other sanctions. The laws that may affect our ability to operate include, but are not limited to:

- the Federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, 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 a federal healthcare program, such as the Medicare and Medicaid programs. 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;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which impose criminal and civil penalties, through government, civil whistleblower or qui tam actions, on individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the Affordable Care Act) and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the U.S. FDCA, which prohibits, among other things, the adulteration or misbranding of drugs;
- the Foreign Corrupt Practices Act and similar worldwide anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our current and potential product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Coverage and reimbursement may be limited or unavailable in certain market segments for REQORSA, GPX-002 and our future product candidates, if approved, which could make it difficult for us to sell REQORSA, GPX-002 and our future product candidates profitably.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, insurance companies and other third-party payors, and others in the medical community. Even if we obtain approval to commercialize our current and potential product candidates outside of the United States, a variety of risks associated with international operations could materially affect our business. Due to the novel nature of our technology, we face uncertainty related to pricing and reimbursement for our current and potential product candidates. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. If market opportunities for our current and potential product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Successful sales of our products, if our current and potential product candidates are approved, depend on the availability of coverage and adequate reimbursement from third-party payors. In addition, because our current and potential product candidates represent new approaches to the treatment of cancer and diabetes, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our current and potential product candidates. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement for products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products and to justify the level of coverage and reimbursement relative to other therapies, with no assurance that coverage and adequate reimbursement will be obtained. Third party payors may also have difficulty in determining the appropriate coverage of REQORSA and our other potential product candidates that are combination products, if approved, due to the fact that they are combination products that include another drug. To the extent there are any delays in determining such coverage or inadequate coverage and reimbursement for all aspects of our combination therapies, it would adversely affect the market acceptance, demand and use of our current and potential product candidates. Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

We intend to seek approval to market our current and potential product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our current and potential product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our current and potential product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our current and potential product candidates will depend significantly on the availability of coverage and adequate reimbursement from third-party payors for our current and potential product candidates and may be affected by existing and future health care reform measures.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could affect our ability to sell our products profitably. In particular the Affordable Care Act and its implementing regulations, among other things, subjected biological products to potential competition by lower-cost biosimilars, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our current and potential product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. In November 2020, the United States Supreme Court held oral arguments on the U.S. Court of Appeals for the Fifth Circuit's decision that held that the individual mandate is unconstitutional. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the Affordable Care Act and our business.

Since January 2017, former President Trump signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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." Additionally, on January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress also could consider subsequent legislation to repeal or repeal and replace other elements of the Affordable Care Act. We continue to evaluate the possible impact of the Affordable Care Act, as amended, and the possible repeal and/or replacement of the Affordable Care Act on our business.

In late 2018, the Centers for Medicare & Medicaid Services, or CMS, issued an advance notice of proposed rulemaking describing a potential mandatory model to test Medicare reimbursement based on an "International Pricing Index," or IPI. More recently, CMS published an interim final rule that establishes a Most Favored Nation, or MFN, Model for Medicare Part B drug payment. This regulation would substantially change the drug reimbursement landscape as it bases Medicare Part B payment for 50 selected drugs on prices in foreign countries instead of average sales price, or ASP, and establishes a fixed add-on payment in place of the current 6 percent (4.3 percent after sequestration) of ASP. The MFN drug payment amount is expected to be lower than the current ASP-based limit because U.S. drug prices are generally the highest in the world. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule, and it faces uncertain prospects for implementation.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current and potential product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We are subject to a variety of risks associated with international operations which could materially adversely affect our business.

We anticipate that we will be subject to additional risks in commercializing our product candidates outside the United States, including the following, any one or combination of which could have a material adverse effect on our business:

- different regulatory requirements for approval of product candidates in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods, fires and medical epidemics.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We may become subject to federal, state, local, and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products, including numerous environmental, health and safety laws and regulations, such as those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may in the future involve the use of hazardous materials, including chemicals and biological materials. Our operations may 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. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may incur substantial costs in order 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. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our current product candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we have and may continue to enter into collaborations with companies that have the required expertise. Additionally, if any of our product candidates receive marketing approval, we may enter into sales and marketing arrangements with third parties. If we are unable to enter into arrangements on acceptable terms, or at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in engaging collaborators. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our current and potential product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to such third party.

One or more of our collaboration partners may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization efforts. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us. In addition, any collaboration that we enter into may not be successful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of such development. If we are unable to reach agreements with suitable collaborators for our product candidates, we may face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them. As a result, we may be unable to commercialize products or programs if we are unable to engage a suitable collaborator, which may have a material adverse effect on our operating results and financial condition.

We rely, in part, and expect to continue to rely, in part, on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely in part on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we have or will have agreements governing their activities, we may have limited influence over their actual performance because we control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. These CROs 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.

We and our CROs are required to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving any marketing applications. In addition, our ongoing and future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our current and potential product candidates. Accordingly, if our CROs fail to comply with applicable regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements, or for any 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 product candidates. As a result, our financial results and the commercial prospects may be harmed, our costs could increase and our ability to generate revenues could be limited or delayed.

We rely, and expect to continue to rely, on third parties to distribute, manufacture and perform release testing for our current and future product candidates and other key materials and if such third parties do not carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for our product candidates.

We rely, and expect to continue to rely on third-party CDMOs to produce REQORSA and expect to do so with GPX-002 and future product candidates and other key materials and on third-party contract testing organizations, or CTOs, for the establishment and performance of validated product release assays, but we have not entered into binding agreements with any such CMOs or CTOs to support commercialization. Additionally, any CDMO may not have specific experience producing our product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our products at the quality, quantities, locations and timing needed to support commercialization. We do not have full control of these CDMOs, and they may prioritize other customers or be unable to provide us with enough manufacturing capacity to meet our objectives. We may change our manufacturing process, and there can be no guarantee that the regulatory authorities will approve any new process in a timely manner, or ever. Also, as a consequence of the manufacturing change, there may be a requirement to conduct additional preclinical safety or efficacy studies, develop new manufacturing and release assays and/or repeat all or part of the ascending dose safety study in animals or humans. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products.

Historically, part of our manufacturing process was conducted in manufacturing facilities at MD Anderson. We have completed the technology transfer from MD Anderson to experienced commercial contract development and manufacturing organizations and have scaled-up clinical production of REQORSA in quantities we believe are sufficient for our Acclaim-1 and Acclaim-2 clinical trials. No assurance can be given that such contract manufacturers will be able to, and will receive all approvals to, produce product sufficient for all of our clinical trial needs moving forward or for commercialization. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our contract manufacturers may be difficult and could be costly if we do make such a change, which could result in our inability to manufacture our product candidates and a delay in the development of our product candidates and their commercial sale, should they be approved. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur higher costs to manufacture our product candidates. There can be no guarantee that the regulatory authorities will approve any new process in a timely manner or ever. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products.

In connection with our manufacturing activities, we may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Further, we have not fully completed the characterization and validation activities necessary for commercial and regulatory approvals. If our manufacturing and testing partners do not enable such regulatory approvals, our commercialization efforts may be harmed. If such third-party manufacturers are unable to produce REQORSA, GPX-002 or future product candidates in the necessary quantities, or in compliance with cGMP or in compliance with pertinent regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our products, if approved, would be materially harmed. The manufacturing processes used by our contract manufacturers to manufacture product candidates must be approved by the FDA as part of our BLA package and the facilities used by our contract manufacturers must maintain a compliance status acceptable to the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. Although we provide specifications, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for the manufacture of our product candidates. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory agencies, we will not be able to secure and/or maintain regulatory approval covering their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly affect our ability to develop, obtain regulatory approval for or market our future product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our current and future product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials, devices and equipment from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There is a small number of suppliers for certain key materials and components that are used to manufacture our current and future product candidates. Such suppliers may not sell these key materials to our manufacturers at the times or quantities we need them or on commercially reasonable terms. We may not have any control over the process or timing of the acquisition of these key materials by our manufacturers.

We also expect to rely on other third parties to store and distribute our products for our clinical trials. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our current and future product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

Our leading drug candidate, REQORSA, is based upon patents and related technology covered by the MD Anderson License Agreement, under which we have rights to patents covering use of various genes, including the TUSC2 gene, for treatment of cancer, as well as know-how and related intellectual property. In 2007, the MD Anderson License Agreement was sublicensed by Introgen to IRI and in 2009 this sublicense was assigned by IRI to us, and we granted back to IRI a nonexclusive, royalty-free license to use and practice the licensed technology for non-commercial research purposes. As consideration for this assignment, we agreed to assume all of IRI's obligations to MD Anderson under the MD Anderson License Agreement, including ongoing patent related expenses and royalty obligations. IRI also agreed in 2011, pursuant to the 2011 IRI Collaboration Agreement, to provide additional technology licensing opportunities and services to us in return for monthly payments and our obligation to pay to IRI a royalty of 1% on sales of products licensed to us under the MD Anderson License Agreement. We also granted a non-exclusive, royalty-free sublicense to IRI in 2011 for non-commercial research purposes. IRI's obligations to provide additional technology licensing opportunities and services to us, and our obligation to make monthly payments to IRI, were terminated in 2012; however, our obligation to pay the 1% royalty to IRI upon sales of products licensed to us under the MD Anderson License Agreement is ongoing. This royalty obligation continues for 21 years after the later of the termination of the MD Anderson License Agreement and the termination of the sublicense assigned by IRI to us. IRI is controlled by Rodney Varner and his immediate family members. Mr. Varner is currently Chairman of our board of directors, having joined our board of directors on August 15, 2012, and has been our Chief Executive Officer since August 29, 2012 and President since August 10, 2020; accordingly, in 2009 and 2011, when the above referenced agreements between IRI and Genprex were entered into, Mr. Varner was neither a member of our board of directors nor an executive officer of Genprex. When the 2011 IRI Collaboration Agreement was entered into, Mr. Varner was deemed to be an "affiliate" of the Company due to his beneficial ownership of approximately 39% of our issued and outstanding shares at that time. Although we believe that these transactions were conducted on an arm's length basis, it is possible that the terms were less favorable to us than they might have been in a transaction with an unrelated party.

Risks Related to Our Intellectual Property

If we fail to comply with obligations pursuant to our license agreements, we could lose intellectual property and other rights that are important to our business.

Pursuant to the 2020 MD Anderson License Agreement, we hold worldwide, exclusive license rights to certain inventions covering the therapeutic use of TUSC2 and other genes and polypeptides that have been shown to have cancer fighting properties, as well as a number of related technologies. In addition, pursuant to the UP License Agreement, UP granted us a worldwide, exclusive license to certain licensed technology, and a worldwide, non-exclusive license to use certain related know-how, all related to diabetes gene therapy. In addition, we expect to enter into additional license agreements in the future. Our existing and future license agreements may impose various payment and other obligations on us. If we fail to comply with our obligations under these agreements, our licensors may have the right to terminate our licenses, in which event we would not be able to market products covered by such licenses.

Moreover, in the event we need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, we may fail to obtain any of such licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to develop or license replacement technology, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In certain cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In addition, in certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe 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 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.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

The intellectual property rights we have licensed from MD Anderson and the UP are subject to the rights of the U.S. government.

The rights we have obtained pursuant to our license agreements with MD Anderson and the UP are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between such institution and the U.S. government. Additionally, to the extent there is any conflict between our license agreement and applicable laws or regulations, applicable laws and regulations will prevail. Similarly, to the extent there is any conflict between our license agreement with one of these institutions and the institution's funding agreement with the US government, the terms of the funding agreement will prevail. Some, and possibly all, of our licensed intellectual property rights have been developed in the course of research funded by the U.S. government. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. Government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if the U.S. government determines that adequate steps have not been taken to commercialize the invention, that government action is necessary to meet public health or safety needs, that government action is necessary to meet requirements for public use under federal regulations, or that the right to use or sell such inventions is exclusively licensed to an entity within the U.S. and substantially manufactured outside the U.S. without the U.S. government's prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e.g., manufacturing substantially all of the invention in the U.S.). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title in any country in which a patent application is not filed within specified time limits. Furthermore, certain inventions are subject to transfer restrictions during the term of these agreements and for a period thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business.

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization. It is also possible that as research and development progresses, the direction of our intellectual property strategy and patent portfolio will change, resulting in strategic business decisions to allow certain patents or patent applications to be abandoned or lapse.

With respect to patent rights, we do not know whether any of the pending patent applications relating to any of our current and future product candidates will result in the issuance of patents that effectively protect our technology or products, or if any of our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor's patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the US Patent and Trademark Office ("USPTO") and corresponding foreign patent offices. Numerous US and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current and future product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may in the future assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, or any final product itself, the holders of any such patents may be able to block our ability to develop and commercialize such product candidate unless we obtained a license under the applicable patents, which license may not be available on acceptable terms, if at all, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which may hinder our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and diversion of our management's attention. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which licenses may not be on acceptable terms or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we believe that we have rights to the intellectual property, through licenses from third parties to develop our product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties on reasonable terms, if at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on and intend to continue to rely on third parties to manufacture our current and future product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions of such agreements, the need to share trade secrets and other confidential information increases the risk that such trade secrets may become known by our competitors, may be inadvertently incorporated into the technology of others, may be used inappropriately to create new inventions or may be disclosed or used in violation of such agreements.

Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure may impair our competitive position and have a material adverse effect on our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Obtaining and maintaining our 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 fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ an outside firm and rely on our outside counsel to pay these fees due to non-US patent agencies. The USPTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners, including MD Anderson or UP, initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/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 also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our current and potential product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current and potential product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We currently and in the future may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and result in a diversion of management's attention.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have potential ownership disputes arising, for example, from conflicting obligations of consultants, collaborators or others who are involved in developing our current and potential product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and is currently implementing wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We have not yet registered the trademark for REQORSA™, and failure to secure such registration could adversely affect our business.

While we have submitted a trademark application for the mark "REQORSA," this mark has not yet been approved by the USPTO. During trademark registration proceedings, our application may be rejected. Although we would be given an opportunity to respond to the rejection of a trademark application, we may be unable to overcome such rejection. In addition, with respect to the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademark, and our trademark may not survive such proceedings. Moreover, any name we propose to use with our current and potential product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents with respect to product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in 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, 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 biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent 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 and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Employee Matters and Managing Growth

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that our product candidates will be approved by the FDA. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third-party sales collaborators may not be able to build and maintain an effective marketing or sales force, and we may experience difficulty in managing the growth of our organization. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

As of March 15, 2021, we had 12 full-time employees. As we advance our product candidates through preclinical studies and clinical trials, we will need to increase our clinical trial management, product development, manufacturing, regulatory, and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. We may not be able to attract or retain qualified personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the development, regulatory, commercialization and business development expertise of our management team, key employees and consultants. Any of our executive officers or key employees or consultants may terminate their employment or engagement with us at any time. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic 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 product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate and enter into various acquisitions and strategic partnerships, including licensing or acquiring additional products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- difficulties in achieving anticipated cost savings, synergies, business opportunities, and growth prospects from any business combination;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Moreover, we may not be able to locate suitable acquisition opportunities and such inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to our Securities

The market price of our common stock may be highly volatile, and you may lose all or part of your investment.

The market price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- inability to obtain additional funding;
- adverse results or delays in preclinical or clinical trials;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- any delay in filing an IND or BLA for our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- failure to develop successfully and commercialize our product candidates;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products and product candidates;
- inability to obtain adequate product supply for our product candidates or inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical and biotechnology industries by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders;
- trading volume of our common stock; and
- other events or factors, many of which may be out of our control, including, but not limited to, pandemics such as COVID-19, war, or other acts of God.

In addition, companies trading in the stock market in general, and The Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded. The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock;

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

Global credit and financial markets have experienced volatility and disruptions in past years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, concerns about medical epidemics, and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur, particularly as a result of the ongoing COVID-19 pandemic. 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, or do not improve, 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 difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

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 product 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.

Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act") could cause our financial reports to be inaccurate.

We are required pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. If we fail to implement any required improvements to our disclosure controls and procedures, we may be obligated to report control deficiencies, in which case we could become subject to regulatory sanction or investigation. Further, such an outcome could damage investor confidence in the accuracy and reliability of our financial statements.

Our management has concluded that our internal controls over financial reporting were, and continue to be, ineffective, and as of the year ended December 31, 2020 as a result of a material weakness in our internal controls due to the lack of segregation of duties. While management is working to remediate the material weakness, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

We have no intention of declaring dividends in the foreseeable future.

We have never declared or paid cash dividends on our capital stock, and we do not currently anticipate declaring any dividends in the foreseeable future. We anticipate that we will retain all future earnings for the development, operation, and expansion of our business. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock, if any, to earn a return on their investment.

We are an emerging growth company and smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of 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 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 nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. 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 $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public 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.

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 take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies; however, we have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and places significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended ("Exchange Act") and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control 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" or "smaller reporting 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 of 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 consequences.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline. We are unable to predict the effect that sales may have on the market price of our common stock. If any shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. In addition, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline.

Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.

We are authorized to issue up to 10,000,000 shares of preferred stock, none of which are outstanding as of March 15, 2021. This 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. The ability of our board of directors to issue preferred stock also could have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

In addition, our organizational documents contain provisions that may have the effect of discouraging, delaying or preventing a change of control of, or unsolicited acquisition proposals, that a stockholder might consider favorable. These include provisions:

- requiring at least 66-2/3% of the voting power of all of our then-outstanding shares of capital stock entitled to vote generally in the election of directors, voting together as a single class, to amend the Amended and Restated Bylaws;
- providing that the authorized number of directors may be changed only by resolution of the board of directors;
- providing that the directors may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding shares of capital stock entitled to vote generally at the election of directors;
- providing that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- dividing our board of directors into three classes;
- requiring that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- providing that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder’s notice;
- that do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- providing that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

In addition, Delaware law makes it difficult for stockholders that recently have acquired a large interest in a corporation to cause the merger or acquisition of the corporation against the directors' wishes. Under Section 203 of the Delaware General Corporation Law, a Delaware corporation may not engage in any merger or other business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder except in limited circumstances, including by approval of the corporation's board of directors.

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.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws contains an exclusive forum provision with respect to certain actions which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable and discourage lawsuits against us or our current or former directors or officers and/or stockholders in such capacity.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the following actions must be brought solely and exclusively in the Court of Chancery of the State of Delaware (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee of the Company arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (iv) any action asserting a claim against us or any director or officer or other employee of the Company governed by the internal affairs doctrine. We believe that the exclusive forum provision may not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We believe that to the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, we believe that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers or other employees. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, results of operations, and financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate and executive offices are located at 1601 Trinity Street, Bldg. B, #3.312.09, Austin, Texas 78712. Our lease for such office expires on April 30, 2021. We believe our current facilities and those that we believe are available to us are sufficient to meet our current needs and that suitable space will be available as and when needed. We do not own any real property.

Item 3. Legal Proceedings.

From time to time, we may become involved in various lawsuits and legal proceedings. 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. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on The Nasdaq Capital Market under the symbol "GNPX" on March 29, 2018. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 15, 2021, there were approximately 155 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

For the year ended December 31, 2020, we issued and sold the following unregistered securities:

1) On October 1, 2020, we issued an aggregate of 5,000 shares of our common stock to a consultant in consideration of services.

2) On December 4, 2020, we issued an aggregate of 31,432 shares of our common stock to a consultant in consideration of services.

The foregoing issuance of securities was not registered under the Securities Act or the securities laws of any state, and the securities were offered and issued in reliance on the exemption from registration under the Securities Act afforded by Section 4(a)(2).

Item 6. Selected Financial Data.

As a smaller reporting company, we are not required to provide the information required by this item.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") contains certain forward-looking statements. Historical results may not indicate future performance. Our forward-looking statements reflect our current views about future events, are based on assumptions and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those contemplated by these statements. Factors that may cause differences between actual results and those contemplated by forward- looking statements include, but are not limited to, those discussed in "Risk Factors." We undertake no obligation to publicly update or revise any forward-looking statements, including any changes that might result from any facts, events, or circumstances after the date hereof that may bear upon forward-looking statements. Furthermore, we cannot guarantee future results, events, levels of activity, performance, or achievements.

Overview

We are a clinical stage gene therapy company focused on developing life-changing treatments for cancer and diabetes. Our lead cancer drug candidate, REQORSA™ Immunogene therapy drug (sometimes referred to as GPX-001), is being developed to treat NSCLC. The active agent in REQORSA is a TUSC2 gene expressing plasmid that is encapsulated in a DOTAP cholesterol nanoparticle. TUSC2 is a tumor suppressor gene which has both tumor killing (via apoptosis) and immunomodulatory effects. We utilize our novel proprietary ONCOPREX® Nanoparticle Delivery System to deliver the TUSC2 gene expressing plasmid to cancer cells. The TUSC2 gene is one of a series of genes whose therapeutic use is covered by our exclusive worldwide licenses from MD Anderson.

We are planning to initiate our Acclaim-1 and Acclaim-2 clinical trials in 2021. Acclaim-1 is a Phase 1/2 clinical trial using a combination of REQORSA with AstraZeneca PLC's Tagrisso® in patients with late-stage NSCLC with mutated epidermal growth factor receptors ("EGFRs") whose disease progressed after treatment with Tagrisso. In January 2020, we received FDA Fast Track Designation for the Acclaim-1 patient population. Acclaim-2 is a Phase 1/2 clinical trial using a combination of REQORSA with Merck & Co.'s Keytruda® in late-stage NSCLC patients who are low expressors (1% to 49%) of the PD-L1.

In diabetes, we are developing a gene therapy that is exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh") for the treatment of Type 1 and Type 2 diabetes. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. Our diabetes product candidate is currently being evaluated in preclinical studies.

Oncology Platform

Utilizing our non-viral ONCOPREX Nanoparticle Delivery System, we are developing cancer treatments that are designed to administer cancer fighting genes. We encapsulate the gene-expressing plasmids using ONCOPREX lipid nanoparticles, and administer them intravenously, where they are then taken up by tumor cells and express proteins that are missing or found in low quantities in the tumor cells. With our lead drug candidate, REQORSA, there is a multimodal mechanism of action whereby REQORSA interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and modulates the immune response against cancer cells. REQORSA has also been shown to block mechanisms that create drug resistance.

We believe that our ONCOPREX Nanoparticle Delivery System could allow delivery of a number of cancer-fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer. We believe that REQORSA's combination of pan-kinase inhibition, direct induction of apoptosis, anti-cancer immune modulation and complementary action with targeted drugs and immunotherapies is unique, and positions REQORSA to provide treatment for patients with NSCLC and possibly other cancers, who are not benefitting from current therapies.

Diabetes Gene Therapy

Our diabetes gene therapy, also referred to as GPX-002, was developed by lead researcher Dr. George Gittes, at the Rangos Research Center at the UPMC Children's Hospital. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. The therapy utilizes a procedure in which an adeno-associated virus vector delivers Pdx1 and MafA genes to the pancreas.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act 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. Although we are an emerging growth company, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. We have implemented all new accounting pronouncements that are in effect and may affect our financial statements, and we do not believe that there are any other new accounting pronouncements that have been issued that would have a material impact on our financial position or results of operations.

Notwithstanding the foregoing, subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain exemptions, including, without limitation, the exemption from the requirements (i) to provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. 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 $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1.0 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.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our financial statements appearing in this Annual Report on Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain**.**

Research and Development Costs

We record accrued expenses for costs invoiced from research and development activities conducted on our behalf by third-party service providers, which include the conduct of preclinical studies and clinical trials and use of contract research and manufacturing activities. We record the costs of research and development activities based upon the amount of services provided, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. These costs are a significant component of our research and development expenses. Purchased materials to be used in future research are capitalized and included in research and development supplies.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment in any of our clinical trials may vary from our estimates and could result in our reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Income Taxes

Deferred tax assets or liabilities are recorded for temporary differences between financial statement and tax basis of assets and liabilities, using applicable rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. We have provided a full valuation allowance on our deferred tax assets, which primarily consist of cumulative net operating losses from April 1, 2009 (inception) to December 31, 2020. Due to our history of operating losses since inception and losses expected to be incurred in the foreseeable future, a full valuation allowance was considered necessary.

Impairment of Long-Lived Assets

Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value.

Off-Balance Sheet Arrangements

As of December 31, 2020 and 2019, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K or any commitments or contractual obligations.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into three categories: research and development, general and administrative, and depreciation.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as the discovery and development of our current and potential product candidates;
- costs related to production and storage of clinical supplies, including fees paid to contract manufacturers, manufacturing consultants, and cold-storage facilities;
- fees paid to clinical consultants, clinical trial sites and vendors, including CROs in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as patient screening fees, laboratory work, and statistical compilation and analysis;
- costs related to compliance with drug development regulatory requirements;
- costs related to staffing and personnel associated with research and development activities, including wages, taxes, benefits, leases, overheads, supplies, and share-based compensation.

We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our current and potential product candidates into and through clinical trials, as we pursue regulatory approval of our current and potential product candidates in the United States and Europe, and as we expand our research programs to include new therapies and new therapy combinations. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our current and potential product candidates may be affected by a variety of factors including the quality of our current and potential product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our current or future product candidates. As a result of the uncertainties discussed above, 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 our product candidates, if at all.

General and administrative. General and administrative expense consists of personnel related costs, which include salaries, as well as the costs of professional services, such as accounting and legal, travel, facilities, information technology and other administrative expenses. We expect our general and administrative expense to increase in future periods due to the anticipated growth of our business and related infrastructure as well as accounting, insurance, investor relations, and other costs associated with being a public company.

Depreciation. Depreciation expense consists of depreciation from our fixed assets consisting of our property, equipment, and furniture. We depreciate our assets over their estimated useful life. We estimate furniture and computer and office equipment to have a 5-year life.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following summarizes our results of operations for the years ended December 31, 2020 and 2019.

Research and Development Expense. Research and development ("R&D") expense was $7,302,923 for the year ended December 31, 2020 as compared to $1,967,007 for the year ended December 31, 2019. This increase of $5,335,916, or 271%, is due to the hiring of new employees and consultants to develop strategy for and execute on the launch of our Acclaim-1 and Acclaim-2 clinical trials, major advancements in our manufacturing programs providing drug product for our Acclaim-1 and Acclaim-2 clinical trials, and research of novel therapeutic approaches for the treatment of cancer using REQORSA and immunotherapies. These R&D activities will continue throughout 2021 and thereafter and will continue to include costs related to the launch and conduct of the Acclaim-1 and Acclaim-2 clinical trials, the development and execution on related manufacturing strategies and processes required to support these, and potentially other, clinical programs, and additional preclinical research.

General and Administrative Expense. General and administrative ("G&A") expense for the year ended December 31, 2020 was $10,635,881 as compared to $8,702,596 for the year ended December 31, 2019. The increase of $1,933,285, or 22% is mostly due to an increase in financing costs and legal fees associated with our registered direct offerings in 2020 as well as greater than normal share-based compensation expense associated with the accelerated vesting of options for a former executive pursuant to his separation agreement. Notwithstanding these expenses, some G&A expenses decreased for the year ended December 31, 2020 due to reclassification of expenses associated with R&D personnel to more accurately reflect expenses associated with their job function as well as reduced travel and office expenses as the result of travel restrictions and social distancing guidelines put in place as a result of the COVID-19 pandemic.

Interest Income. Interest income was $18,811 and $27,905 for the years ended December 31, 2020 and 2019, respectively. This decrease of $9,094, or 33%%, was due to changes in balances and a significant drop in interest rates of our money market instruments for the year ended December 31, 2020 as opposed to the prior year.

Interest Expense. There was no interest expense for the years ended December 31, 2020 and 2019 because we satisfied all debt obligations and repaid all short-term loans prior to 2019. As of December 31, 2020, we had no outstanding debt.

Depreciation Expense. Depreciation expense was $22,777 and $13,070 for the years ended December 31, 2020 and 2019, respectively. The increase of $9,707, or 74%, in depreciation was driven by increased purchase of equipment for use by employees and manufacturing partners for research activities in the year ended in December 31, 2020.

Liquidity and Capital Resources

From inception through December 31, 2020, we have never generated revenue from product sales and have incurred net losses in each year. As of December 31, 2020, we had an accumulated deficit of $58,422,229. We have funded our operations primarily through the sale and issuance of capital stock. During 2019, we sold 3,167,986 shares of common stock and warrants to purchase 3,167,986 shares of common stock for total net proceeds of $1,178,491 pursuant to a registered direct offering. For the year ended December 31, 2020, we sold an aggregate of 16,697,884 shares of common stock for total net proceeds of $34,493,423 pursuant to registered direct offerings and issued 7,104,524 shares of common stock with gross proceeds of $3,857,886 from warrant and option exercises.

As of December 31, 2020, we had $27,319,685 in cash.

We do not expect to generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our current and potential product candidates, or other product candidates to which we may acquire rights, which we expect will take a number of years and which is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations, which include conducting our Acclaim-1 and Acclaim-2 clinical trials expected to be initiated in 2021. Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to curtail or cease our operations. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

Based on our current cash, we estimate that we will be able to fund our expenditure requirements for our current operations and planned clinical trial activities into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently plan due to incorrect assumptions or due to a decision to expand our activities beyond those currently planned.

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2020 and 2019:

	Years Ended December 31,	
	2020	**2019**
Net cash used in operating activities	$ (13,935,086)	$ (6,918,721)
Net cash used in investing activities	(2,337,250)	(946,899)
Net cash provided by financing activities	41,589,529	1,267,194
Net increase (decrease) in cash	25,317,193	(6,598,426)

Cash used in operating activities

Net cash used in operating activities was $13,935,086 and $6,918,721 for the years ended December 31, 2020 and 2019, respectively. The increase of $7,016,365, or 101%%, in net cash used in operating activities in 2020 was due to an increase in financing costs and legal fees associated with our fundraising activities in early and late 2020 and significant increases to our headcount and service providers in preparation for the launch of our Acclaim-1 and Acclaim-2 clinical trials planned for 2021.

Cash used in investing activities

Net cash used in investing activities was $2,337,250 and $946,899 for the years ended December 31, 2020 and 2019, respectively. The increase in net cash used in investing activities of $1,390,351, or 147%, was primarily due to a major investment in manufacturing materials for the year ended December 31, 2020 that are currently being used to manufacture REQORSA for our planned clinical trials. Investments in property and equipment and intellectual property increased marginally for the year ended December 31, 2020 compared to the year ended December 31, 2019.

Cash provided by financing activities

Net cash provided by financing activities was $41,589,529 and $1,267,194 for the years ended December 31, 2020 and 2019, respectively. The increase of $40,322,335, or 3,182%, in net cash provided by financing activities was due to our selling common stock in capital raising activities throughout the year ended December 31, 2020.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are included after Part IV of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company’s management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective due to material weakness in our internal control over financial reporting due to lack of segregation of duties.

Management's Report on Internal Control over Financial Reporting

Our principal executive officer and our principal accounting and financial officer are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our management concluded that our internal controls over financial reporting were, and continue to be, ineffective as of December 31, 2020 due to a material weakness in our internal controls due to the lack of segregation of duties.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of certain events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In light of the material weakness described below, we performed additional analysis and other post-closing procedures to ensure our financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

During the last quarter of fiscal 2020 and as our operational activities increased, management determined and continues to determine that it does not have sufficient segregation of duties within its accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness.

Remediation Plans

Management has begun implementing a remediation plan to address the control deficiency that led to the material weakness. The remediation plan includes implementing the following:

- new accounting software, processes, and workflows to further segregate duties among limited accounting staff;
- specific review procedures, including the added involvement of our General Counsel, hired in 2020, to review all accounting transactions following a given period in an effort to enhance accuracy of reporting;
- specific review procedures, including the added involvement of our VP of Manufacturing, to enhance controls associated with the reporting of inventory values;
- the formation of a formal Disclosure Committee that has oversight responsibility for the accuracy and timeliness of disclosures made by the Company through the establishment of controls and procedures and the monitoring of their integrity and effectiveness; and
- additional hiring of accounting staff to further segregate accounting responsibilities.

We currently plan to have our enhanced review procedures and documentation standards in place and operating by the end of 2021. Our goal is to remediate this material weakness by the end of 2022, subject to there being sufficient opportunities to conclude, through testing, that the enhanced controls are operating effectively.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to the information that will be contained in our definitive proxy statement (the "Proxy Statement") for the 2021 annual meeting of stockholders (the "Annual Meeting"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2020.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial statements.

The financial statements and supplementary data required by this item begin on page F-1.

(a)(2) Financial Statement Schedules.

All schedules are omitted because the required information is inapplicable or the information is presented in the financial statements and the related notes.

(a)(3) Exhibits.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on April 10, 2018.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on April 10, 2018.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
4.2	Warrant Agreement, dated November 3, 2016, issued to Viet Ly, incorporated by reference to Exhibit 4.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
4.3	Form of Underwriter's Warrant Agreement, incorporated by reference to Exhibit 4.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
4.4	Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on May 10, 2018.
4.5	Warrant Agreement, dated July 27, 2018, issued to Cancer Revolution, LLC, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on August 6, 2018.
4.6	Warrant Agreement, dated July 27, 2018, issued to Inception Capital Management, LLC, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on August 6, 2018.
4.7	Warrant Agreement, dated July 27, 2018, issued to Cancer Biotech, LLC, incorporated by reference to Exhibit 4.3 of the Registrant's Current Report on Form 8-K filed on August 6, 2018.
4.8	Form of Warrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on November 22, 2019.
4.9	Description of Registrant's Securities, incorporated by reference to Exhibit 4.12 of the Registrant's Annual Report on Form 10-K filed March 30, 2020.
4.10	Warrant Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on April 28, 2020.
4.11*	Warrant Agreement, dated August 10, 2020, issued to Capital City Technical Consulting, Inc.
4.12*	Amended and Restated Warrant Agreement, dated August 10, 2020, issued to DABS Advanced Biotech Solutions, LLC.
4.13*	Amended and Restated Warrant Agreement, dated August 10, 2020, issued to DABS Advanced Biotech Solutions, LLC.
4.14*	Description of Registrant's Securities.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.2+	Registrant's 2009 Equity Incentive Plan and Forms of Grant Notices and Agreements thereunder, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.3+	Genprex, Inc. 2018 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder, incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K filed April 17, 2018.

Exhibit Number	Description of Exhibit
10.4+	Genprex, Inc. 2018 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K filed April 17, 2018.
10.5+	Genprex, Inc. Non-Employee Director Compensation Policy, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 8, 2018.
10.6	Patent and Technology License Agreement dated effective July 20, 1994, by and between the Board of Regents of the University of Texas System, The University of Texas M.D. Anderson Cancer Center and Intron Therapeutics, Inc., incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.7	Amendment No. 3 to Patent and Technology License Agreement dated October 4, 2001, incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.8	Technology Sublicense Agreement effective March 7, 2007, by and between Introgen Therapeutics, Inc., and Introgen Research Institute, Inc., incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.9	Assignment and Collaboration Agreement effective April 13, 2009, by and between Gensolve, Inc. and the Registrant, incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.10	Technology License Agreement dated as of February 26, 2010, by and between Introgen Research Institute, Inc. and P53, Inc., incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.11	Technology Sublicense Agreement effective June 1, 2011, by and between the Registrant and Introgen Research Institute, Inc., incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.12	Amended Collaboration and Assignment Agreement effective July 1, 2011, by and between Introgen Research Institute, Inc. and the Registrant, incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.13	Clinical Study Agreement dated February 10, 2014, by and between The University of Texas M.D. Anderson Cancer Center and the Registrant, incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.14	Amendment No. 1 to Clinical Study Agreement dated June 25, 2015, incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.15+	Amended and Restated Executive Employment Agreement, dated May 23, 2018, by and between the Registrant and Julien L. Pham, M.D., M.P.H., incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 30, 2018.
10.16+	Executive Employment Agreement dated April 13, 2018, by and between the Registrant and Rodney Varner, incorporated by reference to Exhibit 10.16 of the Registrant's Annual Report on Form 10-K filed on April 17, 2018.
10.17+	Executive Employment Agreement dated April 13, 2018, by and between the Registrant and Ryan Confer, incorporated by reference to Exhibit 10.17 of the Registrant's Annual Report on Form 10-K filed on April 17. 2018.
10.18	Securities Purchase Agreement dated as of May 6, 2018, by and between the Registrant and the persons named on the signature pages thereto, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 10, 2018.
10.19	Form of Registration Rights Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 10, 2018.

Exhibit Number	Description of Exhibit
10.20+	Consulting Agreement, dated August 13, 2018, by and between the Registrant and Viet Ly, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 14, 2018.
10.21	Form of Securities Purchase Agreement dated November 20, 2019, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 22, 2019.
10.22	Form of Securities Purchase Agreement dated January 16, 2020, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 17, 2020.
10.23	Form of Securities Purchase Agreement dated January 23, 2020, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 24, 2020.
10.24	Exclusive License Agreement dated as of February 11, 2020, by and between the Registrant and the University of Pittsburgh – Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 18, 2020.
10.25	Form of Securities Purchase Agreement dated February 19, 2020, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 20, 2020.
10.26+	Executive Employment Agreement dated March 12, 2020, by and between the Registrant and Catherine Vaczy, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on March 23, 2020.
10.27+	Executive Employment Agreement dated March 12, 2020, by and between the Registrant and Michael Redman, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on March 23, 2020.
10.28	Separation Agreement dated as of April 27, 2020, by and between the Registrant and Julien L Pham, MD, MPH, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on April 28, 2020.
10.29*++	Amendment No. 1 to Patent and Technology License Agreement, dated March 3, 2021, by and between the Registrant and The University of Texas M.D. Anderson Cancer Center.
23.1*	Consent of Daskzal Bolton LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) of the Securities Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) of the Securities Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Document.

* Filed herewith.
\+ Indicates management contract or compensatory plan.
++ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Item 16. Form 10–K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

GENPREX, INC.

Date: March 26, 2021

By: /s/ J. Rodney Varner
J. Rodney Varner
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ J. Rodney Varner J. Rodney Varner	Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer)*	March 26, 2021
/s/ Ryan M. Confer Ryan M. Confer	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 26, 2021
/s/ Brent Longnecker Brent Longnecker	Member of the Board of Directors	March 26, 2021
/s/ Jose Antonio Moreno Toscano Jose Antonio Moreno Toscano	Member of the Board of Directors	March 26, 2021
/s/ Will R. Wilson, Jr. Will R. Wilson, Jr.	Member of the Board of Directors	March 26, 2021

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Stockholders of Genprex, Inc.
Austin, Texas

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Genprex, Inc. (the "Company") at December 31, 2020 and 2019, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively referred to as 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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 audits. 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as whole, and we are not, by communicating the critical matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of equity transactions

As described in the *Equity* Note to the financial statements, the Company has complex equity transactions including the use of stock options and warrants. The estimates that management used in calculating the price value depend on assumptions specific to the nature of the management service activities with regard to the amount of the price model.
The principal consideration for our determination surrounding equity transactions as a critical audit matter is the significant judgment by management when developing the valuation of options and warrants. This, in turn, led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to the price model used to calculate equity transactions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included evaluating the use of the fair value-based method of accounting for stock-based compensation for options granted to employees, independent consultants and contractors. The Company measures options granted at fair value determined as of the grant date, and recognizes the expense over the periods in which the related services are rendered based on the terms and conditions of the awards. Evaluation of management's assumptions related to the price model and evaluating whether assumptions used by management were reasonable considering the current and past performance of equity, the consistency, and whether these assumptions were consistent with evidence obtained in other areas of the audit.

/s/ Daszkal Bolton LLP

We have served as the Company's auditor since 2014.

Boca Raton, FL

March 26, 2021

Genprex, Inc.

Balance Sheets

	2020	2019
Assets		
Current assets:		
Cash	$ 27,319,685	$ 2,002,492
Accounts receivable	127	655
Prepaid expenses and other	384,553	171,716
Supplies	3,011,042	801,780
Total current assets	30,715,407	2,976,643
Property and equipment, net	39,441	44,654
Other assets:		
Security deposits	10,741	21,732
Intellectual property, net	601,625	491,200
Total other assets	612,366	512,932
Total assets	$ 31,367,214	$ 3,534,229
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 192,968	$ 436,258
Other current liabilities	257,756	74,426
Total current liabilities	450,724	510,684
Investment unit	—	—
Commitments and contingencies		
Stockholders' equity:		
Common stock $0.001 par value: 200,000,000 shares authorized; 43,117,681 and 19,263,841 shares issued and outstanding, respectively	43,118	19,264
Additional paid-in capital	89,295,601	43,483,740
Accumulated deficit	(58,422,229)	(40,479,459)
Total stockholders' equity	30,916,490	3,023,545
Total liabilities and stockholders' equity	$ 31,367,214	$ 3,534,229

See accompanying notes to the financial statements

Genprex, Inc.

Statements of Operations

	Year Ended December 31,	
	2020	**2019**
Revenues	$ —	$ —
Cost and expenses:		
Depreciation	22,777	13,070
Research and development	7,302,923	1,967,007
General and administrative	10,635,881	8,702,596
Total costs and expenses	17,961,581	10,682,673
Operating loss	(17,961,581)	(10,682,673)
Interest income	18,811	27,905
Net loss	$ (17,942,770)	$ (10,654,768)
Net loss per share — basic and diluted	$ (0.51)	$ (0.66)
Weighted average number of common shares — basic and diluted	35,522,875	16,026,980

See accompanying notes to the financial statements

Genprex, Inc.

Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2018	15,239,148	$ 15,240	$ 38,690,586	$ (29,824,691)	$ 8,881,135
Issuance of stock for cash	3,517,986	3,518	1,263,676	—	1,267,194
Issuance of stock for services	506,707	506	469,082	—	469,588
Share based compensation	—	—	3,060,396	—	3,060,396
Net loss	—	—	—	(10,654,768)	(10,654,768)
Balance at December 31, 2019	19,263,841	$ 19,264	$ 43,483,740	$ (40,479,459)	$ 3,023,545
Issuance of stock for cash	23,802,408	23,802	41,565,727	—	41,589,529
Issuance of stock for services	51,432	52	154,596	—	154,648
Share based compensation	—	—	4,091,538	—	4,091,538
Net loss	—	—	—	(17,942,770)	(17,942,770)
Balance at December 31, 2020	43,117,681	$ 43,118	$ 89,295,601	$ (58,422,229)	$ 30,916,490

See accompanying notes to the financial statements

Genprex, Inc.

Statements of Cash Flows

	2020	2019
Cash flows from operating activities:		
Net loss	$ (17,942,770)	$ (10,654,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	22,777	13,070
Share based compensation	4,246,186	3,529,984
Changes in operating assets and liabilities:		
Accounts receivable	528	8,642
Prepaid expenses and other	(212,837)	65,135
Deposits	10,991	(3,647)
Accounts payable and accrued expenses	(247,290)	141,189
Other current liabilities	187,329	(18,326)
Net cash used in operating activities	(13,935,086)	(6,918,721)
Cash flows from investing activities:		
Additions to property and equipment	(17,564)	(33,370)
Additions to intellectual property	(110,424)	(111,749)
Additions to research and development supplies	(2,209,262)	(801,780)
Net cash used in investing activities	(2,337,250)	(946,899)
Cash flows from financing activities:		
Proceeds from issuances of common stock	41,589,529	1,267,194
Net cash provided by financing activities	41,589,529	1,267,194
Net increase (decrease) in cash	25,317,193	(6,598,426)
Cash, beginning of year	2,002,492	8,600,918
Cash, end of year	$ 27,319,685	$ 2,002,492

See accompanying notes to the financial statements

Note 1 – Description of Business and Basis of Presentation

We are a clinical stage gene therapy company focused on developing life-changing treatments for cancer and diabetes. Our lead cancer drug candidate, REQORSA™ Immunogene therapy drug (sometimes referred to as GPX-001), is being developed to treat non-small cell lung cancer ("NSCLC"). The active agent in REQORSA is a TUSC2 gene expressing plasmid that is encapsulated in a DOTAP cholesterol nanoparticle. TUSC2 is a tumor suppressor gene which has both tumor killing (via apoptosis) and immunomodulatory effects. We utilize our novel proprietary ONCOPREX® Nanoparticle Delivery System to deliver the TUSC2 gene expressing plasmid to cancer cells. The TUSC2 gene is one of a series of genes whose therapeutic use is covered by our exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson").

We are planning to initiate our Acclaim-1 and Acclaim-2 clinical trials in 2021. Acclaim-1 is a Phase 1/2 clinical trial using a combination of REQORSA with AstraZeneca PLC's Tagrisso® in patients with late-stage NSCLC with mutated epidermal growth factor receptors ("EGFRs") whose disease progressed after treatment with Tagrisso. In January 2020, we received Food and Drug Administration ("FDA") Fast Track Designation for the Acclaim-1 patient population. Acclaim-2 is a Phase 1/2 clinical trial using a combination of REQORSA with Merck & Co.'s Keytruda® in late-stage NSCLC patients who are low expressors (1% to 49%) of the protein programmed death-ligand 1 ("PD-L1").

In diabetes, we are developing a gene therapy that is exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh") for the treatment of Type 1 and Type 2 diabetes. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. Our diabetes product candidate is currently being evaluated in preclinical studies.

Oncology Platform

Utilizing our non-viral ONCOPREX Nanoparticle Delivery System, we are developing cancer treatments that are designed to administer cancer fighting genes. We encapsulate the gene-expressing plasmids using ONCOPREX lipid nanoparticles, and administer them intravenously, where they are then taken up by tumor cells and express proteins that are missing or found in low quantities in the tumor cells. With our lead drug candidate, REQORSA, there is a multimodal mechanism of action whereby REQORSA interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and modulates the immune response against cancer cells. REQORSA has also been shown to block mechanisms that create drug resistance.

We believe that our ONCOPREX Nanoparticle Delivery System could allow delivery of a number of cancer-fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer. We believe that REQORSA's combination of pan-kinase inhibition, direct induction of apoptosis, anti-cancer immune modulation and complementary action with targeted drugs and immunotherapies is unique, and positions REQORSA to provide treatment for patients with NSCLC and possibly other cancers, who are not benefitting from current therapies.

Diabetes Gene Therapy

Our diabetes gene therapy, also referred to as GPX-002, was developed by lead researcher Dr. George Gittes, at the Rangos Research Center at the University of Pittsburgh Medical Center Children's Hospital. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. The therapy utilizes a procedure in which an adeno-associated virus vector delivers Pdx1 and MafA genes to the pancreas.

Capital Requirements, Liquidity and Going Concern Considerations

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP") applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, as shown in the accompanying financial statements, we have sustained substantial losses from operations since inception and have no current source of revenue. In addition, we have used, rather than provided, cash in our operations. We expect to continue to incur significant expenditures to further clinical trials for the commercial development of our patents.

Management recognizes that we must obtain additional resources to successfully commercialize our intellectual property. To date, we have received funding in the form of equity and debt, and we plan to seek additional funding in the future. However, no assurances can be given that we will be successful in raising additional capital. If we are not able to timely and successfully raise additional capital, the timing of our clinical trials, financial condition and results of operations will continue to be materially affected. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities.

Note 2 – Summary of Significant Accounting Policies

The Company's financial statements have been prepared in accordance with GAAP. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. In our opinion the financial statements include all adjustments (consisting of normal recurring accruals) necessary to make the financial statements not misleading. The results of operations for any interim periods are not necessarily indicative of results to be expected for the full year. A summary of our significant accounting policies consistently applied in the preparation of the accompanying financial statements follows.

Capital Stock

In connection with the Company's initial public offering ("IPO") in April 2018, all of the Company's preferred stock and non-voting common stock were converted into shares of the Company's common stock. The Company's common stock was then forward-split at a ratio of 6.6841954-to-1. Furthermore, prior to the closing of the IPO, the Company's Certificate of Incorporation was amended and restated to provide the Company with the authority to issue up to 210,000,000 shares of stock consisting of 200,000,000 shares of common stock at a par value of $0.001 per share and 10,000,000 shares of preferred stock at a par value of $0.001 per share.

Use of Estimates

The preparation of our financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash

We consider all highly liquid short-term investments with an initial maturity of three months or less to be cash equivalents. Any amounts of cash in financial institutions which exceed FDIC insured limits expose us to cash concentration risk. We have no cash equivalents, and had $27,091,596 and $1,761,278 in excess of FDIC insured limits of $250,000 at December 31, 2020 and December 31, 2019 respectively.

Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for cash, accounts receivable, accounts payable and accrued expenses approximate fair value because of the immediate or short-term maturity of these financial instruments.

Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures, defines fair value, provides a consistent framework for measuring fair value under GAAP and expands fair value financial statement disclosure requirements. ASC 820's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. ASC 820 classifies these inputs into the following hierarchy:

Level 1:	Quoted prices for identical instruments in active markets.
Level 2:	Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.
Level 3:	Instruments with primarily unobservable value drivers.

Property and Equipment

Furniture and equipment are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Routine maintenance and repairs are charged to expense as incurred and major renovations or improvements are capitalized.

Research and Development Materials Costs

Research and development expenditures consist of costs incurred to conduct research and development activities. These include payments to collaborative research partners, manufacturing partners, and clinical strategy partners, wages and associated employee benefits, facilities and overhead costs. These expenditures relate to our preclinical, Phase 1, and Phase 2 clinical trials and are expensed as incurred. Purchased materials to be used in future research are capitalized and included in research and development supplies. Research and development supplies purchased and capitalized for future use was $3,011,042 and $801,780 at December 31, 2020 and December 31, 2019, respectively.

Awards

In 2010, we were awarded $4.5 million from the State of Texas Emerging Technology Fund ("TETF"). The award was received in two tranches of $2.25 million during 2010 and 2011. The award proceeds were used for the development and future commercialization of our nanomolecular therapy product for the treatment of cancer. In consideration for the award, we provided the TETF with an "Investment Unit", consisting of (i) a Promissory Note ("Note") and (ii) a right to purchase our equity shares ("Warrant"). The funds received for this award were assigned to the Investment Unit, and classified separately from equity as "mezzanine" in the balance sheet.

In 2010, we also were awarded approximately $244,500 from the U.S. Treasury Department for our QTDP Program Nanoparticle Therapy for Lung Cancer. The award was received during 2011 for our historical activities, and required no prospective expenditures. We accounted for these funds received as revenue at that time.

Intellectual Property

Intellectual property consists of legal and related costs associated with patents and other proprietary technology and rights developed, acquired, licensed by, or maintained by us that we believe contribute to a probable economic benefit toward such patents and activities. These costs incurred in connection with obtaining and maintaining intellectual property protection, such as patent applications and patent maintenance, are capitalized. Intellectual property is stated at cost, to be amortized on a straight-line basis over the estimated useful lives of the assets.

Accounting for Stock-Based Compensation

We use the fair value-based method of accounting for stock-based compensation for options granted to employees, independent consultants and contractors. We measure options granted at fair value determined as of the grant date, and recognize the expense over the periods in which the related services are rendered based on the terms and conditions of the award. Generally, where the award only has a service condition, the requisite service period is the same as the vesting period.

Financial Instruments

We have elected the Fair Value Option to account for the Investment Unit at fair value as a combined hybrid financial instrument containing a Warrant and a Note (see Note 4 - Investment Unit Note). Prior to its exercise, the Warrant component was not classified within equity, as the exercise price of the warrants was affected by the market price of our stock in a future qualifying financing transaction and was not considered to be indexed to our own stock. The Note is not classified within liabilities, as our management can determine the timing of the repayment obligation, if any. As a result, the Warrant and Note that comprised the Investment Unit were aggregated and classified within the mezzanine section of the balance sheet.

Due to the contingent terms of the financial instruments, changes in the fair value of the Investment Unit were calculated and realized in earnings. There were no changes in the fair value of the Investment Unit at December 31, 2020.

In August 2019, the remaining articles of the Investment Unit were terminated.

Long-Lived Assets

We review long-lived assets and certain identifiable intangibles held and used for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In evaluating the fair value and future benefits of its intangible assets, management performs an analysis of the anticipated undiscounted future net cash flow of the individual assets over the remaining amortization period. We recognize an impairment loss if the carrying value of the asset exceeds the expected future cash flows. During the years ended December 31, 2020 and December 31, 2019, there were no deemed impairments of our long-lived assets.

Recent Accounting Developments

Accounting pronouncements issued but not effective until after December 31, 2020 are not expected to have a significant effect on our financial condition, results of operations, or cash flows.

Note 3 – Intellectual Property

On February 11, 2020, we entered into an exclusive license agreement with the University of Pittsburgh for patented gene therapy technologies relating to the potential treatment of type 1 and type 2 diabetes.

On May 4, 2020, the Company entered into an exclusive worldwide license agreement with The Board of Regents of the University of Texas System on behalf of MD Anderson relating to a portfolio of 16 patent applications and related technology for the treatment of cancer using the Company's lead drug candidate and immunotherapies.

We have exclusive license agreements on 28 issued patents and 17 pending patent applications worldwide for technologies developed by researchers at the National Cancer Institute, MD Anderson, the University of Texas Southwestern Medical Center, and the University of Pittsburgh. These patents comprise various therapeutic, diagnostic, technical and processing claims. These license rights will be amortized on a straight-line basis over the estimated period of useful lives of the underlying patents or the license agreements.

Note 4 – Investment Unit

The TETF was created as an incentive for economic development to the Texas economy by providing financial support that leverages private investment for the creation of high-quality technology jobs in Texas. The award received required us to comply with certain performance conditions to ensure the monies the Company received were used for development activities in the state of Texas, and that we maintained our corporate nexus in Texas. Further, in connection with the award, the Company issued an Investment Unit to the TETF. On September 25, 2017 and again on August 16, 2019, the Company entered into Termination Agreements with the Texas Treasury Safekeeping Trust Company, the entity managing and controlling TETF interests, that terminated Article II and the all remaining Articles of the Investment Unit, respectively, so that the entirety of the Investment Unit was effectively terminated. As further described below, the Investment Unit consisted of a Promissory Note and a Right to Purchase.

Promissory Note

The Promissory Note was an obligation to repay the $4.5 million principal amount, with interest accrued at 8% per annum, but only if an event of default occurred prior to August 13, 2020. If no event of default occurred prior to August 13, 2020, the Promissory Note and all related interest would be cancelled. The Note was cancelled on August 16, 2019.

Consistent with the stated objectives of the TETF, an event of default that would trigger the repayment obligation under the Promissory Note was a failure to maintain our principal place of business or our principal executive offices headquartered in the State of Texas (referred to as the “Residency Requirement”) until August 13, 2020.

Warrant

The Warrant was an obligation to issue (a Right to purchase by the TETF) shares of the same class of stock as issued in the Company's next financing transition (“First Qualifying Financing Transaction”), at 80% of the per share transaction value (effectively a 20% discount). Alternatively, the TETF could exercise its right to purchase at any time prior to the occurrence of a First Qualifying Financial Transaction for $0.001 per share.

The Warrant included a provision that required changes in the strike price, driven by the pricing of the First Qualifying Financing Transaction. As a result, the Warrant embedded in the Investment Unit was accounted for as a derivative financial instrument and classified outside of equity under ASC 815-40-15 as the settlement adjustment from the future transaction did not permit for the strike price to be considered fixed.

On March 12, 2014, the TETF exercised its Right to Purchase for $0.001 per share, and we issued to the TETF an aggregate of 184,797 shares of our Series B preferred stock. These shares were subsequently forward-split and converted to 1,235,219 shares of common stock in connection with our IPO.

Accounting for the Investment Unit

We accounted for the Investment Unit as a hybrid financial instrument under Financial Accounting Standards Board ("FASB") Statement 155, and measured the Investment Unit at the amount of proceeds received from the TETF award. The First Qualifying Financial Transaction occurred during December 2013, resulting in an adjustment to the fair value of the Investment Unit in the amount of approximately $2.5 million. The TETF exercised the Warrant for $0.001 per share. We received notice of purchase from the TETF during March 2014, and issued 184,797 shares of Series B preferred stock, which has since been converted to 1,235,219 shares of common stock upon completion of the Company’s IPO. Upon exercise by the TETF of the Warrant, the remaining component within the Investment Unit was the Promissory Note. The Investment Unit was valued at zero, because our obligation to repay the Promissory Note arose from an event of default (a failure to maintain the Texas Residency Requirement), which was an event which rested entirely within our control.

Note 5 – Equity

Registered Direct Offerings

On November 22, 2019, the Company completed a registered direct offering ("2019 RDO"), whereby the Company sold to investors an aggregate of 3,167,986 shares of the Company's common stock at $0.40 per share and warrants to purchase up to 3,167,986 shares of the Company's common stock at an exercise price of $0.46 per share. The warrants were first exercisable on May 22, 2020. The Company received net proceeds of approximately $1,093,000 after commissions and expenses. Additionally, the placement agent was issued warrants to purchase common stock equal to 7% of the aggregate number of shares of common stock issued and issuable pursuant to the 2019 RDO (including shares underlying any warrants), or 443,518 shares of common stock at an exercise price of 125% of the 2019 RDO price per share, or $0.50 per share.

In connection with the closing of the 2019 RDO, the Company further adjusted the warrants to purchase up to 2,283,740 shares of the Company's common stock, which had been issued as part of the Company's May 9, 2018 private placement and adjusted in August 2018 to (i) reduce the exercise price for each share from $4.25 per share to $0.46 per share, (ii) extend the date upon which such warrants could be exercised to May 22, 2020, and (iii) extend the termination date of such warrants by six months and one day.

On January 21, 2020, the Company completed a registered direct offering, in which the Company sold to an accredited investor 961,000 shares of the Company's common stock at $0.24 per share. The Company received net proceeds of approximately $200,000 after commissions and expenses.

On January 23, 2020, the Company completed a registered direct offering, in which the Company sold to investors an aggregate of 7,620,000 shares of the Company's common stock at $1.05 per share. The Company received net proceeds of approximately $7.2 million after commissions and expenses.

On February 19, 2020, the Company amended its Registration Statement on Form S-3 to increase the maximum offering size by approximately $3,000,000. On February 21, 2020, the Company completed a registered direct offering under the amended S-3 Registration Statement, in which the Company sold to investors an aggregate of 5,000,000 shares of the Company's common stock at $3.50 per share. The Company received net proceeds of approximately $16 million after commissions and expenses.

On December 24, 2020, the Company completed a registered direct offering, in which the Company sold to an accredited investor 3,116,884 shares of the Company's common stock at $3.85 per share. The Company received net proceeds of approximately $11.2 million after commissions and expenses.

Stock Issuances

During the year ended December 31, 2020, we issued (i) 16,697,884 shares of common stock from registered direct offerings for cash proceeds of $37,731,643, (ii) 1,277,743 shares of common stock from the exercise of options for cash proceeds of $1,320,155, (iii) 5,511,599 shares of common stock from the exercise of warrants for cash proceeds of $2,537,731, (iv) 199,630 shares of common stock from the exercise of cashless warrants, and (v) 51,432 shares of common stock for service provided to us, valued at $154,648.

During the year ended December 31, 2019, we issued (i) 3,167,986 shares of common stock from the Company's 2019 RDO for cash proceeds of $1,267,194, (ii) 506,707 shares of common stock for service provided to us, valued at $469,588, and (iii) we issued 350,000 shares of common stock held in abeyance for an investor from our May 2018 private placement.

Preferred Stock

In connection with the Company's IPO, all preferred stock included in Series A through Series G, totaling 1,394,953 shares were converted into 9,324,177 shares of common stock in association with the forward-split (See Note 2 - Capital Stock). Upon the completion of the IPO, the Company is authorized to issue 10,000,000 shares of preferred stock at a par value of $0.001 per share, none of which are outstanding as of December 31, 2020.

Common Stock

Upon the completion of the IPO, all of the Company's non-voting common stock automatically converted into voting common stock on a one-to-one basis. Immediately following the completion of the IPO, the Company is authorized to issue 200,000,000 shares of common stock at a par value of $0.001 per share, all of which is voting common stock. There were 43,117,681 shares of common stock outstanding at December 31, 2020.

Common Stock Purchase Warrants

Common stock purchase warrant activity for the years ended December 31, 2020 and 2019 respectively are as follows:

	Number of Warrants	Weighted Avg. Exercise Price
Outstanding at January 1, 2019	3,864,552	$ 2.36
Issued	3,611,504	0.47
Cancelled or expired	—	—
Exercised	—	—
Outstanding at December 31, 2019	7,476,056	$ 1.45
Issued	550,000	2.41
Cancelled or expired	(44,528)	0.50
Exercised	(5,826,781)	0.47
Outstanding at December 31, 2020	2,154,747	$ 4.37
Exercisable at December 31, 2020	1,904,747	$ 4.61

In the year ending December 31, 2020, (i) investors and placement agents of the Company's May 2018 private placement and 2019 RDO exercised warrants to purchase 5,511,599 shares of common stock for cash proceeds of $2,537,731, (ii) the Company issued 315,182 shares of common stock and cancelled 44,528 shares of common stock to placement agents of the 2019 RDO for the exercise of warrants via cashless exercise, and (iii) the Company issued warrants to purchase up to 550,000 shares of common stock to service providers, including 500,000 shares of common stock to Cancer Revolution, LLC at an exercise price of $2.27 per share and 50,000 shares of common stock to Capital City Technical Consulting, Inc. at an exercise price of $3.81 per share. In the year ending December 31, 2020, we recorded share-based compensation of $450,000 associated with Company milestone-based vesting of the Cancer Revolution, LLC warrants. We expect to record $124,000 of share-based compensation for time-based vesting over the next three years and another $300,000 of share-based compensation based on performance-based vesting.

In the year ending December 31, 2019, we (i) issued warrants to purchase 3,167,986 shares of our common stock at $0.46 per share to the investors in the Company's 2019 RDO, (ii) issued warrants to purchase 443,518 shares of our common stock at $0.58 per share to the underwriter of the Company's 2019 RDO, and (iii) reduced the exercise price of the warrants, issued to investors in the Company's May 2018 private placement, to purchase 2,283,740 shares of the Company's common stock from $4.25 per share to $0.46 per share.

On January 29, 2018, the Company entered into an agreement with a consultant whereby the Company agreed to grant warrants to purchase 6,000 shares of our common stock at $5.00 per share in consideration of services valued at $30,000 provided to the Company. As of December 31, 2020, the Company has not issued these warrant shares.

2018 Equity Incentive Plan

The Company's board of directors and stockholders have approved and adopted the Company's 2018 Equity Incentive Plan ("2018 Plan"), which became effective on the completion of the IPO on April 3, 2018. The 2018 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, other forms of equity compensation and performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to the Company's non-employee directors and consultants, and affiliates.

A total of 4,160,000 shares of common stock are available under the 2018 Plan, which includes 554,963 shares of common stock reserved for issuance under our 2009 Equity Incentive Plan that were added to the 2018 Plan. No further grants will be made under the 2009 Plan and any shares subject to outstanding stock options under the 2009 Plan that would otherwise be returned to the 2009 Plan will instead be added to the shares initially reserved under the 2018 Plan.

In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year, beginning on January 1, 2019 by 5% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the administrator of the 2018 Plan. On January 1, 2019 and 2020, the number of shares of common stock reserved for issuance under the 2018 Plan was increased by an aggregate of 761,957 and 963,192 shares, respectively.

2018 Employee Stock Purchase Plan

The Company's board of directors and stockholders have approved and adopted the Company's 2018 Employee Stock Purchase Plan ("ESPP"), which became effective on the completion of the IPO on April 3, 2018. The ESPP authorizes the issuance of 208,500 shares of the Company's common stock pursuant to purchase rights granted to our eligible employees. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2019 by the lesser of 2% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a number determined by the administrator of the ESPP. The administrator of the ESPP, which is our Board of Directors, determined not to increase the number of shares for issuance under the ESPP on January 1, 2019 or January 1, 2020 due to the ESPP not currently being utilized.

Stock Options

As of December 31, 2020, the Company has outstanding stock options to purchase 6,844,069 shares of common stock that have been granted to various officers, directors, employees, vendors and independent contractors. These options can vest immediately or over periods ranging from twelve (12) to forty-eight (48) months, are exercisable for a period of ten years, and enable the holders to purchase shares of our common stock at exercise prices ranging from $0.001 - $9.80. The per-share fair values of these options range from $0.001 to $7.93, based on Black-Scholes-Merton pricing models with the following assumptions:

Expected term (in years):	10
Risk-free rate:	0.12% – 1.55%
Volatility:	79.89% – 83.31%
Dividend yield:	0%

In the year ending December 31, 2020, the Company (i) granted stock options to purchase an aggregate of 2,466,529 shares of the Company's common stock with exercise prices ranging from $1.28 to $4.42 per share to employees, board members, and consultants, (ii) cancelled options to purchase 327,640 shares of common stock at exercise prices ranging from $5.29 to $9.80 due to expiration of options and separation of a former executive, and (iii) issued 1,277,743 shares of the Company's common stock upon the exercise of options held by former board members and a former executive with exercise prices ranging from $0.015 to $2.15 per share.

In the year ending December 31, 2019, Company granted stock options to employees and consultants to purchase 1,744,300 shares of common stock with exercise prices ranging from $0.30 to $1.62 per share and cancelled options to purchase 297,058 shares of common stock due to the inactivity of service providers.

The weighted average remaining contractual term for the outstanding options at December 31, 2020 and 2019 is 7.06 and 7.45 years, respectively.

Stock option activity for the years ended December 31, 2020 and 2019, respectively, is as follows:

	Number of Shares	Weighted Avg. Exercise Price
Outstanding at January 1, 2019	4,535,681	$ 3.31
Options granted	1,744,300	1.48
Options exercised	—	—
Options expired	(297,058)	—
Outstanding at December 31, 2019	5,982,923	$ 2.66
Options granted	2,466,529	2.87
Options exercised	(1,277,743)	1.03
Options expired	(327,640)	8.31
Outstanding at December 31, 2020	6,844,069	$ 2.81
Exercisable at December 31, 2020	4,491,545	$ 2.75

Share-Based Compensation

In the year ending December 31, 2020, the Company's total share-based compensation was approximately $4.3 million, of which approximately $3.6 million represents the vesting of options issued to service providers, executives, employees, and board members. The Company's total compensation cost related to non-vested time-based stock option awards granted to executives, employees, and board members and not yet recognized was approximately $4.7 million the year ending December 31, 2020. The Company expects to record this stock-based compensation expense over the next three years using a graded vesting method. As of December 31, 2020, the weighted average term over which these expenses are expected to be recognized are 2.15 years.

As of December 31, 2020, there are no performance-based stock option awards outstanding.

In the year ended December 31, 2019, the Company's total share-based compensation was approximately $3.5 million with approximately $3.0 million representing the vesting of options issued to service providers, employees, and board members.

Note 6 - Related Party Transactions

Introgen Research Institute

Introgen Research Institute ("IRI") is a Texas-based technology company, currently affiliated with Rodney Varner, our Chief Executive Officer and director. In April 2009, prior to Mr. Varner becoming an officer and director of our Company in August 2012, we entered into an Assignment and Collaboration Agreement with IRI, providing us with the exclusive right to commercialize a portfolio of intellectual property. This agreement was amended in 2011 to include additional sublicensing of additional intellectual property made available to IRI from MD Anderson.

Viet Ly

The Company entered into a consulting agreement with Viet Ly on April 19, 2018. The Company agreed to pay Mr. Ly $175,000 initially, with compensation variable from time-to-time as determined by the Company, for strategic consulting services. The Company paid Mr. Ly an aggregate of $28,500 during the quarter ended September 30, 2020 for strategic services. In addition, in April 2020, the Company issued Cancer Revolution LLC, an entity owned by Mr. Ly, a warrant to purchase up to 500,000 shares of common stock at the fair market value of the common stock on the date of issuance that vests based on the achievement of Company milestones.

Note 7 - Commitments and Contingencies

Leases

On April 16, 2018, the Company executed a service agreement with CIC Innovation Communities, LLC to establish and lease offices at the Cambridge Innovation Center in Cambridge, Massachusetts. On April 1, 2020, the Company provided notice of cancellation of our lease in the Cambridge Innovation Center in Cambridge, Massachusetts, effective April 30, 2020.

On April 16, 2018, the Company executed a space utilization agreement with the Board of Regents of the University of Texas System to establish and lease offices at the Dell Medical School in Austin, Texas. The lease runs through April 30, 2021 and the Company pays $462 per month to occupy this location.

Commitments

MD Anderson

We have entered into a clinical study agreement with the MD Anderson, to administer the Company's phase 1/2 clinical trial, combining REQORSA-nanoparticles and Tarceva in Stage 4 lung cancer patients. The trial was expected to run through the end of 2018 with a projected total cost of approximately $2 million. Payments are due and payable when invoiced throughout the clinical trial period. The agreement may be terminated at any time. In 2020, the Company received from the Food and Drug Administration Fast Track Designation ("FTD") for its Acclaim-1 trial which combines REQORSA plus Tagrisso in patients who have previously failed Tagrisso treatment. Given the FTD and with Tagrisso now considered a new standard of care in the US for NSCLC with an EGFR mutation, we are no longer enrolling ONC-002 and plan to initiate Acclaim-1 and Acclaim-2 in 2021.

In July 2018, the Company entered into a two-year sponsored research agreement with MD Anderson to sponsor preclinical studies focused on the combination of REQORSA with an immunotherapy with a projected total cost of approximately $2 million. Payments are due and payable when invoiced throughout the clinical trial period. The agreement may be terminated at any time. This agreement has been extended through May 2022.

In 2009, we agreed to assume certain contractual and other obligations of IRI in consideration for the sublicense rights, expertise, and assistance associated with the assignment of certain technologies and intellectual property. We also agreed to pay royalties of one percent (1%) on sales of resulting certain licensed products, for a period of 21 years following the termination of the last of the Technology Sublicense Agreement dated March 7, 2007 by and between Introgen Therapeutics, Inc., and IRI, and we assumed patent prosecution costs and an annual minimum royalty of $20,000 payable to the National Institutes of Health.

National Institutes of Health

Our $191,393 payment obligation to the National Institutes of Health ("NIH") represented a current obligation, of which $15,393 of 2016 patent prosecution costs were paid in the fourth quarter of 2016 and $176,000 was included in Accounts Payable at December 31, 2016 (consisting of accrued annual royalties of $140,000 and patent costs of $36,000). During the first quarter of 2017, we modified the terms of our accrued royalty obligation to NIH. Under the modified agreement, NIH agreed to extinguish $120,000 of the accrued royalties payable to them in consideration for payment by us of (i) accrued patent costs of $36,000, (ii) a royalty payment of $20,000, and (iii) a contingent payment of $240,000, increasing at $20,000 per year starting in 2018, to be paid upon our receipt of FDA approval. The payments for the patent costs of $36,000 and royalties of $20,000 were paid during the second quarter of 2017.

As a result of our modified agreement with the NIH, we have recognized the exchange of the $120,000 fixed obligation for the $240,000 contingent obligation as a $120,000 reduction to intellectual property expense (classified within General and Administrative Expense) during the first quarter of 2017. The $240,000 contingent obligation which increases annually by $20,000 and is $300,000 as of December 31, 2020 will be recognized when we obtain regulatory approval (the event that triggers the payment obligation).

University of Pittsburgh

As part of our License Agreement with the University of Pittsburgh in February 2020, we agreed to (i) an initial licensing fee of $25,000, (ii) annual maintenance fees of $25,000 for the first three years and $40,000 for each subsequent year following the first anniversary of the agreement, (iii) royalties between 1.5% to 3% of net sales of licensed technologies, (iv) an annual minimal royalty payment of $250,000 per year beginning in the year of the first commercial sale of licensed technology, (v) a share of non-royalty sublicense income of 20%, and (vi) milestone payments of an aggregate of $3,975,000. The agreement expires upon the later of (i) 20 years after the first commercial sale of the licensed technology thereunder and (ii) expiration of the last valid claim under the patent rights, subject to earlier termination pursuant to the terms of the agreement.

Contingencies

From time to time we may become subject to threatened and/or asserted claims arising in the ordinary course of our business. Management is not aware of any matters, either individually or in the aggregate, that are reasonably likely to have a material impact on our Company's financial condition, results of operations or liquidity.

Note 8 - Significant Events

In March 2020, the outbreak of COVID-19 caused by a novel strain of the coronavirus was recognized as a pandemic by the World Health Organization. The pandemic has become increasingly widespread in the United States, including markets in which the Company operates or may operate in the future. The COVID-19 pandemic has had a notable impact on general economic conditions, including, but not limited to, the temporary closures of many businesses, "shelter in place" orders and other governmental regulations, reduced consumer spending due to both job losses and other effects attributable to the COVID-19, in addition to many other unknowns. To date, the Company has not experienced any material impact on its financial results or operations as a result of the COVID-19 pandemic. The extent to which the COVID-19 pandemic could impact the Company's operations or financial results is uncertain. The Company continues to monitor the impact of the COVID-19 pandemic closely.

Note 9 – Income Taxes

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate to income before provision for income taxes. The sources and tax effects of the differences are as follows:

Income tax provision at the federal statutory rate	21%
Effect of operating losses	(21)%
	0%

At December 31, 2020, the Company has a net operating loss carryforward of approximately $44.6 million for Federal and state purposes. This loss will be available to offset future taxable income. If not used, this carryforward will begin to expire in 2029. The deferred tax asset relating to the operating loss carryforward has been fully reserved at December 31, 2020 and December 31, 2019. The principal differences between the operating loss for income tax purposes and reporting purposes are shares issued for services and share-based compensation and a temporary difference in depreciation expense.

Note 10 – Subsequent Events

Reserves of 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan

On January 1, 2021, the total shares of common stock reserved under the 2018 Equity Incentive Plan increased 2,155,884 shares. On March 17, 2021, the Company's Board of Directors determined that no additional shares would be reserved during the 2021 fiscal year for the 2018 Employee Stock Purchase Plan given that no shares have yet been issued under the plan.

Share Issuances

On January 1, 2021, the Company issued 5,000 shares of common stock to a service provider in consideration of services. On March 18, 2021, the Company issued 38,056 shares of common stock for $61,651 in cash to a former executive upon the exercise of a stock option granted under the 2018 Equity Incentive Plan.

Option & Warrant Issuances

On February 10, 2021, the Company's Board of Directors approved the (i) grant of stock options under the 2018 Equity Incentive Plan to purchase a total of 210,000 shares of common stock to employees and consultants, and (ii) an issuance of a warrant to purchase up to 17,500 shares of common stock to a consultant, at the fair market value of the common stock on the date of issuance.

Registered Direct Offering

On February 10, 2021, the Company completed a registered direct offering, in which the Company sold to investors an aggregate of 4,000,000 shares of the Company's common stock at $6.25 per share. The Company received net proceeds of approximately $23.2 million after commissions and expenses.

License Agreement

On March 3, 2021, the Company entered into an amendment (the "MD License Amendment") to the Patent and Technology License Agreement dated May 4, 2020 with MD Anderson. The MD License Amendment grants the Company a worldwide, exclusive, sublicensable license to an additional portfolio of six patents and one patent application and related technology for methods for treating cancer by administration of a TUSC2 therapy in conjunction with EGFR inhibitors or other anti-cancer therapies in patients predicted to be responsive to TUSC2 therapy. Pursuant to the MD License Amendment, the Company agreed to (i) pay annual maintenance fees ranging from the mid five figures to the low six figures, (ii) total milestone payments of $6,150,000, (iii) a one-time fee in the mid five figures and (iv) certain patent related expenses.

Executive Compensation

On March 19, 2021, the Company's Compensation Committee approved (i) annual incentive awards of an aggregate of $599,667 and (ii) the grant of stock options under the 2018 Equity Incentive Plan to purchase an aggregate of 1,095,000 shares of the Company's common stock to Company executives.

THE PURCHASE RIGHTS EVIDENCED BY THIS WARRANT AGREEMENT AND THE SHARES OF CAPITAL STOCK ISSUABLE UPON EXERCISE OF SUCH PURCHASE RIGHTS HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED OR ANY STATE SECURITIES LAWS. SUCH SECURITIES CANNOT BE SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF WITHOUT REGISTRATION OF SUCH SECURITIES UNDER ALL APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR COMPLIANCE WITH AN APPLICABLE EXEMPTION THEREFROM.

GENPREX, INC.
WARRANT AGREEMENT
August 10, 2020

No. 2020W-2

THIS CERTIFIES THAT, for value received, Capital City Technical Consulting, Inc. or its successors and permitted assigns pursuant to the terms hereof (the "***Warrantholder***"), is entitled to purchase from Genprex, Inc., a Delaware corporation (the "***Company***"), subject to the terms set forth below, fifty thousand (50,000) fully paid and non-assessable shares (subject to adjustment as provided herein) (the "***Warrant Shares***") of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), at a purchase price of $3.81 in cash per Warrant Share (the "***Exercise Price***"), subject to the provisions and upon the terms and conditions hereinafter set forth. The term "***Warrant Agreement***" as used herein shall refer to this Warrant Agreement, as the same may be amended or amended and restated.

1. **Exercise Period**. Subject to the terms and conditions of this Warrant Agreement, the purchase rights evidenced by this Warrant Agreement may be exercised as follows:

a. With respect to 16,667 Warrant Shares, in whole or in part, at any time and from time to time after August 10, 2021, provided certain Consulting Agreement dated June 2, 2020, by and between the Company and the Warrantholder (as amended by that Amendment No. 1 dated as of August 3, 2020, by and between the Company and the Warrantholder, the "***Consulting Agreement***") has not expired or terminated, for any reason or no reason, before that date, and before the earliest to occur of (i) 5:00 p.m. (Central Time) on the fifth year following the termination of the Consulting Agreement for any reason or no reason, (ii) the consummation of an Extraordinary Transaction (as defined herein) and (iii) 5:00 p.m. (Central Time) on the ten-year anniversary of the date of this Warrant Agreement (the earliest to occur of (i), (ii) and (iii), the "***Expiration Date***");

b. With respect to an additional 16,667 Warrant Shares, in whole or in part, at any time and from time to time after August 10, 2022, provided the Consulting Agreement has not expired or terminated, for any reason or no reason, before that date, and before the Expiration Date; and

c. With respect to an additional 16,666 Warrant Shares, in whole or in part, at any time and from time to time after August 10, 2023, provided the Consulting Agreement has not terminated, for any reason or no reason, before that date, and before the Expiration Date.

2. **Exercise**.

a. Cash Exercise. The purchase rights evidenced by this Warrant Agreement may be exercised by the Warrantholder, in whole or in part, by the surrender of this Warrant Agreement (with a duly completed and executed notice of exercise in the form attached hereto as **Exhibit A** (the "***Notice of Exercise***")) at the principal office of the Company, accompanied by the payment to the Company, in cash, by wire transfer or by certified check payable to the Company, of an amount equal to the product of (i) the Exercise Price times (ii) the number of Warrant Shares as to which the purchase rights evidenced by this Warrant Agreement are being exercised (which number of Warrant Shares shall be stated in the duly executed Notice of Exercise). Upon receipt by the Company at such office of this Warrant Agreement and a duly executed Notice of Exercise in proper form for exercise, together with the aggregate Exercise Price due to the Company, the Warrantholder shall be deemed to have become, and shall be treated for all purposes as, the record holder of the number of the Warrant Shares as to which the purchase rights set forth in this Warrant Agreement have been so exercised (and such Warrant Shares shall be deemed, to the fullest extent permitted by law, to have been issued) immediately prior to the close of business on the date upon which the purchase rights evidenced by this Warrant Agreement are exercised as aforesaid.

b. Cashless Exercise. In lieu of exercising the purchase rights evidenced by this Warrant Agreement by payment in cash by wire transfer or certified check pursuant to Section 2(a) above, the Warrantholder may elect to receive the number of Warrant Shares equal to the value of the purchase rights evidenced by this Warrant Agreement (or the portion thereof being exercised), by surrender of this Warrant Agreement to the Company, together with a duly completed and executed Notice of Exercise, in which event the Company shall issue to the Warrantholder Warrant Shares in accordance with the following formula:

X = Y(A-B)/A

where

X = The number of Warrant Shares to be issued to the Warrantholder;

Y = The number of Warrant Shares for which the purchase rights evidenced by this Warrant Agreement are being exercised;

A = The Fair Market Value of one share of the Company's common stock (a "***Share***"); and

B = The Exercise Price.

For purposes of this Section 2, the "***Fair Market Value***" of a Share is defined as follows:

i. if the Company's Common Stock is traded on a securities exchange, the value shall be deemed to be the average of the closing prices of the Shares on such exchange for the five (5) trading day period prior to the date the Notice of Exercise is submitted in connection with the exercise of the purchase rights evidenced by this Warrant Agreement;

ii. if the Company's Common Stock is actively traded over-the-counter, the value shall be deemed to be the average of the closing bid prices of the Shares for the five (5) trading day period prior to the date the Notice of Exercise is submitted in connection with the exercise of the purchase rights evidenced by this Warrant Agreement; or

iii. if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Company's Board of Directors.

c. Certificates; Partial Exercise. In the event of any exercise of the purchase rights evidenced by this Warrant Agreement pursuant to this Section 2, the Company will use commercially reasonable efforts to execute and deliver a certificate or certificates evidencing the Warrant Shares so purchased to the Warrantholder within five (5) Business Days (as defined below) after the Company's receipt of the Notice of Exercise and payment as described in this Section 2. If the purchase rights evidenced by this Warrant Agreement are exercised in part only, unless the purchase rights evidenced by this Warrant Agreement have been fully exercised or expired, the Company shall use commercially reasonable efforts to deliver within such five (5) Business Day period to the Warrantholder a new Warrant Agreement evidencing the rights of the Warrantholder to purchase the balance of the Warrant Shares purchasable hereunder. For purposes of this Warrant Agreement, "***Business Day***" means any day, except a Saturday, Sunday or legal holiday, on which banking institutions in New York, New York, are required to be open.

d. Fractions of a Warrant Share. The Company shall not be required to issue any fraction of a Warrant Share in connection with the exercise of the purchase rights evidenced by this Warrant Agreement pursuant to this Section 2. At its option, the Company may pay to the Warrantholder, in lieu of any fraction of a Warrant Share resulting from the exercise of the purchase rights evidenced by this Warrant Agreement, an amount of cash equal to the product of (a) the applicable fraction of a Warrant Share multiplied by (b) the Fair Market Value of a share of Common Stock.

3. Exercise in Connection with an Extraordinary Transaction.

a. Definitions. For purposes of this Section 3, "***Extraordinary Transaction***" shall mean (i) a merger or consolidation in which the Company is a constituent corporation and the shares of Common Stock are converted, exchanged or cancelled, (ii) a conversion, reorganization or reclassification of the capital stock of the Company in which the shares of Common Stock are converted, exchanged or cancelled (other than a merger or consolidation provided in clause (i) hereof), (iii) a transaction or series of related transactions which constitute(s) a sale, lease or exchange of all or substantially all of the property and assets of the Company, including its goodwill and its corporate franchises, or (iv) a transaction or series of related transactions which constitute(s) a dissolution or liquidation of the Company.

b. Early Termination. If there shall occur any Extraordinary Transaction, then, to the extent not previously exercised, the purchase rights evidenced by this Warrant Agreement shall expire and terminate upon the consummation of such Extraordinary Transaction.

c. Conditional Exercise. Notwithstanding any other provision of this Warrant Agreement, if an exercise of all or any portion of the purchase rights evidenced by this Warrant Agreement is to be made in connection with an Extraordinary Transaction, the exercise of all or any portion of the purchase rights evidenced by this Warrant Agreement may, at the election of the Warrantholder, be conditioned upon the consummation of such Extraordinary Transaction, in which case, such exercise shall not be deemed to be effective until immediately prior to the consummation of such Extraordinary Transaction.

4. Stock Fully Paid; Reservation of Warrant Shares. The Company covenants and agrees that all Warrant Shares from time to time issuable upon exercise of the purchase rights evidenced by this Warrant Agreement have been duly authorized and, when issued upon such exercise, shall be validly issued, fully paid and non-assessable, and free from all taxes, liens and charges with respect to the issuance thereof. The Company hereby covenants and agrees that the Company will, at all times through the Expiration Date, reserve and keep available out of its aggregate authorized but unissued shares of Common Stock, the number of Warrant Shares deliverable upon the exercise of the purchase rights evidenced by this Warrant Agreement.

5. Adjustment. The number of Warrant Shares purchasable upon the exercise of the purchase rights evidenced by this Warrant Agreement shall be subject to adjustment from time to time upon the occurrence of certain events, as follows:

a. In case the outstanding shares of Common Stock shall be subdivided into a greater number of shares or combined into a smaller number of shares, the number of Warrant Shares to be received by the Warrantholder upon exercise of the purchase rights evidenced by this Warrant Agreement shall be appropriately adjusted such that the proportion of the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement to the total number of outstanding shares of Common Stock immediately prior to such subdivision or combination is equal to the proportion of the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement to the total number of outstanding shares of Common Stock immediately after such subdivision or combination, and the Exercise Price shall be proportionately adjusted such that the aggregate Exercise Price of all the purchase rights then evidenced by this Warrant Agreement shall remain unchanged.

b. In the case the Company shall hereafter declare a dividend or distribution to all holders of the outstanding shares of Common Stock in shares of Common Stock, the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement shall be increased by dividing such number by a fraction, (i) the numerator of which shall be the number of shares of Common Stock outstanding at the close of business on such record date, and (ii) the denominator of which shall be the sum of (x) the number of shares of Common Stock outstanding at the close of business on such record date and (y) the total number of shares of Common Stock constituting such dividend or distribution. If any dividend or distribution of the type described in this Section 5(b) is declared but not so paid or made, the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement shall again be adjusted to the number of Warrant Shares that would be issuable upon exercise of the purchase rights evidenced by this Warrant Agreement if such dividend or distribution had not been declared.

c. The Company will not, by amendment of its certificate of incorporation or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at times in good faith assist in the carrying out of all the provisions of this Section 5 and in the taking of all such lawful action as may be necessary or appropriate in order to protect the rights of the Warrantholder under this Section 5 against impairment.

6. Notices of Record Dates and Adjustments.

   a. If at any time prior to the full exercise or expiration of the purchase rights evidenced by this Warrant Agreement, (i) an Extraordinary Transaction shall occur or (ii) the Company shall make or issue, or fix a record date for the determination of holders of shares of Common Stock entitled to receive, a dividend or other distribution payable in any securities of the Company other than shares of Common Stock (including, but not limited to, any other class of capital stock or debt securities), then in each such event, the Company shall give written notice of such event at least fifteen (15) days prior to the date fixed as a record date or the date of closing the transfer books for the determination of the stockholders entitled to such dividend, distribution, conversion or exchange of securities or subscription rights, or entitled to vote on such proposed dissolution, liquidation, winding up, sale or Extraordinary Transaction. Such notice shall specify such record date or the date of the closing of the transfer books, as the case may be.

   b. Whenever an adjustment is required pursuant to Section 5, the Company shall, within thirty (30) days after such adjustment, deliver a certificate signed by its chief executive officer or chief financial officer to the Warrantholder setting forth, in reasonable detail, the event requiring the adjustment, the amount of the adjustment, the method by which such adjustment was calculated and number of Warrant Shares (or other securities) purchasable upon exercise of the purchase rights evidenced by this Warrant Agreement after giving effect to such adjustment.

7. Legend. Each certificate evidencing Warrant Shares issued upon exercise of this Warrant Agreement shall bear the following legend substantially in the form set forth below:

   "THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. SUCH SECURITIES CANNOT BE SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF WITHOUT REGISTRATION OF SUCH SECURITIES UNDER ALL APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR COMPLIANCE WITH AN APPLICABLE EXEMPTION THEREFROM."

8. Rights as Stockholder. Notwithstanding any other provision of this Warrant Agreement, prior to the proper exercise of the purchase rights evidenced by this Warrant Agreement by the Warrantholder in accordance with the terms of this Warrant Agreement, no Warrantholder, as such, shall be entitled to vote or receive dividends or distributions or be deemed the holder of Warrant Shares, nor shall anything contained herein be construed to confer upon the Warrantholder, as such, any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof (or by written consent in lieu of any such meeting), or to receive notice of meetings, or to receive dividends or distributions or otherwise. Upon the proper exercise of the purchase rights evidenced by this Warrant Agreement in accordance with the terms of this Warrant Agreement, the Warrantholder shall for all purposes be deemed to have become the holder of record of the Warrant Shares represented thereby on, and such certificate shall be dated as of, the date upon which the purchase rights evidenced by this Warrant Agreement are exercised with respect to such Warrant Shares in accordance with the terms hereof.

9. Modification and Waiver. The Company may change, waive, discharge, terminate or amend any provision of this Warrant Agreement with the consent of Warrantholder.

10. Termination. The purchase rights evidenced by this Warrant Agreement shall terminate on the Expiration Date. Notwithstanding the foregoing, the purchase rights evidenced by this Warrant Agreement will terminate on any earlier date when all of the purchase rights evidenced by this Warrant Agreement have been exercised or pursuant to Section 3(b).

11. Notices. Any notice required to be given or delivered to the Warrantholder or the Company shall be sent by certified or registered mail, postage prepaid, or by overnight courier, to such Warrantholder at its address indicated on the signature page of this Agreement or as shown on the books and records of the Company or to the Company at the address indicated on the signature page of this Warrant Agreement. All such notices shall be effective on the day following the date such notice is deposited in the mails or with such overnight courier, as the case may be, in each case addressed as aforesaid, unless otherwise provided herein.

12. Restrictions on Assignment; Transfer of Shares.

    a. This Warrant Agreement, the purchase rights evidenced by this Warrant Agreement and the Warrant Shares issued upon the exercise of the purchase rights evidenced by this Warrant Agreement (collectively, the "***Securities***") shall not be assigned, sold, pledged, transferred or otherwise disposed of except in compliance with the Securities Act of 1933, as amended, and applicable state securities laws. None of the Securities shall be transferred unless and until: (i) the Company has received the opinion of counsel for the Warrantholder that the Securities may be transferred pursuant to an exemption from registration under the Securities Act and applicable state securities laws, the availability of which is established to the reasonable satisfaction of the Company, or (ii) a registration statement relating to the offer and sale of the Securities has been filed by the Company and declared effective by the Commission and compliance with applicable state securities law has been established.

    b. In addition to the requirements set forth in Section 12(a), in order to make any permitted assignment, the Warrantholder must deliver to the Company the assignment form attached hereto duly executed and completed, together with this Warrant Agreement and payment of all transfer taxes, if any, and upon compliance with the requirements of Section 12(a), payable in connection therewith. The Company shall within ten (10) business days after receipt of such assignment form and payment, if any, transfer this Warrant Agreement on the books of the Company and shall execute and deliver a new Warrant Agreement or Warrant Agreements of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Warrant Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

13. Binding Effect on Successors. To the fullest extent permitted by law, and except as otherwise provided in this Warrant Agreement, this Warrant Agreement shall be binding upon any entity succeeding the Company by merger, consolidation or acquisition of all or substantially all of the Company's assets, and all of the covenants and agreements of the Company shall inure to the benefit of the successors and permitted assigns of the Warrantholder. This Warrant Agreement shall be binding upon and inure to the benefit of the Company and the Warrantholder and their respective successors and permitted assigns.

14. Lost Warrant Agreement. The Company covenants to the Warrantholder that upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction, or mutilation of this Warrant Agreement and, in the case of any such loss, theft or destruction, upon receipt of the Warrantholder's unsecured indemnification agreement, or in the case of any such mutilation upon surrender and cancellation of this Warrant Agreement, the Company will make and deliver a new Warrant Agreement in lieu of the lost, stolen, destroyed or mutilated Warrant Agreement.

15. Governing Law. This Warrant Agreement shall be governed in all respects by and construed in accordance with the laws of the State of Delaware (without regard to any conflict of laws principle that would apply the law of another jurisdiction), whether as to its validity, construction, capacity, performance or otherwise.

16. Consent to Jurisdiction. ANY LEGAL ACTION, SUIT OR PROCEEDING ARISING OUT OF OR BASED UPON THIS WARRANT AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY MAY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF TEXAS, IN EACH CASE, LOCATED IN THE CITY OF AUSTIN, TEXAS, AND TO THE FULLEST EXTENT PERMITTED BY LAW, EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS. TO THE FULLEST EXTENT PERMITTED BY LAW, IN ANY SUCH ACTION, SUIT OR PROCEEDING, SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT BY MAIL TO SUCH PARTY'S ADDRESS SET FORTH HEREIN SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUCH ACTION, SUIT OR PROCEEDING BROUGHT IN ANY SUCH COURT. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY ACTION, SUIT OR PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH ACTION, SUIT OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

17. Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS WARRANT AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, SUIT OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY TO THIS WARRANT AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (i) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (ii) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (iii) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (iv) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 17.

[Signature Page Follows]

IN WITNESS WHEREOF, this Warrant Agreement is executed as of the date first written above.

COMPANY:

GENPREX, INC.

/s/ Rodney Varner

Name: Rodney Varner

Title: Chief Executive Officer

Address:
Dell Medical Center, Health Discovery Building
1601 Trinity Street, Bldg. B, Suite 3.312.09
Austin, TX 78712

ACCEPTED AND AGREED:
WARRANTHOLDER:

CAPITAL CITY TECHNICAL CONSULTING, INC.

By: K. David Weidner, Ph.D.

Name: K. David Weidner

Title:

Address:

THE PURCHASE RIGHTS EVIDENCED BY THIS WARRANT AGREEMENT AND THE SHARES OF CAPITAL STOCK ISSUABLE UPON EXERCISE OF SUCH PURCHASE RIGHTS HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. SUCH SECURITIES CANNOT BE SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF WITHOUT REGISTRATION OF SUCH SECURITIES UNDER ALL APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR COMPLIANCE WITH AN APPLICABLE EXEMPTION THEREFROM.

GENPREX, INC.
AMENDED AND RESTATED WARRANT AGREEMENT
Effective Date: August 10, 2020 (the "*Effective Date*")
Effective date of Original Warrant: December 17, 2015

THIS AMENDED AND RESTATED WARRANT AGREEMENT (this "*Warrant Agreement*") amends, restates and replaces in its entirety that Warrant Agreement effective as of December 17, 2015, by and between Genprex, Inc. and DABS Advanced Biotech Solutions, LLC, which became exercisable 18 months after December 17, 2015 (the "*Original Warrant*"). Upon the execution of this Warrant Agreement on behalf of Genprex, Inc. and on behalf of DABS Advanced Biotech Solutions, LLC, the Original Warrant is terminated and cancelled hereby, effective as of the Effective Date set forth above, and replaced in its entirety by this Warrant Agreement.

The substantive changes to the Original Warrant effected by this Warrant Agreement: (a) provide for the net exercise of the purchase rights represented by this Warrant Agreement; (b) provide for the termination of this Warrant Agreement if not previously exercised upon an Extraordinary Transaction (as defined below); (c) reflect the April 2018 conversion of each share of Non-Voting Common Stock of Genprex, Inc. into one share of Common Stock of Genprex, Inc.; and (d) reflect the April 2018 forward stock split, subsequent to the conversion described in (c), of each share of Common Stock of Genprex, Inc. into 6.6841954 shares of Common Stock of Genprex, Inc.

THIS CERTIFIES THAT, for value received, DABS Advanced Biotech Solutions, LLC, or its successors and permitted assigns pursuant to the terms hereof (the "*Warrantholder*"), is entitled to purchase from Genprex, Inc., a Delaware corporation (the "*Corporation*"), subject to the terms set forth below, 102,702 fully paid and non-assessable shares (subject to adjustment as provided herein) (the "*Warrant Shares*") of the Corporation's Common Stock, par value $0.001 per share (the "*Common Stock*"), at a purchase price of $4.87 in cash per Warrant Share (the "*Exercise Price*"), subject to the provisions and upon the terms and conditions hereinafter set forth. The term "*Warrant Agreement*" as used herein shall refer to this Warrant Agreement, as the same may be amended or amended and restated.

The Original Warrant was issued pursuant to that certain Consultant Agreement, made and entered into as of the effective date of the Original Warrant, by and between the Corporation and the Warrantholder.

1. Exercise Period. Subject to the terms and conditions of this Warrant Agreement, the purchase rights evidenced by this Warrant Agreement may be exercised, in whole or in part, at any time and from time to time from and after the vesting date ("Vesting Date") which is the sooner of: (a) one year after a registration statement filed by the Company under the Securities Act of 1933 (15 USC 77f) becomes effective and the Company's securities commence trading on the OTCBB, NASDAQ, or other national securities market, (the "Registration Date"), and (b) eighteen (18) months after the date of the Original Warrant, and before 5:00 p.m. (Central Time) on the fifth anniversary of the Vesting Date (the "Expiration Date"). Upon the Expiration Date this Warrant Agreement will expire and be of no further force or effect.

2. Method of Exercise; Payment; Issuance of New Warrants.

   a. Cash Exercise. The purchase rights evidenced by this Warrant Agreement may be exercised by the Warrantholder, in whole or in part, by the surrender of this Warrant Agreement (with a duly executed notice of exercise in the form attached hereto as **Exhibit A** (the "*Notice of Exercise*")) at the principal office of the Corporation, accompanied by the payment to the Corporation, in cash, by wire transfer, or by certified check payable to the Corporation, of an amount equal to the product of (i) the Exercise Price times (ii) the number of Warrant Shares as to which the purchase rights evidenced by this Warrant Agreement is being exercised (which number of Warrant Shares shall be stated in the duly executed Notice of Exercise). Upon receipt by the Corporation at such office of this Warrant Agreement and a duly executed Notice of Exercise in proper form for exercise, together with the aggregate Exercise Price due to the Corporation, the Warrantholder shall be deemed to have become the holder of record of, and shall be treated for all purposes as the record holder of, the number of the Warrant Shares set forth in such Notice of Exercise (and such Warrant Shares shall be deemed, to the fullest extent permitted by law, to have been issued) immediately prior to the close of business on the date upon which the purchase rights evidenced by this Warrant Agreement is exercised as aforesaid.

   b. Cashless Exercise. In lieu of exercising the purchase rights evidenced by this Warrant Agreement by payment in cash by wire transfer or certified check pursuant to Section 2(a) above, the Warrantholder may elect to receive the number of Warrant Shares equal to the value of the purchase rights evidenced by this Warrant Agreement (or the portion thereof being exercised), by surrender of this Warrant Agreement to the Corporation, together with a duly completed and executed Notice of Exercise, in which event the Corporation shall issue to the Warrantholder Warrant Shares in accordance with the following formula:

$$X = Y(A-B)/A$$

where

X = The number of Warrant Shares to be issued to the Warrantholder;

Y = The number of Warrant Shares for which the purchase rights evidenced by this Warrant Agreement are being exercised;

A = The Fair Market Value of one share of the Corporation's common stock (a "*Share*"); and

B = The Exercise Price.

For purposes of this Section 2, the "*Fair Market Value*" of a Share is defined as follows:

i. if the Corporation's Common Stock is then listed or traded on a national securities exchange for at least ten (10) consecutive trading days immediately preceding such date of determination, the daily volume-weighted average price of such security for the ten (10) consecutive trading days immediately preceding such date of determination as reported by Bloomberg, L.P. (or, if no such price is reported by Bloomberg, L.P. for any particular trading day during such ten (10) trading day period, the daily volume-weighted average price of such security as officially reported for such trading day on the principal securities exchange on which such security is then listed or admitted to trading shall be used for the purposes of calculating such ten (10) trading day volume-weighted average price); or

ii. if the Corporation's Common Stock is not then listed or traded on a national securities exchange for at least ten (10) consecutive trading days immediately preceding such date of determination, the fair market value as determined by the board of directors of the Corporation (the "*Board*") in good faith, as evidenced by a resolution or resolutions of the Board.

c. Certificates; Partial Exercise. In the event of any exercise of the purchase rights evidenced by this Warrant Agreement pursuant to this Section 2, the Corporation will use commercially reasonable efforts to execute and deliver certificates evidencing the Warrant Shares so purchased to the Warrantholder within ten (10) Business Days (as defined below) from the Corporation's receipt of the Notice of Exercise. If the purchase rights evidenced by this Warrant Agreement are exercised in part only, unless the purchase rights evidenced by this Warrant Agreement have been fully exercised or expired, the Corporation shall use commercially reasonable efforts to deliver to the Warrantholder a new Warrant Agreement evidencing the rights of the Warrantholder to purchase the balance of the Warrant Shares purchasable hereunder within such ten (10) Business Day period. For purposes of this Warrant Agreement, "*Business Day*" means any day, except a Saturday, Sunday or legal holiday, on which banking institutions in New York, New York, are required to be open.

d. Fractions of a Warrant Share. The Corporation shall not be required to issue any fraction of a Warrant Share in connection with the exercise of the purchase rights evidenced by this Warrant Agreement pursuant to this Section 2. At its option, the Corporation may pay to the Warrantholder, in lieu of any fraction of a Warrant Share resulting from the exercise of the purchase rights evidenced by this Warrant Agreement, an amount of cash equal to the product of (a) the applicable fraction of a Warrant Share multiplied by (b) the Fair Market Value of a share of Non-Voting Common Stock.

3. Exercise in Connection with an Extraordinary Transaction.

a. Definitions. For purposes of this Section 3, "*Extraordinary Transaction*" shall mean (i) a merger or consolidation in which the Corporation is a constituent corporation and the shares of Non-Voting Common Stock are converted, exchanged or cancelled, (ii) a conversion, reorganization or reclassification of the capital stock of the Corporation in which the Non-Voting Common Stock are converted, exchanged or cancelled (other than a merger or consolidation provided in clause (i) hereof), (iii) a transaction or series of related transactions which constitute(s) a sale, lease or exchange of all or substantially all of the property and assets of the Corporation, including its goodwill and its corporate franchises, or (iv) a transaction or series of related transactions which constitute(s) a dissolution or liquidation of the Corporation.

b. Early Termination. If there shall occur any Extraordinary Transaction, then, to the extent not previously exercised, the purchase rights evidenced by this Warrant Agreement shall expire and terminate upon the consummation of such Extraordinary Transaction.

c. Conditional Exercise. Notwithstanding any other provision of this Warrant Agreement, if an exercise of any all or any portion of the purchase rights evidenced by this Warrant Agreement is to be made in connection with an Extraordinary Transaction, the exercise of all or any portion of the purchase rights evidenced by this Warrant Agreement may, at the election of the Warrantholder, be conditioned upon the consummation of such Extraordinary Transaction, in which case, such exercise shall not be deemed to be effective until immediately prior to the consummation of such Extraordinary Transaction.

4. Stock Fully Paid; Reservation of Warrant Shares. The Corporation covenants and agrees that all Warrant Shares from time to time issuable upon exercise of the purchase rights evidenced by this Warrant Agreement have been duly authorized and, when issued upon such exercise, shall be validly issued, fully paid and non-assessable, and free from all taxes, liens and charges with respect to the issuance thereof. The Corporation hereby covenants and agrees that the Corporation will, at all times through the Expiration Date, reserve and keep available out of its aggregate authorized but unissued shares of Non-Voting Common Stock, the number of Warrant Shares deliverable upon the exercise of the purchase rights evidenced by this Warrant Agreement.

5. Adjustment. The number of Warrant Shares purchasable upon the exercise of the purchase rights evidenced by this Warrant Agreement shall be subject to adjustment from time to time upon the occurrence of certain events, as follows:
    a. In case the outstanding shares of Common Stock shall be subdivided into a greater number of shares or combined into a smaller number of shares, the number of Warrant Shares to be received by the Warrantholder upon exercise of the purchase rights evidenced by this Warrant Agreement shall be appropriately adjusted such that the proportion of the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement to the total number of outstanding shares of Common Stock immediately prior to such subdivision or combination is equal to the proportion of the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement to the total number of outstanding shares of Common Stock immediately after such subdivision or combination, and the Exercise Price shall be proportionately adjusted such that the aggregate Exercise Price of all the purchase rights then evidenced by this Warrant Agreement shall remain unchanged.

    b. In the case the Corporation shall hereafter declare a dividend or distribution to all holders of the outstanding shares of Common Stock in shares of Common Stock, the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement shall be increased by dividing such number by a fraction, (i) the numerator of which shall be the number of shares of Common Stock outstanding at the close of business on such record date, and (ii) the denominator of which shall be the sum of (x) the number of shares of Common Stock outstanding at the close of business on such record date and (y) the total number of shares of Common Stock constituting such dividend or distribution. If any dividend or distribution of the type described in this Section 5(b) is declared but not so paid or made, the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement shall again be adjusted to the number of Warrant Shares that would be issuable upon exercise of the purchase rights evidenced by this Warrant Agreement if such dividend or distribution had not been declared.

    c. In the event the Corporation shall make or issue, or fix a record date for the determination of holders of shares of Common Stock entitled to receive, a dividend or other distribution payable in any securities of the Corporation other than shares of Common Stock (including, but not limited to, any other class of capital stock or debt securities), then and in each such event the Board shall, to the fullest extent permitted by law, take all lawful actions so that the Warrantholder shall receive upon exercise of the purchase rights evidenced by this Warrant Agreement, in addition to the number of Warrant Shares receivable upon exercise of the purchase rights evidenced by this Warrant Agreement, the number of such other securities of the Corporation which the Warrantholder would have received had the purchase rights evidenced by this Warrant Agreement been exercised on the date of such event and had such holder thereafter, during the period from the date of such event to and including the date of exercise, retained such securities receivable by such holder as aforesaid during such period, giving application to all adjustments called for during such period under this Section 5 as applied to such distributed securities.

6. Legend. Each certificate evidencing Warrant Shares issued upon exercise of this Warrant Agreement shall bear the following legends substantially in the forms set forth below:

"THE SECURITIES OF REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. SUCH SECURITIES CANNOT BE SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF WITHOUT REGISTRATION OF SUCH SECURITIES UNDER ALL APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR COMPLIANCE WITH AN APPLICABLE EXEMPTION THEREFROM."

"THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO RESTRICTIONS ON ASSIGNMENT AND TRANSFER CONTAINED IN AN AGREEMENT WITH THE CORPORATION WHICH IS ON FILE IN THE PRINCIPAL OFFICES OF THE CORPORATION. THE HOLDER OF THIS CERTIFICATE MAY OBTAIN A COPY OF SUCH RESTRICTIONS UPON WRITTEN REQUEST TO THE CORPORATION."

7. Rights as Stockholder. Notwithstanding any other provision of this Warrant Agreement, prior to the proper exercise of the purchase rights evidenced by this Warrant Agreement by the Warrantholder in accordance with the terms of this Warrant Agreement, no Warrantholder, as such, shall be entitled to vote or receive dividends or distributions or be deemed the holder of Warrant Shares, nor shall anything contained herein be construed to confer upon the Warrantholder, as such, any of the rights of a stockholder of the Corporation or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof (or by written consent in lieu of any such meeting), or to receive notice of meetings, or to receive dividends or distributions or otherwise. Upon the proper exercise of the purchase rights evidenced by this Warrant Agreement in accordance with the terms of this Warrant Agreement, the Warrantholder shall for all purposes be deemed to have become the holder of record of the Warrant Shares represented thereby on, and such certificate shall be dated as of, the date upon which the purchase rights evidenced by this Warrant Agreement is exercised with respect to such Warrant Shares in accordance with the terms hereof.

8. Modification and Waiver. The Corporation may change, waive, discharge, terminate or amend any provision of this Warrant Agreement with the consent of Warrantholder.

9. Termination. The purchase rights evidenced by this Warrant Agreement shall terminate on the Expiration Date. Notwithstanding the foregoing, the purchase rights evidenced by this Warrant Agreement will terminate on any earlier date when all of the purchase rights evidenced by this Warrant Agreement have been exercised or pursuant to Section 3(b).

10. Notices. Any notice required to be given or delivered to the Warrantholder or the Corporation shall be sent by certified or registered mail, postage prepaid, to such Warrantholder at its address indicated on the signature page of this Agreement or as shown on the books and records of the Corporation or to the Corporation at the address indicated on the signature page of this Warrant Agreement. All such notices shall be effective on the day following the date such notice is deposited in the mails, addressed as aforesaid, unless otherwise provided herein.

11. Restrictions on Assignment, Transfer of Shares. The purchase rights evidenced by this Warrant Agreement and the Warrant Shares issued upon the exercise of the purchase rights evidenced by this Warrant Agreement will be restricted against transfer, and Warrantholder will not enter into any contract, option, or other agreement for the sale or transfer of such shares, warrants or Warrant Shares, until the sooner of: (i) 180 days after the Corporation's initial public offering of its Common Stock; (ii) sale of more than sixty-five percent of the Corporation's issued and outstanding common stock by its stockholders to persons who are not stockholders of the Corporation as of the date hereof; (iii) sale by the Corporation of substantially all of its assets; or (iv) five years from the date hereof; or (v) written consent of the Corporation to such transfer. Further, this Warrant Agreement and the Warrant Shares may not be transferred unless the Corporation receives an opinion of legal counsel reasonably acceptable to it that such transfer will not violate the Securities Act of 1933 or any other federal or state securities law, unless this requirement is waived in writing by the Corporation.

12. Binding Effect on Successors. To the fullest extent permitted by law, this Warrant Agreement shall be binding upon any entity succeeding the Corporation by merger, consolidation or acquisition of all or substantially all of the Corporation's assets, and all of the covenants and agreements of the Corporation shall inure to the benefit of the successors and permitted assigns of the Warrantholder. This Warrant Agreement shall be binding upon and inure to the benefit of the Corporation and the Warrantholder and their respective successors and permitted assigns. The Warrantholder shall not be permitted to assign any of its rights, interests or obligations hereunder without the express written consent of the Corporation.

13. Lost Warrant Agreement. The Corporation covenants to the Warrantholder that upon receipt of evidence reasonably satisfactory to the Corporation of the loss, theft, destruction, or mutilation of this Warrant Agreement and, in the case of any such loss, theft or destruction, upon receipt of the Warrantholder's unsecured indemnification agreement, or in the case of any such mutilation upon surrender and cancellation of this Warrant Agreement, the Corporation will make and deliver a new Warrant Agreement in lieu of the lost, stolen, destroyed or mutilated Warrant Agreement.

14. Governing Law. This Warrant Agreement shall be governed in all respects by and construed in accordance with the laws of the State of Delaware (without regard to any conflict of laws principle that would apply the law of another jurisdiction), whether as to its validity, construction, capacity, performance or otherwise.

15. Consent To Jurisdiction. ANY LEGAL ACTION, SUIT OR PROCEEDING ARISING OUT OF OR BASED UPON THIS WARRANT AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY MAY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF TEXAS, IN EACH CASE, LOCATED IN THE CITY OF AUSTIN, AND, TO THE FULLEST EXTENT PERMITTED BY LAW, EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS. TO THE FULLEST EXTENT PERMITTED BY LAW, IN ANY SUCH ACTION, SUIT OR PROCEEDING, SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT BY MAIL TO SUCH PARTY'S ADDRESS SET FORTH HEREIN SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUCH ACTION, SUIT OR PROCEEDING BROUGHT IN ANY SUCH COURT. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY ACTION, SUIT OR PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH ACTION, SUIT OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

16. Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS WARRANT AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, SUIT OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY TO THIS WARRANT AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (i) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (ii) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (iii) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (iv) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 16.

[Signature Page Follows]

IN WITNESS WHEREOF, this Amended and Restated Warrant Agreement is executed effective as of the Effective Date.

GENPREX, INC.

/s/ Rodney Varner
Name: Rodney Varner
Title: Chief Executive Officer
Dell Medical Center, Health Discovery Building
1601 Trinity Street, Suite 3.312.09
Austin, Texas 78712

ACCEPTED AND AGREED:
WARRANTHOLDER:

DABS ADVANCED BIOTECH SOLUTIONS, LLC

By: /s/ Timothy J Collins

Name: Timothy J Collins
Title: Partner
Address:

THE PURCHASE RIGHTS EVIDENCED BY THIS WARRANT AGREEMENT AND THE SHARES OF CAPITAL STOCK ISSUABLE UPON EXERCISE OF SUCH PURCHASE RIGHTS HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. SUCH SECURITIES CANNOT BE SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF WITHOUT REGISTRATION OF SUCH SECURITIES UNDER ALL APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR COMPLIANCE WITH AN APPLICABLE EXEMPTION THEREFROM.

GENPREX, INC.
AMENDED AND RESTATED WARRANT AGREEMENT
Effective Date: August 10, 2020 (the "*Effective Date*")
Effective date of Original Warrant: December 17, 2015

THIS AMENDED AND RESTATED WARRANT AGREEMENT (this "*Warrant Agreement*") amends, restates and replaces in its entirety that Warrant Agreement effective as of December 17, 2015, by and between Genprex, Inc. and DABS Advanced Biotech Solutions, LLC, which became exercisable 30 months after December 17, 2015 (the "*Original Warrant*"). Upon the execution of this Warrant Agreement on behalf of Genprex, Inc. and on behalf of DABS Advanced Biotech Solutions, LLC, the Original Warrant is terminated and cancelled hereby, effective as of the Effective Date set forth above, and replaced in its entirety by this Warrant Agreement.

The substantive changes to the Original Warrant effected by this Warrant Agreement: (a) provide for the net exercise of the purchase rights represented by this Warrant Agreement; (b) provide for the termination of this Warrant Agreement if not previously exercised upon an Extraordinary Transaction (as defined below); (c) reflect the April 2018 conversion of each share of Non-Voting Common Stock of Genprex, Inc. into one share of Common Stock of Genprex, Inc.; and (d) reflect the April 2018 forward stock split, subsequent to the conversion described in (c), of each share of Common Stock of Genprex, Inc. into 6.6841954 shares of Common Stock of Genprex, Inc.

THIS CERTIFIES THAT, for value received, DABS Advanced Biotech Solutions, LLC, or its successors and permitted assigns pursuant to the terms hereof (the "*Warrantholder*"), is entitled to purchase from Genprex, Inc., a Delaware corporation (the "*Corporation*"), subject to the terms set forth below, 102,702 fully paid and non-assessable shares (subject to adjustment as provided herein) (the "*Warrant Shares*") of the Corporation's Common Stock, par value $0.001 per share (the "*Common Stock*"), at a purchase price of $4.87 in cash per Warrant Share (the "*Exercise Price*"), subject to the provisions and upon the terms and conditions hereinafter set forth. The term "*Warrant Agreement*" as used herein shall refer to this Warrant Agreement, as the same may be amended or amended and restated.

The Original Warrant was issued pursuant to that certain Consultant Agreement, made and entered into as of the effective date of the Original Warrant, by and between the Corporation and the Warrantholder.

1. Exercise Period. Subject to the terms and conditions of this Warrant Agreement, the purchase rights evidenced by this Warrant Agreement may be exercised, in whole or in part, at any time and from time to time from and after the vesting date ("Vesting Date") which is the sooner of: (a) two years after a registration statement filed by the Company under the Securities Act of 1933 (15 USC 77f) becomes effective and the Company's securities commence trading on the OTCBB, NASDAQ, or other national securities market, (the "Registration Date"), and (b) thirty (30) months after the date of the Original Warrant, and before 5:00 p.m. (Central Time) on the fifth anniversary of the Vesting Date (the "Expiration Date"). Upon the Expiration Date this Warrant Agreement will expire and be of no further force or effect.

2. Method of Exercise; Payment; Issuance of New Warrants.

   a. Cash Exercise. The purchase rights evidenced by this Warrant Agreement may be exercised by the Warrantholder, in whole or in part, by the surrender of this Warrant Agreement (with a duly executed notice of exercise in the form attached hereto as **Exhibit A** (the "*Notice of Exercise*")) at the principal office of the Corporation, accompanied by the payment to the Corporation, in cash, by wire transfer, or by certified check payable to the Corporation, of an amount equal to the product of (i) the Exercise Price times (ii) the number of Warrant Shares as to which the purchase rights evidenced by this Warrant Agreement is being exercised (which number of Warrant Shares shall be stated in the duly executed Notice of Exercise). Upon receipt by the Corporation at such office of this Warrant Agreement and a duly executed Notice of Exercise in proper form for exercise, together with the aggregate Exercise Price due to the Corporation, the Warrantholder shall be deemed to have become the holder of record of, and shall be treated for all purposes as the record holder of, the number of the Warrant Shares set forth in such Notice of Exercise (and such Warrant Shares shall be deemed, to the fullest extent permitted by law, to have been issued) immediately prior to the close of business on the date upon which the purchase rights evidenced by this Warrant Agreement is exercised as aforesaid.

   b. Cashless Exercise. In lieu of exercising the purchase rights evidenced by this Warrant Agreement by payment in cash by wire transfer or certified check pursuant to Section 2(a) above, the Warrantholder may elect to receive the number of Warrant Shares equal to the value of the purchase rights evidenced by this Warrant Agreement (or the portion thereof being exercised), by surrender of this Warrant Agreement to the Corporation, together with a duly completed and executed Notice of Exercise, in which event the Corporation shall issue to the Warrantholder Warrant Shares in accordance with the following formula:

$$X = Y(A-B)/A$$

where

X = The number of Warrant Shares to be issued to the Warrantholder;

Y = The number of Warrant Shares for which the purchase rights evidenced by this Warrant Agreement are being exercised;

A = The Fair Market Value of one share of the Corporation's common stock (a "*Share*"); and

B = The Exercise Price.

For purposes of this Section 2, the "*Fair Market Value*" of a Share is defined as follows:

i. if the Corporation's Common Stock is then listed or traded on a national securities exchange for at least ten (10) consecutive trading days immediately preceding such date of determination, the daily volume-weighted average price of such security for the ten (10) consecutive trading days immediately preceding such date of determination as reported by Bloomberg, L.P. (or, if no such price is reported by Bloomberg, L.P. for any particular trading day during such ten (10) trading day period, the daily volume-weighted average price of such security as officially reported for such trading day on the principal securities exchange on which such security is then listed or admitted to trading shall be used for the purposes of calculating such ten (10) trading day volume-weighted average price); or

ii. if the Corporation's Common Stock is not then listed or traded on a national securities exchange for at least ten (10) consecutive trading days immediately preceding such date of determination, the fair market value as determined by the board of directors of the Corporation (the "*Board*") in good faith, as evidenced by a resolution or resolutions of the Board.

c. Certificates; Partial Exercise. In the event of any exercise of the purchase rights evidenced by this Warrant Agreement pursuant to this Section 2, the Corporation will use commercially reasonable efforts to execute and deliver certificates evidencing the Warrant Shares so purchased to the Warrantholder within ten (10) Business Days (as defined below) from the Corporation's receipt of the Notice of Exercise. If the purchase rights evidenced by this Warrant Agreement are exercised in part only, unless the purchase rights evidenced by this Warrant Agreement have been fully exercised or expired, the Corporation shall use commercially reasonable efforts to deliver to the Warrantholder a new Warrant Agreement evidencing the rights of the Warrantholder to purchase the balance of the Warrant Shares purchasable hereunder within such ten (10) Business Day period. For purposes of this Warrant Agreement, "*Business Day*" means any day, except a Saturday, Sunday or legal holiday, on which banking institutions in New York, New York, are required to be open.

d. Fractions of a Warrant Share. The Corporation shall not be required to issue any fraction of a Warrant Share in connection with the exercise of the purchase rights evidenced by this Warrant Agreement pursuant to this Section 2. At its option, the Corporation may pay to the Warrantholder, in lieu of any fraction of a Warrant Share resulting from the exercise of the purchase rights evidenced by this Warrant Agreement, an amount of cash equal to the product of (a) the applicable fraction of a Warrant Share multiplied by (b) the Fair Market Value of a share of Non-Voting Common Stock.

3. Exercise in Connection with an Extraordinary Transaction.

a. Definitions. For purposes of this Section 3, "*Extraordinary Transaction*" shall mean (i) a merger or consolidation in which the Corporation is a constituent corporation and the shares of Non-Voting Common Stock are converted, exchanged or cancelled, (ii) a conversion, reorganization or reclassification of the capital stock of the Corporation in which the Non-Voting Common Stock are converted, exchanged or cancelled (other than a merger or consolidation provided in clause (i) hereof), (iii) a transaction or series of related transactions which constitute(s) a sale, lease or exchange of all or substantially all of the property and assets of the Corporation, including its goodwill and its corporate franchises, or (iv) a transaction or series of related transactions which constitute(s) a dissolution or liquidation of the Corporation.

b. Early Termination. If there shall occur any Extraordinary Transaction, then, to the extent not previously exercised, the purchase rights evidenced by this Warrant Agreement shall expire and terminate upon the consummation of such Extraordinary Transaction.

c. Conditional Exercise. Notwithstanding any other provision of this Warrant Agreement, if an exercise of any all or any portion of the purchase rights evidenced by this Warrant Agreement is to be made in connection with an Extraordinary Transaction, the exercise of all or any portion of the purchase rights evidenced by this Warrant Agreement may, at the election of the Warrantholder, be conditioned upon the consummation of such Extraordinary Transaction, in which case, such exercise shall not be deemed to be effective until immediately prior to the consummation of such Extraordinary Transaction.

4. Stock Fully Paid; Reservation of Warrant Shares. The Corporation covenants and agrees that all Warrant Shares from time to time issuable upon exercise of the purchase rights evidenced by this Warrant Agreement have been duly authorized and, when issued upon such exercise, shall be validly issued, fully paid and non-assessable, and free from all taxes, liens and charges with respect to the issuance thereof. The Corporation hereby covenants and agrees that the Corporation will, at all times through the Expiration Date, reserve and keep available out of its aggregate authorized but unissued shares of Non-Voting Common Stock, the number of Warrant Shares deliverable upon the exercise of the purchase rights evidenced by this Warrant Agreement.

5. Adjustment. The number of Warrant Shares purchasable upon the exercise of the purchase rights evidenced by this Warrant Agreement shall be subject to adjustment from time to time upon the occurrence of certain events, as follows:
    a. In case the outstanding shares of Common Stock shall be subdivided into a greater number of shares or combined into a smaller number of shares, the number of Warrant Shares to be received by the Warrantholder upon exercise of the purchase rights evidenced by this Warrant Agreement shall be appropriately adjusted such that the proportion of the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement to the total number of outstanding shares of Common Stock immediately prior to such subdivision or combination is equal to the proportion of the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement to the total number of outstanding shares of Common Stock immediately after such subdivision or combination, and the Exercise Price shall be proportionately adjusted such that the aggregate Exercise Price of all the purchase rights then evidenced by this Warrant Agreement shall remain unchanged.

    b. In the case the Corporation shall hereafter declare a dividend or distribution to all holders of the outstanding shares of Common Stock in shares of Common Stock, the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement shall be increased by dividing such number by a fraction, (i) the numerator of which shall be the number of shares of Common Stock outstanding at the close of business on such record date, and (ii) the denominator of which shall be the sum of (x) the number of shares of Common Stock outstanding at the close of business on such record date and (y) the total number of shares of Common Stock constituting such dividend or distribution. If any dividend or distribution of the type described in this Section 5(b) is declared but not so paid or made, the number of Warrant Shares issuable upon exercise of the purchase rights evidenced by this Warrant Agreement shall again be adjusted to the number of Warrant Shares that would be issuable upon exercise of the purchase rights evidenced by this Warrant Agreement if such dividend or distribution had not been declared.

    c. In the event the Corporation shall make or issue, or fix a record date for the determination of holders of shares of Common Stock entitled to receive, a dividend or other distribution payable in any securities of the Corporation other than shares of Common Stock (including, but not limited to, any other class of capital stock or debt securities), then and in each such event the Board shall, to the fullest extent permitted by law, take all lawful actions so that the Warrantholder shall receive upon exercise of the purchase rights evidenced by this Warrant Agreement, in addition to the number of Warrant Shares receivable upon exercise of the purchase rights evidenced by this Warrant Agreement, the number of such other securities of the Corporation which the Warrantholder would have received had the purchase rights evidenced by this Warrant Agreement been exercised on the date of such event and had such holder thereafter, during the period from the date of such event to and including the date of exercise, retained such securities receivable by such holder as aforesaid during such period, giving application to all adjustments called for during such period under this Section 5 as applied to such distributed securities.

6. Legend. Each certificate evidencing Warrant Shares issued upon exercise of this Warrant Agreement shall bear the following legends substantially in the forms set forth below:

"THE SECURITIES OF REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. SUCH SECURITIES CANNOT BE SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF WITHOUT REGISTRATION OF SUCH SECURITIES UNDER ALL APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR COMPLIANCE WITH AN APPLICABLE EXEMPTION THEREFROM."

"THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO RESTRICTIONS ON ASSIGNMENT AND TRANSFER CONTAINED IN AN AGREEMENT WITH THE CORPORATION WHICH IS ON FILE IN THE PRINCIPAL OFFICES OF THE CORPORATION. THE HOLDER OF THIS CERTIFICATE MAY OBTAIN A COPY OF SUCH RESTRICTIONS UPON WRITTEN REQUEST TO THE CORPORATION."

7. Rights as Stockholder. Notwithstanding any other provision of this Warrant Agreement, prior to the proper exercise of the purchase rights evidenced by this Warrant Agreement by the Warrantholder in accordance with the terms of this Warrant Agreement, no Warrantholder, as such, shall be entitled to vote or receive dividends or distributions or be deemed the holder of Warrant Shares, nor shall anything contained herein be construed to confer upon the Warrantholder, as such, any of the rights of a stockholder of the Corporation or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof (or by written consent in lieu of any such meeting), or to receive notice of meetings, or to receive dividends or distributions or otherwise. Upon the proper exercise of the purchase rights evidenced by this Warrant Agreement in accordance with the terms of this Warrant Agreement, the Warrantholder shall for all purposes be deemed to have become the holder of record of the Warrant Shares represented thereby on, and such certificate shall be dated as of, the date upon which the purchase rights evidenced by this Warrant Agreement is exercised with respect to such Warrant Shares in accordance with the terms hereof.

8. Modification and Waiver. The Corporation may change, waive, discharge, terminate or amend any provision of this Warrant Agreement with the consent of Warrantholder.

9. Termination. The purchase rights evidenced by this Warrant Agreement shall terminate on the Expiration Date. Notwithstanding the foregoing, the purchase rights evidenced by this Warrant Agreement will terminate on any earlier date when all of the purchase rights evidenced by this Warrant Agreement have been exercised or pursuant to Section 3(b).

10. Notices. Any notice required to be given or delivered to the Warrantholder or the Corporation shall be sent by certified or registered mail, postage prepaid, to such Warrantholder at its address indicated on the signature page of this Agreement or as shown on the books and records of the Corporation or to the Corporation at the address indicated on the signature page of this Warrant Agreement. All such notices shall be effective on the day following the date such notice is deposited in the mails, addressed as aforesaid, unless otherwise provided herein.

11. Restrictions on Assignment, Transfer of Shares. The purchase rights evidenced by this Warrant Agreement and the Warrant Shares issued upon the exercise of the purchase rights evidenced by this Warrant Agreement will be restricted against transfer, and Warrantholder will not enter into any contract, option, or other agreement for the sale or transfer of such shares, warrants or Warrant Shares, until the sooner of: (i) 180 days after the Corporation's initial public offering of its Common Stock; (ii) sale of more than sixty-five percent of the Corporation's issued and outstanding common stock by its stockholders to persons who are not stockholders of the Corporation as of the date hereof; (iii) sale by the Corporation of substantially all of its assets; or (iv) five years from the date hereof; or (v) written consent of the Corporation to such transfer. Further, this Warrant Agreement and the Warrant Shares may not be transferred unless the Corporation receives an opinion of legal counsel reasonably acceptable to it that such transfer will not violate the Securities Act of 1933 or any other federal or state securities law, unless this requirement is waived in writing by the Corporation.

12. Binding Effect on Successors. To the fullest extent permitted by law, this Warrant Agreement shall be binding upon any entity succeeding the Corporation by merger, consolidation or acquisition of all or substantially all of the Corporation's assets, and all of the covenants and agreements of the Corporation shall inure to the benefit of the successors and permitted assigns of the Warrantholder. This Warrant Agreement shall be binding upon and inure to the benefit of the Corporation and the Warrantholder and their respective successors and permitted assigns. The Warrantholder shall not be permitted to assign any of its rights, interests or obligations hereunder without the express written consent of the Corporation.

13. Lost Warrant Agreement. The Corporation covenants to the Warrantholder that upon receipt of evidence reasonably satisfactory to the Corporation of the loss, theft, destruction, or mutilation of this Warrant Agreement and, in the case of any such loss, theft or destruction, upon receipt of the Warrantholder's unsecured indemnification agreement, or in the case of any such mutilation upon surrender and cancellation of this Warrant Agreement, the Corporation will make and deliver a new Warrant Agreement in lieu of the lost, stolen, destroyed or mutilated Warrant Agreement.

14. Governing Law. This Warrant Agreement shall be governed in all respects by and construed in accordance with the laws of the State of Delaware (without regard to any conflict of laws principle that would apply the law of another jurisdiction), whether as to its validity, construction, capacity, performance or otherwise.

15. Consent To Jurisdiction. ANY LEGAL ACTION, SUIT OR PROCEEDING ARISING OUT OF OR BASED UPON THIS WARRANT AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY MAY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF TEXAS, IN EACH CASE, LOCATED IN THE CITY OF AUSTIN, AND, TO THE FULLEST EXTENT PERMITTED BY LAW, EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS. TO THE FULLEST EXTENT PERMITTED BY LAW, IN ANY SUCH ACTION, SUIT OR PROCEEDING, SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT BY MAIL TO SUCH PARTY'S ADDRESS SET FORTH HEREIN SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUCH ACTION, SUIT OR PROCEEDING BROUGHT IN ANY SUCH COURT. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY ACTION, SUIT OR PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH ACTION, SUIT OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

16. Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS WARRANT AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, SUIT OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY TO THIS WARRANT AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (i) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (ii) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (iii) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (iv) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 16.

[Signature Page Follows]

IN WITNESS WHEREOF, this Amended and Restated Warrant Agreement is executed effective as of the Effective Date.

GENPREX, INC.

/s/ Rodney Varner
Name: Rodney Varner
Title: Chief Executive Officer
Dell Medical Center, Health Discovery Building
1601 Trinity Street, Suite 3.312.09
Austin, Texas 78712

ACCEPTED AND AGREED:
WARRANTHOLDER:

DABS ADVANCED BIOTECH SOLUTIONS, LLC

By: /s/ Timothy J Collins

Name: Timothy J Collins
Title: Partner
Address:

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2020, Genprex, Inc. (the "Company") had one class of security registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), its common stock, par value $0.001 per share (the "Common Stock").

Description of Common Stock

The following description of the Company's Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and the Company's Amended and Restated Bylaws (the "Bylaws" and together with the Certificate of Incorporation, the "Charter Documents"), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.12 is a part. The Company encourages you to read its Certificate of Incorporation, Bylaws, and the applicable provisions of the Delaware General Corporation Law (the "DGCL"), for additional information.

Authorized Capital Shares

The Company's authorized capital shares consist of 200,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). As of December 31, 2020, there were 43,117,681 shares of Common Stock issued and outstanding and no shares of Preferred Stock issued and outstanding.

Voting Rights

Holders of the Company's Common Stock are entitled to one vote per share on each matter properly submitted to the stockholders of the Company for their vote; provided, however, that except as otherwise required by law, that holders of Common Stock are not entitled to vote on any amendments to the Certificate of Incorporation relating solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other series of Preferred Stock to vote thereon by law or pursuant to the Certificate of Incorporation. The Company's Charter Documents do not provide for cumulative voting in the election of directors.

Dividend Rights

Holders of the Company's Common Stock are entitled, subject to the rights, privileges, restrictions and conditions attaching to any other class of shares ranking in priority to the Common Stock, to receive any dividend declared by the Company's board of directors out of the Company's assets which are legally available. Such dividends may be paid in cash, in property, or in shares of the Company's capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

Liquidation Rights

Upon the Company's liquidation, dissolution or winding-up, holders of the Company's Common Stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of the Company's outstanding shares of Preferred Stock.

Preemptive, Conversion and Subscription Rights

Holders of the Company's Common Stock have no preemptive, conversion or subscription rights.

Applicable Anti-Takeover Law

Set forth below is a summary of the provisions of the Company's Certificate of Incorporation and Bylaws and the DGCL that could have the effect of delaying or preventing a change in control of the Company. The following description is only a summary, and it is qualified by reference to the Certificate of Incorporation, Bylaws and relevant provisions of the DGCL.

Delaware Anti-Takeover Law

The Company is subject to Section 203 of the DGCL ("Section 203") which generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, owned 15% or more of a corporation's outstanding voting securities.

Certificate of Incorporation and Bylaws

Board of Directors Vacancies

The Company's Charter Documents provide that, subject to the rights of the holders of any series of Preferred Stock, all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum. Further, the Company's directors may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of the Company's then outstanding capital stock. In addition, pursuant to the Company's Certificate of Incorporation, the number of directors constituting the Company's board of directors may be changed only by resolution of the Company's board of directors.

Special Meeting of Stockholders

The Company's Charter Documents require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent. In addition, pursuant to the Company's Bylaws, special meetings of the Company's stockholders may be called only by the chairman of the board, the Company's Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

Stockholder Proposals

The Company's Bylaws provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice.

Staggered Board

The Company's Charter Documents provide that the Company's board of directors shall be divided into three classes and that directors shall be elected for a term of three years.

Exclusive Forum

The Company's Charter Documents provide that unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for state law claims with respect to: (i) any derivative action or proceeding brought in the name or right of the Company or on its behalf, (ii) any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of the DGCL or the Company's Certificate of Incorporation or Bylaws or (iv) any action asserting a claim against the Company or any of the Company's directors, officers or other employees governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Transfer Agent and Registrar

The Company's transfer agent and registrar is VStock Transfer, LLC whose address is 18 Lafayette Place, Woodmere, New York 11598.

Listing

The Company's Common Stock is listed on The Nasdaq Capital Market under the symbol "GNPX."

[*] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Amendment No. 1 to
Patent and Technology License Agreement

This Amendment No. 1 to Patent and Technology License Agreement ("**Amendment No. 1**") is effective as of the date of the last authorized signature affixed hereto (the "**Amendment No. 1 Date**") and is made by and among The Board of Regents ("**Board**") of The University of Texas System ("**System**"), on behalf of The University of Texas M. D. Anderson Cancer Center ("**MD Anderson**"), a member institution of System, and Genprex, Inc., having a place of business at Dell Medical School, Health Discovery Building, 1601 Trinity Street, Bldg. B #3.312.09, Austin, Texas 78712 ("**Licensee**"). Capitalized terms used in this Amendment No. 1 and not otherwise defined herein shall have the meanings set forth in the Original Agreement (as defined below).

Recitals

A. Licensee and Board entered into that certain Patent and Technology License Agreement dated May 4th, 2020 (the "**Original Agreement**").

B. Licensee and Board desire to add technology and patent rights related to MD Anderson's Information Disclosure Report MDA11-043 to the Licensed Subject Matter of the Original Agreement.

Accordingly, in consideration of the mutual covenants contained herein, the sufficiency of which is hereby acknowledged, Licensee and Board, on behalf of MD Anderson, hereby agree to the following:

I. **Amendments**

1. Section 2.24 of the Original Agreement is deleted and replaced with new Section 2.24 as follows:

"2.24 Sale or Sold means the transfer or disposition of a Licensed Product for value; provided, however, that a transfer or disposition of a Licensed Product for value shall not be included in Sales if (a) the transfer is to Licensee or a Sublicensee that does not acquire such Licensed Product for end use or (b) the transfer is to a Royalty Free Practitioner. As used herein, "Royalty-Free Practitioner" means MD Anderson and the following individuals: Jack A. Roth, M.D., David Stewart, M.D.; Charles Lu, M.D.; and Ignacio I. Wistuba, M.D. ("Practitioner Inventors"), and any partner or associate who practices medicine with one or more of the Practitioner Inventors, but with respect to such partner or associate, only for such time as he/she is engaged in a bona fide medical practice with one or more of the Practitioner Inventors."

2. New Section 2.30 is added to Article II of the Original Agreement as follows:

"2.30. MDA11-043 Valid Claim means a Valid Claim of any Patent Right claiming technology described in MDA11-043."

3. New Section 3.5 is added to Article III of the Original Agreement as follows:

"Notwithstanding anything to the contrary in this Agreement, with respect to subject matter described in MDA11-043, the grant of Section 3.1 is subject to any encumbrance arising or resulting from research support or funding under either of the following: (a) the Commonwealth Phase I Study grant for the project titled "Commonwealth Phase I Study" (MDA Acct. number 894464) and the Helen & Jin Ryu Fund for Gene Therapy grant for the project titled "Gene Therapy for Lung Cancer" (MDA Acct. No. 812206)."

4. Section 4.1(c) of the Original Agreement is deleted in its entirety and replaced with the following new Section 4.1(c):

"4.1(c) Annual Maintenance Fees. Nonrefundable annual license maintenance fees ("Annual Maintenance Fees") as follows:

i. $[*], escalating by $[*] per year, until First Sale; *provided*, however, in no event shall an Annual Maintenance Fee exceed $[*]. By way of clarification and not by limitation, the Annual Maintenance Fee due for the second, third, fourth *etc*. anniversaries of the Agreement shall be $[*], $[*], $[*], *etc*., up to a maximum of $[*]."

The Annual Maintenance Fees will not reduce the amount of any other payment provided for in this Article IV. The Annual Maintenance Fees will be payable within thirty (30) calendar days of each anniversary of the Effective Date.

5. To add a Milestone Event, Section 4.1(f) of the Original Agreement is deleted in its entirety and replaced with the following new Section 4.1(f):

(f) The following Milestone Payments are payable for each occurrence of each Milestone Event as set forth in Table 4.1(f), regardless of whether the milestone is achieved by Licensee, a Sublicensee or Affiliate:

Table 4.1(f)

Milestone Event	Milestone Payment
1. [*]	[*] Dollars ($[*])
2. [*]	[*] Dollars ($[*])
3. [*]	[*] Dollars ($[*])
4. [*]	[*] Dollars ($[*])
5. [*]	[*] Dollars ($[*])
6. [*]	[*]Dollars ($[*])

For clarity, Milestone Event No. 5 shall be payable if the jurisdiction of the second Regulatory Approval of the Licensed Product is the same as, or different from, the jurisdiction of the first Regulatory Approval of such Licensed Product. Milestone Payments related to the foregoing Milestone Events are payable one-time on a Licensed Product-by-Licensed Product basis.

6. Section 14.2 of the Original Agreement is modified to update Licensee's address for receipt of notices as follows:

Genprex, Inc.
3300 Bee Cave Road
Suite 650-227
Austin, TX 78746

The remainder of Section 14.2 remains unchanged.

7. Exhibit A of the Original Agreement is deleted in its entirety and replaced with the following new Exhibit A:

EXHIBIT I

MD Anderson Invention Disclosure Report ("IDR") Number	**Inventors/Creators**	**IDR Title**	**U.S. and foreign (outside U.S.) patent applications/patent numbers**
[*]	[*]	[*]	[*]
[*]	[*]	[*]	See list in row below:
		[*]	

II. **Consideration**

1. In consideration of rights granted by Board to Licensee under this Amendment No. 1 and in addition to the additional consideration provided in new Sections 4.1(c) and 4.1(f), Licensee agrees to pay MD Anderson each of the following:

a. Patent Expenses: All unreimbursed Patent Expenses related to patents and patent application for subject matter described in MDA11-043 prior to or after the Effective Date for so long as the Original Agreement remains in effect. MD Anderson will invoice Licensee after this Amendment No. 1 has been fully executed by all Parties for such unreimbursed Patent Expenses incurred as of as of the Amendment No. 1 Date and on a quarterly basis thereafter as provided in the Original Agreement. The invoiced amounts will be due and payable by Licensee within thirty (30) calendar days of invoice.

b. Amendment Fee. As a condition precedent to the inclusion of rights related to MDA11-043 as Licensed Subject Matter in the Original Agreement, a nonrefundable amendment fee in the amount of $[*] ("Amendment Fee"). This upfront licensee fee will not reduce the amount of any other payment provided for in the Original Agreement, and is due and payable not later than thirty (30) calendar days after the Amendment No. 1 Date. The obligation to timely pay the Amendment Fee is not subject to any cure period.

III. **General**

1. Licensee and Board, on behalf of MD Anderson, acknowledge and agree that, except as set forth in this Amendment No. 1, the terms and conditions of the Original Agreement shall remain in full force and effect on a going forward basis.

[Signatures appear on the following page]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment No. 1.

BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS SYSTEM,
on behalf of
THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER
By /s/ Ben Melson_____
Ben Melson
Senior Vice President,
Chief Financial Officer
The University of Texas
M. D. Anderson Cancer Center
Date: March 3, 2021

Approved as to Content:
By /s/ Ferran Prat _____
Ferran Prat, J.D., Ph.D.
Senior Vice President, Research
Administration & Industry Relations
M. D. Anderson Cancer Center
Date: March 3, 2021

GENPREX, INC.
By /s/ Rodney Varner _____
Printed Name: Rodney Varner
Title: President & Chief Executive Officer
Date: March 3, 2021

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Genprex, Inc.
Austin, Texas

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File no. 333-237543) and the Registration Statement on Form S-3 (File no. 333-239134) of Genprex, Inc., of our report dated March 26, 2021 relating to the consolidated financial statements at and for the years ended December 31, 2020 and 2019, which appear in this Annual Report on Form 10-K.

/s/ Daszkal Bolton LLP

Boca Raton, Florida
March 26, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Rodney Varner, certify that:

1. I have reviewed this annual report on Form 10-K of Genprex, Inc., a Delaware corporation (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 in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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 26, 2021

By: /s/ J. Rodney Varner
J. Rodney Varner
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan M. Confer, certify that:

1. I have reviewed this annual report on Form 10-K of Genprex, Inc., a Delaware corporation (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 in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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 26, 2021

By: /s/ Ryan M. Confer
Ryan M. Confer
Chief Financial Officer
(Principal Financial and Accounting 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 on Form 10-K of Genprex, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, J. Rodney Varner, Chief Executive Officer of the Company, and Ryan M. Confer, Chief Financial Officer of the Company, hereby certifies, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended and 18 U.S.C. § 1350, as adopted pursuant to § 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 operations of the Company.

Date: March 26, 2021

By: /s/ J. Rodney Varner
J. Rodney Varner
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Ryan M. Confer
Ryan M. Confer
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Report, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.