





**2005 ANNUAL REPORT** 



"Through a company-wide focus on a clearly defined set of strategic imperatives and corresponding operating objectives, during 2005 we strengthened Quidel Corporation's competitive position, expanded our market share, positioned ourselves for future growth and substantially improved our financial results."

# Caren L. Mason

President and Chief Executive Officer

# **To Our Stockholders**

I am pleased to report that 2005 was a year of significant progress for Quidel, with important achievements in several key areas.

# **Furthering Our Competitive Advantage**

One of our strategic imperatives focused upon the deliverable of achieving increased sales and market share in our core products, the QuickVue® tests for influenza, Strep A and pregnancy. As part of our Quidel Value Build (QVB<sup>TM</sup>) program, we sponsored clinical research to demonstrate the superior quality of selected tests and provided our distributors and end users with the "proof" they need to sell and use our products.

For example, in October of 2005, we announced the results of a clinical study conducted to further validate the performance of our QuickVue Influenza A+B test. The study was completed in Australia during that continent's flu season from July through September 2005 and showed 96% sensitivity (true positive identification) and 97% specificity (true negative identification) in detecting Type A influenza when final results were validated using the RT PCR (reverse transcription-polymerase chain reaction) method for laboratory accuracy. The protocol of the clinical study was approved in advance by Australia's National Research and Evaluation Ethics Committee and was conducted at general practitioner offices across New South Wales. In addition, in May of 2005, we announced the results of an analytical study conducted by the University of Rochester Medical Center, which found that our QuickVue Influenza A+B test had the highest sensitivity, 95% of the time, when compared with certain competing rapid tests and has added benefits in terms of ease-of-use and rapid time to result.

The market is responding to our QVB validation strategy. In 2005, sales of our influenza tests rose 32%, while Strep A and pregnancy test sales each grew by 19%. The market share statistics were equally impressive. The latest U.S. data covering sales through distributors, as of December 31, 2005, showed that our share of the rapid point-of-care ("POC") diagnostic market is as follows:

- 66% for influenza, up 6 points from last year
- 46% for Strep A, up 3 points from last year
- 50% for pregnancy, up 1 point from last year

We also made excellent progress toward our goal of strengthening and streamlining distributor relationships. Throughout the year, we established preferred partner agreements with leading U.S. distributors, which focus on both revenue predictability and overall profitability. We are very proud that one of our largest distributors, Physician Sales and Service (PSS), chose Quidel as its "2005 Manufacturer of the Year."

In presenting the award to us, PSS cited our ability to significantly grow revenue through its sales force, our development of innovative products and programs, the quality of our account team and our focus on pleasing our mutual customers. This is an outstanding achievement considering the hundreds of leading medical products companies that

do business with PSS. In addition, another of our largest distributors, Cardinal Health, recognized Quidel for extraordinary industry performance, and named us as one of their outstanding suppliers for 2005 in the category of marketing excellence.

# **Opening New Markets**

The clear leadership position of the QuickVue brand is an asset that we intend to leverage with additional diagnostic solutions to drive growth and profitability. In September 2005, we acquired an immunochemical fecal occult blood (iFOB) test, and following a number of product enhancements, we launched this test in January 2006 as the QuickVue iFOB test. We believe this test will become a very important product for Quidel as more than 50 million fecal occult blood tests are sold annually in the U.S. as an important tool in the early detection of colorectal cancer. We believe the QuickVue iFOB test has the potential for significant clinical and economic advantages over competitive tests, and we plan to validate those advantages through QVB in order to accelerate market acceptance.

We also took important steps to establish a strong position in additional target markets, including reproductive health and bone health. During 2005, we began preparing our QuickVue test for Candida for market introduction, which is anticipated for late 2006. We believe this rapid diagnostic to be an important product as symptoms of infectious vaginitis result in more than 10 million patient visits to an OB/GYN physician every year. Importantly, we do not expect the market for the iFOB test nor the Candida test to have seasonal sales patterns, and accordingly, both will support our objective of minimizing the impact of seasonality on our financial performance.

In addition, our Specialty Products Group (SPG) secured strategic co-marketing agreements with Cambrex Bio Science Walkersville, Inc. and Nordic Bioscience Diagnostics. These partnerships will leverage Quidel's global capabilities to collaborate with osteoporosis research institutions for the development of new markers that may benefit osteoporosis and post-menopausal patients. They also will provide a gateway for Quidel to expand its growth and development in the global bone health industry by tapping into new, international markets and sales opportunities.

# **Establishing Industry Leadership**

As part of QVB, we established two important Medical Advisory Boards consisting of renowned leaders in the fields of Reproductive Health and Infectious Disease. Both Boards are comprised of thought-leaders from academia and private practice in the U.S. and overseas, and it is truly an honor to have physicians and researchers of this caliber advising Quidel.

The Reproductive Health Advisory Board will focus on a review of our reproductive health product portfolio to determine if there might be other applications for existing products, in addition to gaining greater insight into clinician attitudes towards POC testing and assessing market opportunities for future product development. Additional goals include helping us to identify and support relevant clinical research.

Our Infectious Disease Advisory Board is currently focused on the appropriate utilization of rapid tests for influenza in public health, emergency preparedness, and seasonal as well as pandemic planning.

We are also indeed fortunate to have made two very strong additions to our corporate Board of Directors. Jack Schuler, a former president of Abbott Laboratories and one of the most respected executives in the medical diagnostics industry, and Rod Dammeyer, a recognized expert in finance and capital investment, joined our Board in February 2006. We look forward to working with Jack and Rod, and to their assistance in building greater value for our shareholders.

# **Improving Financial Results**

As a result of the work described above and on the pages that follow, we posted strong operating and financial results in 2005. We delivered substantially improved revenue and earnings from continuing operations, exclusive of litigation settlement, for the full year 2005 and continued to capitalize on the investments and meet the imperatives outlined for market leadership in rapid diagnostic tests at the point of care in infectious disease and reproductive health. For the year ended December 31, 2005, total revenues rose 17% to \$92.3 million, up from \$78.7 million for the year ended December 31, 2004. Total product sales also increased by 17%, and reached \$88.7 million in 2005, with strong contribution from all core product lines.

In the U.S., product sales increased 22% to \$65.8 million. International product sales for 2005 were \$22.9 million, an increase of 3% versus 2004, driven by a 56% increase in influenza product sales mainly offset by the elimination of lower margin sales in underdeveloped markets as part of the realignment of our global distribution network.

Gross margin for 2005 was 58%, up from 54% for 2004, primarily as a result of higher product sales, operating efficiencies, a favorable product and geographic mix, and a price increase on the majority of our products. Our Form 10-K is included with this report for a complete review of our financial results.

As we look ahead into 2006, we anticipate continued revenue growth in our core product lines, as well as incremental revenue contribution from our new product introductions.

We also plan to continue our investments in the following key areas:

- Sales, marketing and QVB to drive revenue growth
- Research and development in acquired and new technologies to assure the Company's position at the forefront of innovation
- Operating efficiencies and manufacturing upgrades to increase gross profit margins

We believe all of these investments will support and expand our leadership position in POC rapid diagnostics, and allow us to take advantage of the growing domestic and international opportunities.

I congratulate our employees on their achievements and success in 2005, and on behalf of the entire team at Quidel, I thank you for your continued support.

And finally, as you read through this annual report, please note that the commitments we make we support through validation. We invite you to measure our performance and our promise as we fully subscribe to the fact that in the end, "it's all about proof."

Sincerely,

Caren L. Mason

President and Chief Executive Officer



Our investment in QVB will assure operational excellence and help drive revenue growth.



New products and technologies position Quidel at the forefront of innovation.



Investments in operating efficiencies, including our "virtual factory" contribute to our gross profit margin improvement.

# **Quidel Value Build™**

"Overall, the Quidel QuickVue Influenza A+B assay was the most sensitive test and has added benefits in terms of ease of use and rapid time to positive result."

Abstract presented by University of Rochester Medical Center,
21st Clinical Virology Symposium and Pan American Symposium for Clinical Virology, May 2005





# Leadership

The Quidel Value Build (QVB™) programs are the strategic platform from which we are strengthening our position of rapid diagnostics leadership, and providing evidence to support the increasingly important role that point-of-care testing plays in healthcare decision making and outcomes. A brand study was completed mid-year to validate the value of the QuickVue brand from the perspective of those who use rapid diagnostic tests—physicians, laboratorians and nurses. This study, conducted by The Brand Institute, concluded that among both users and non-users, products with the QuickVue brand were rated among the highest for accuracy, reliability and consistency. The infuenza and Strep A products received the highest accolades.

QVB encompasses several initiatives but primarily focuses upon clinical and economic proof studies, market leadership, and strong strategic partnerships. In each of these areas, we strive to set the industry standard, and to leverage our position to improve the quality of patient care.

#### **Clinical Studies**

The results of a point-of-care test may have a significant impact on the type, level and cost of subsequent patient treatment. In fact, as many as 70% of treatment decisions are based on the results of diagnostic tests—which account for only 5-6% of a typical hospital's budget. This means healthcare professionals increasingly depend upon the QuickVue brand to give them the confidence to set the course of treatment.



In 2005, our commitment to quality and to evidence-based medicine was reflected in the significant clinical studies we completed with the QuickVue Influenza A+B test and with the QuickVue Advance® pH and Amines test for use in the diagnosis of bacterial vaginosis.

#### INFLUENZA A+B

In 2005, a study conducted under controlled conditions by scientists at the University of Rochester Medical Center in Rochester, N.Y. found that the QuickVue Influenza A+B assay demonstrated the highest analytical sensitivity, at 95%, among the four tests examined for effectiveness in detecting the flu. The study also found that QuickVue Influenza A+B had added benefits in terms of ease of use and time to result.

We followed this with a clinical study performed in Australia during that continent's flu season from July through September 2005, with results showing 96% sensitivity (true positive identification) and 97% specificity (true negative identification) in detecting Type A influenza.

The combination of ease of use—including the acquisition of a sample via a nasal swab—and high sensitivity continues to contribute to the growth of our influenza products in both the physician office lab and acute care setting.

# BACTERIAL VAGINOSIS

In August, in conjunction with key researchers in the U.S. and Canada, Quidel announced results of a clinical study showing that our proprietary layered thin film

"The voice of the customer process was very well demonstrated and impressive in the depth and breadth of the many areas that Quidel uses to ensure customer focus."

Thomas J. SapienzaLead AuditorTUV America



"Quidel has demonstrated its high standards for market research. Their understanding of customer needs and their knowledge of market trends consistently provide us with strong customer support."

 Mark McLoughlin, VP General Manager Scientific Products Distribution Medical Products and Services Cardinal Health



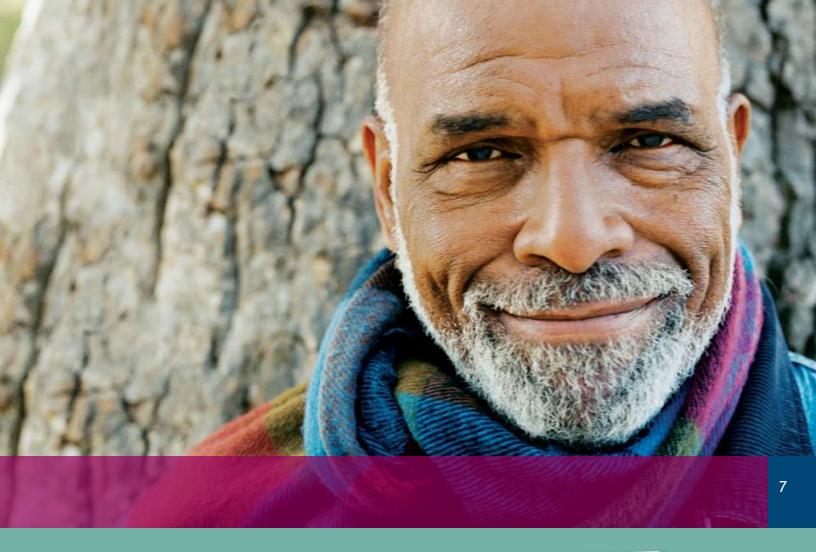
(LTF®) QuickVue Advance pH and Amines test achieved a clinical sensitivity of 92%, specificity of 95% and overall accuracy of 94%, a significant improvement when compared to traditional, more time consuming and more technically demanding procedures such as Amsel clinical criteria and Gram Stain. The test is ideal for use in the physician's office where most of the approximately 10 million visits take place in the U.S. each year, as women seek help for symptoms associated with infectious vaginitis.

# **Market Leadership: New Products**

Quidel's manufacturing infrastructure, distribution network and industry-leading brand name allow us to acquire new point-of-care technologies and achieve widespread, cost-effective introduction to the market. An example of how we can leverage our assets was the 2005 acquisition of an immunochemical fecal occult blood (iFOB) test, which was launched in early 2006 as the QuickVue iFOB test.

This new test has several distinct advantages over the guaiac fecal occult blood test, which accounts for the vast majority of colorectal cancer screening tests today, including:

- Specific detection of human hemoglobin
- No dietary restrictions
- Expected improved patient compliance through our easy, patient-friendly, one-sample regimen
- Improved Medicare reimbursement



We expect that our QuickVue iFOB test will become a very important product for Quidel, as more than 50 million fecal occult blood tests are performed annually in the U.S. We plan to employ many of the same strategies to build the iFOB test market as we have used in successfully building the professional market for influenza testing—programs are developed as a result of strong market research. Programs currently underway include clinical studies, economic studies, market research to better understand payer groups, professional education programs and patient information programs, via print and electronic media.

# **Medical Advisory Boards**

In order to help us make decisions regarding new diagnostic tests, two Medical Advisory Boards were formed in 2005. They will provide insight into their areas of expertise and will take an active role in discussions we will have in the public health arena.

#### REPRODUCTIVE HEALTH ADVISORY BOARD

The members of this panel are well known in the field of reproductive health and are qualified to provide valuable insight into clinicians' attitudes towards point-of-care testing in general, and to help Quidel form educational programs to address key issues. Additional goals include helping Quidel identify and support relevant clinical research efforts.



The QuickVue iFOB test is the newest member of Quidel's rapid diagnostic line of products.



"Quidel consistently provides us with strong marketing programs and provides meaningful market research—understanding the customer's needs and market trends to better serve our end-user."

John Sasen, Executive Vice President, Chief Marketing Officer,
Physician Sales and Services



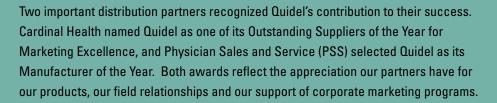
## INFECTIOUS DISEASE ADVISORY BOARD

Given the worldwide focus on the avian flu, initially this panel will focus on the appropriate utilization of rapid tests for influenza in public health, emergency preparedness, and seasonal as well as pandemic planning. Longer term, their experience in both research and clinical practice will help direct broader efforts covering clinical validation, evidence-based economics and the education of the healthcare community as to the benefit of a test-and-treat protocol.

#### **Awards**

2005 saw improved relationships with our distribution partners as well as growth in market share for our core products. We are very proud that on both fronts we received third-party awards and recognition for our success.

From the industry research firm, Frost & Sullivan, Quidel received the 2005 Growth Strategy Leadership of the Year Award. In granting this award, Frost & Sullivan pointed to recognized industry surveys, commenting: "The QuickVue Strep A and influenza brands have been ranked #1 in the point-of-care setting. Quidel is able to understand its customers' requirements and provide products that match them. This has resulted in brand loyalty for Quidel's products being higher than its competitors."



Quidel thanks PSS for their support!

We are proud to have earned these accolades. The awards reflect the hard work and dedication of Quidel employees who, endeavor daily to earn and re-earn the approval of our customers and our partners.

We received the 2005 San Diego Work Place Excellence Award, earning "employer of choice" distinction through a program sponsored by the San Diego Society for Human Resource Management.

Nominated by employees, Quidel was selected from over 140 companies of various sizes. The award recognizes companies who have employed creative strategies that have had a huge benefit to employees while also helping to increase the bottom line.

"The Workplace Excellence Awards spotlight and recognize companies that employ HR practices that increase both employee satisfaction and company performance."

Chana Anderson,
President
San Diego Society for Human
Resource Management

"The project to implement a visual factory in the real time assessment of process performance was very impressive."

Thomas J. SapienzaLead AuditorTUV America





- Strict use of only the highest quality materials
- ISO certified facilities
- Fully-automated manufacturing processes for select products
- Continual monitoring by proprietary digital inspection systems
- Test sampling

A cornerstone of Quidel's success is a commitment to manufacturing processes and quality controls that result in what we define as "operational excellence." Our facilities in San Diego and Santa Clara have received International Organization for Standardization (ISO) 13485:2003 certification, and comply with the FDA Quality System Regulations (QSR) governing the manufacture of medical devices.

Our internal manufacturing process consists of two segments:

# **Processing of Chemical and Biological Materials**

The process begins with the raw materials we obtain from carefully chosen suppliers around the world. These suppliers operate to a certified quality system, and are able to provide objective evidence that their products can consistently meet our requirements. Our chemical and biological laboratories are staffed by well-trained, experienced chemists, who clearly define each raw material specification based on an in-depth understanding of how the material characteristics impact the manufacturing process. During this step of the overall manufacturing process, the labs incorporate state-of-theart automated chromatography, and are devoted to tissue culture, cell culture, protein purification and immunochemistry.



# **Integration of the Materials into Completed Test Units**

Completed test units are manufactured using a series of automated processes designed to minimize product variations that could be caused by standard manual assembly practices. Each step of manufacturing and assembly is monitored by quality assurance and operations teams. Information is collected in real-time utilizing Quidel's advanced digital vision inspection systems which provide continuous feedback on the performance of the assembly process; the qualitative visual test results are translated into a quantifiable test score, ensuring that each manufacturing lot conforms to specific quality control release criteria. In addition, throughout the assembly process, statistically based sampling plans are used to measure the performance and quality of the finished product.

This highly controlled operations environment is an integral part of QVB, and ensures that our products consistently meet our customers' quality and delivery expectations.



captured and translated into visual and graphical metrics. The metrics enable scientists, engineers and management to review and respond to real time factory performance data. This process approach to manufacturing significantly enhances our ability to consistently produce quality products.

# Influenza

"Schools, like other crowded places, are perfect breeding grounds for the influenza virus. By employing a rapid test, we can isolate and treat students, their family as needed, and thereby prevent the spread of this serious disease."

Prof. Dr. med. Georg E. Vogel,
Prof. Vogel is a physician of internal medicine, gastroenterology/nephrology in Munich, Germany
2005 receipient of The Bavarian Order of Merit



One of the most widely publicized and discussed stories in 2005 and continuing into 2006 is the spread of a new strain of avian flu (H5N1) in parts of Asia and Europe. Concerns about the possibility for this strain to mutate into a human-to-human transmitted form, and the prospective worldwide public health impact, are evident in the media. Government agencies, and healthcare organizations and commercial enterprises are compelled to provide clarity about the situation and respond appropriately.

As the leader in the rapid diagnosis of influenza at the point-of-care, Quidel can offer the product development expertise, clinical experience, manufacturing capability and distribution network that may be needed in the event of a potential crisis.

While we have not conducted studies on humans infected with avian influenza viruses, and therefore do not know how well the test will perform with samples from patients actually infected with a new strain of avian influenza, we do know that our QuickVue Influenza A+B test can detect cultured avian influenza viruses, including H5N1. We do believe that should a pandemic occur, every means available to combat the arrival and spread of the disease should be employed.

Quidel is committed to working with public health agencies to help ascertain what role the QuickVue Influenza A+B test might play in the event of a pandemic in the U.S. and throughout the world. During 2005, Company executives met with government and agency officials at the highest levels, were apprised of the latest developments, and took part in planning discussions.



As everyone pays close attention to the worldwide situation, we believe there are several possible roles for the QuickVue Influenza A+B test including:

- Traveler surveillance
- Frontline regional surveillance to help monitor flu outbreaks
- Rapid identification of persons most in need of antiviral medication—which promises to be in short supply

All of these applications would be intended to support the very essential and critical role that our public health service laboratories and the Centers for Disease Control (CDC) will have in isolating and determining the subtype of the actual virus. Quidel intends to remain involved in these important public discussions.

"I found the QuickVue Influenza A+B kit to be as sensitive and reliable in detecting avian influenza viruses of each of the known [viral] subtypes, including H5N1, as it is in detecting human influenza viruses. Therefore, the kit has potential for research and field use in animal surveillance, as well as in human diagnostics should there be a pandemic influenza outbreak."

Professor Hiroshi Kida
Hokkaido University
Japan

# Specialty Products Group (SPG<sup>™</sup>) and Research to Rapids<sup>™</sup>

"At the University of Texas Southwestern Medical Center - Dallas we see many patients with skeletal disorders both in the Mineral Metabolism and Osteoporosis Clinics. We have been using the Metra® BAP and DPD assays for many years as part of our laboratory evaluation and rely on them to not only help us better understand their disease but also manage patient care by assessing their response to various therapeutic interventions."

# Joe Zerwekh, Ph.D.

Frederic C. Barters Professor of Vitamin D Research in Internal Medicine University of Texas, Southwestern Medical Center at Dallas



While Quidel's core products enjoy clear market leadership, the SPG also researches, develops, and markets products which address smaller but critical markets where Quidel has established expertise. To date, the SPG markets nine different assays for various aspects of bone health, with more than 100 other clinical and research products in use in clinical and research institutions worldwide.

# **Products and Opportunities**

Within the SPG reside the Company's core competencies in osteoporosis, metabolic bone disease and biochemical bone markers, including 15 patents on various aspects of collagen. The SPG is also the repository for Quidel's intellectual property portfolio of monoclonal antibodies to markers of inflammatory disease and oncology, many of which have demonstrated promise in the development of new and novel diagnostic and research assays in these disease areas.

Some of these assays have evolved into successfully marketed diagnostic and research tests on a microwell platform. This represents a preliminary step toward potential future development of point-of-care devices. We identify this concept as Research to Rapids. These microwell kits, related products and core technologies are currently marketed by Quidel directly and through select distributors throughout the world under the Quidel® and Metra® brands.



# **Significant Progress**

The SPG is singularly dedicated to building clinical proof around Quidel's panel of proprietary markers for chronic and acute disease states. Researchers around the globe depend on Quidel's SPG for novel, high quality tools for disease research and clinical diagnosis. Scientists in the SPG, working with partners around the globe, are focused on developing new and novel products for bone turnover with potential clinical significance.

One of the SPG's key objectives in 2005 was to improve our support of researchers worldwide by focusing on manufacturing and quality improvements to our kits, utilizing improved chemistries, developing better production techniques and further improving standardization. The success of this effort was demonstrated when we received ISO 13485:2003 accreditation in the fourth quarter of the year.

We expanded and solidified our sales force both in the U.S. and abroad. Our international distribution strategy in the European Union grew to include a master distribution relationship with TECOmedical, a bone specialty distributor.

In 2005, the SPG signed an agreement to market Nordic BioSciences' bone marker, sCTX, in the U.S. A serological bone turnover marker, sCTX is a strong strategic fit with Quidel's existing line of markers for bone metabolism including Metra BAP and Metra DPD. This will allow Quidel to expand its growth and development in the global bone health industry by tapping into new, international markets and sales opportunities.

#### QUIDEL SENIOR MANAGEMENT

## **BOARD OF DIRECTORS**

#### Caren L. Mason

President and Chief Executive Officer

#### Paul E. Landers

Senior Vice President, Finance and Administration, Chief Financial Officer and Secretary

#### Mark E. Paiz

**Chief Operating Officer** 

## Thomas J. Foley, Ph.D.

Chief Technology Officer

#### Mark A. Pulido

**Corporate Information** 

Chairman of the Board Quidel Corporation

#### Caren L. Mason

President and Chief Executive Officer Quidel Corporation

#### **Thomas D. Brown**

Vice Chairman of Condell Medical Center and Retired Senior Vice President, President of the Diagnostics Division of Abbott Laboratories

#### **Rod F. Dammeyer**

President CAC, LLC

#### Thomas A. Glaze

Chairman of the Board Essentialis, Inc.

#### Douglas S. Harrington, M.D.

Chief Executive Officer of Bioanalytical Laboratories of America

# Mary Lake Polan, M.D., Ph.D., M.P.H.

**Emeritus Chair** 

Department of Gynecology and Obstetrics Stanford University School of Medicine

#### Jack W. Schuler

Chairman of the Board Ventana Medical Systems, Inc. and Stericycle, Inc.

#### **Faye Wattleton**

President

Center for the Advancement of Women

#### **Annual Meeting**

The annual meeting of shareholders will be held at 8:30 a.m., Wednesday, May 17, 2006, at:

L'Auberge del Mar 1540 Camino del Mar Del Mar, California 92014

#### **Outside Legal Counsel**

Gibson, Dunn & Crutcher LLP Irvine, California 92614

# Independent Registered Public Accounting Firm

Ernst & Young LLP San Diego, CA 92101

#### **Stockholder Inquiries**

Inquiries related to stock transfer or lost certificates should be directed to the Transfer Agent.

## **Transfer Agent & Registrar**

American Stock Transfer & Trust Company 59 Maiden Lane Plaza Level New York, NY 10038 800.937.5449

#### **Nasdaq Listing**

Quidel common stock is traded on the Nasdaq National Market under the symbol "QDEL."

#### Form 10-K and Form 10-Q

A copy of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports that file with the Securities and Exchange Commission are available without charge upon request. Please contact Investor Relations.

# **Investor Relations**

10165 McKellar Court San Diego, California 92121 USA 858.552.7955 ir@quidel.com

Quidel's press releases and other information are located on Quidel's Web site: www.quidel.com

Quidel® Corporation and the Company's stylized logos, QuickVue®, QuickVue+®, QuickVue Advance®, QuickVue In-Line®, RapidVue®, LTF®, gII®, Metra®, SemiQ®, One Visit. One Step. One Time.® and One Visit. One Test. One Time.® are registered U.S. trademarks of the Company. Research to Rapids<sup>TM</sup>, R2R<sup>TM</sup>, Rub 'n Read<sup>TM</sup> and QVB<sup>TM</sup> (Quidel Value Build) are trademarks of the Company.



#### **Quidel Corporation Headquarters**

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**Quidel, Northern California Operations**Santa Clara, Cal<u>ifornia USA</u>

This Annual Report contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the length and severity of cold and flu seasons, uncertainty surrounding the detection of H5N1 involving human specimens, adverse changes in the competitive and economic conditions in domestic and international markets, actions of our major distributors, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration ("FDA"), intellectual property, product liability, environmental or other litigation, required patent license fee payments not currently reflected in our costs, and lower than anticipated sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in reports and registration statements that we file with the SEC from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this annual report. We undertake no obligation to publicly release the results of any revision of the forward-looking statements.