Opko Health, Inc.
Form 10-K
March 18, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2012

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 001-33528

OPKO HEALTH, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	75-2402409
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4400 Biscayne Blvd., Miami, FL 33137

(Address of Principal Executive Offices, Zip Code)

Registrant s Telephone Number, Including Area Code: (305) 575-4100

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $.01 par value per share	New York Stock Exchange

Securities registered pursuant to section 12(g) of the Act:

None

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

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

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 x No ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large Accelerated filer ¨	Accelerated filer x
Non-Accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of the last business day of the registrant s most recently completed second fiscal quarter was: $620,749,562.

As of March 8, 2013 the registrant had 324,257,735 shares of Common Stock outstanding.

Documents Incorporated by Reference

Portions of the registrant s definitive proxy statement for its 2013 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

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EX-101.INS XBRL Instance Document

EX-101.SCH XBRL Taxonomy Extension Schema Document

EX-101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

EX-101.DEF XBRL Taxonomy Extension Definition Linkbase Document

EX-101.LAB XBRL Taxonomy Extension Label Linkbase Document

EX-101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in Item 1A-Risk Factors of this Annual Report on Form 10-K. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

We have a history of operating losses and we do not expect to become profitable in the near future.

Our technologies are in an early stage of development and are unproven.

Our business is substantially dependent on our ability to develop, launch and generate revenue from our pharmaceutical and diagnostic programs.

Our research and development activities may not result in commercially viable products.

The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.

We may require substantial additional funding, which may not be available to us on acceptable terms, or at all.

We may finance future cash needs primarily through public or private offerings, debt financings or strategic collaborations, which may dilute your stockholdings in the Company.

If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our products.

The loss of Phillip Frost, M.D., our Chairman and Chief Executive Officer, could have a material adverse effect on our business and product development.

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If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

In the event that we successfully evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we fail to acquire and develop other products or product candidates, at all or on commercially reasonable terms, we may be unable to diversify or grow our business.

We have no experience manufacturing our pharmaceutical product candidates other than at our Israeli, Mexican, and Spanish facilities and we therefore rely on third parties to manufacture and supply our pharmaceutical product candidates, and would need to meet various standards necessary to satisfy FDA regulations if and when we commence manufacturing.

We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile, Mexico, Spain, and Brazil for sales in those countries and our active pharmaceutical ingredients (APIs) business in Israel, and the sales force for our laboratory business based in Nashville, Tennessee. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates.

The success of our business will be heavily dependent on the success of Phase 3 clinical trials for CTAP101 Capsules and Fermagate Tablets.

Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.

The success of our business is dependent on the actions of our collaborative partners.

Our license agreement with TESARO, Inc. (TESARO) is important to our business. If TESARO does not successfully develop and commercialize rolapitant, our business could be adversely affected.

If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.

We do not have an exclusive arrangement in place with Dr. Tom Kodadek with respect to technology or intellectual property that may be material to our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We rely heavily on licenses from third parties.

We license patent rights to certain of our technology from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Adverse results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition.

Medicare prescription drug coverage legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products and provide our services profitably.

Failure to obtain and maintain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.

We may not have the funding available to pursue acquisitions.

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Acquisitions may disrupt our business, distract our management, may not proceed as planned, and may also increase the risk of potential third party claims and litigation.

We may encounter difficulties in integrating acquired businesses.

Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

Political and economic instability in Europe and Latin America and political, economic, and military instability in Israel could adversely impact our operations.

We are subject to fluctuations in currency exchange rates in connection with our international businesses.

Our business may become subject to legal, economic, political, regulatory and other risks associated with international operations.

The market price of our Common Stock may fluctuate significantly.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you may not consider to be in your best interests or in the best interests of our stockholders.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as they apply to us, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our Common Stock price may suffer.

We may be unable to maintain our listing on the NYSE, which could cause our stock price to fall and decrease the liquidity of our Common Stock.

Future issuances of Common Stock and hedging activities may depress the trading price of our Common Stock.

Provisions in our charter documents and Delaware law could discourage an acquisition of us by a third party, even if the acquisition would be favorable to you.

We do not intend to pay cash dividends on our Common Stock in the foreseeable future.

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PART I

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the Company , OPKO , we , our , ours , and us r OPKO Health, Inc., a Delaware corporation, including our wholly-owned subsidiaries.

ITEM 1. BUSINESS

OVERVIEW

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including point-of-care tests, laboratory developed tests (LDTs), molecular diagnostics tests, and proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets. We have already established commercial operations in Chile, Mexico, and Spain, which are generating revenue and which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We also recently established pharmaceutical operations in Brazil. We operate a U.S.-based laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended (CLIA), with a urologic focus that we expect will serve as a commercial platform for the U.S. launch of OPKO s next generation test for the early detection of prostate cancer. In addition, we operate a specialty active pharmaceutical ingredients (APIs) manufacturer in Israel, which we expect will play a valuable role in the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products. We continue to actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses.

In late 2011, we acquired a novel diagnostic instrument system that provides rapid, high performance blood test results and enables complex tests to be run in point-of-care settings. The instrument, a novel microfluidics-based system consisting of a disposable test cassette that resembles a credit card and a small desktop analyzer, can provide high performance, central laboratory-grade blood test results within minutes and permit the transition of complex immunoassays and other tests from the centralized reference laboratory to the physician s office or hospital nurses station. We expect this point-of-care instrument system to provide near-term commercialization opportunities through the transition of existing laboratory-based tests, including prostate specific antigen (PSA), vitamin D and testosterone, to our point-of-care system. Longer term, we believe that this instrument system will serve as a platform for the commercialization of our proprietary molecular diagnostics tests.

We have already obtained a CE Mark for our point-of-care diagnostic test for PSA using our system in Europe and we intend to launch the PSA test in Europe in the second half of 2013. We intend to submit our application to the Food and Drug Administration (the FDA) for clearance of the PSA test and expect to begin marketing the test in the U.S. in 2014. We are also presently working to add additional panels for our point-of-care system, including testosterone and vitamin D, and we believe that there are many more applications for the technology, including infectious disease, cardiology, women s health, and companion diagnostics.

We are also developing our next generation prostate cancer tests for both our point-of-care diagnostic system, as well as the laboratory setting in the U.S. utilizing OPKO s novel panel of kallikrein biomarkers and associated algorithm (4Kscore). The panel of markers included in the OPKO 4Kscore is the result of a decade of research by scientists in Europe and the U.S. and the biomarkers markers have been demonstrated in more than 8,000 patients to predict the probability of positive biopsies in men suspected of having prostate cancer. Extensive studies have shown that the use of this novel panel of kallikrein biomarkers and algorithm may reduce the number of unnecessary prostate biopsies by 50% or more, avoiding the frequent complications of pain, bleeding, and infection, which sometimes require hospitalization. In October 2012, our strategic partner, International Health Technology, Ltd. (IHT), launched sales of lab services using this novel panel of biomarkers in the United Kingdom as part of IHT s ProstateCheck program. In December, 2012, we completed the acquisition of Prost-Data, Inc., a CLIA-certified laboratory doing business as OURLab (OURLab). In addition to continuing to operate as a full-service medical laboratory specializing in urologic pathology, OURLab provides us with the commercial platform to support the U.S. development and commercial launch of the 4Kscore for the detection of prostate cancer as a LDT.

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Our innovative molecular diagnostics platform for the development and commercialization of accurate, easy-to-use, blood-based tests utilizes an innovative method for the rapid identification in small blood samples of disease-specific antibodies that can serve as diagnostic biomarkers for a wide range of diseases. We have demonstrated in initial studies that our platform has the ability to identify diagnostic biomarkers for a wide range of diseases to which the immune system reacts, including cancers, autoimmune diseases, neurodegenerative diseases and infectious diseases. This technology platform may also allow for the development of vaccines and highly targeted therapeutic agents. Our most advanced molecular diagnostic test utilizing this technology is a simple blood test for Alzheimer s disease, a debilitating neurodegenerative disease for which there are limited diagnostic options available today. Based on initial clinical work, as described in the journal *Cell* in January 2011, our Alzheimer s test demonstrated an ability to identify and differentiate Alzheimer s patients by detecting elevated levels of antibodies that appear to be unique to Alzheimer s disease. We are continuing work on biomarker and platform optimization to support development of a successful commercial test for Alzheimer s disease. In addition to Alzheimer s disease, we are developing a pipeline of diagnostic tests for other conditions such as non-small cell lung cancer, pancreatic cancer and tuberculosis.

Our product pipeline also includes several pharmaceutical compounds and technologies in research and development for a broad range of indications and conditions. We recently completed the acquisition of Cytochroma Inc. (Cytochroma) whose lead products, both in Phase 3 development, include CTAP101 Capsules, a vitamin D prohormone to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, and Fermagate Tablets, a new and potent non-absorbed phosphate binder to treat hyperphosphatemia in end-stage renal disease (ESRD) patients on chronic hemodialysis.

CTAP101 Capsules have been shown in a phase 2b clinical trial to effectively and safely treat SHPT and the underlying vitamin D insufficiency in pre-dialysis patients. Vitamin D insufficiency arises in CKD due to the abnormal upregulation of CYP24, an enzyme which destroys vitamin D and its metabolites. Studies in CKD patients have demonstrated that currently available over-the-counter and prescription vitamin D products cannot reliably raise blood vitamin D prohormone levels and effectively treat SHPT. CTAP101 Capsules are currently in phase 3 clinical trials in the U.S. If approved, we intend to market our CTAP101 Capsules together with our proprietary point-of-care vitamin D diagnostic test currently in development.

The new phosphate binder, Fermagate Tablets, has been shown to be safe and effective in treating hyperphosphatemia in phase 2 and 3 trials in CKD patients undergoing chronic hemodialysis. Hyperphosphatemia contributes to soft tissue mineralization and affects approximately 90% of dialysis patients. Dialysis patients require ongoing phosphate binder treatment to maintain normal serum phosphorus levels. We are working with U.S. and European regulatory authorities to finalize the remaining Phase 3 clinical program for Fermagate Tablets.

The CKD patient population is large and growing as a result of obesity, hypertension and diabetes, representing a potentially significant market opportunity. We intend to develop CTAP101 Capsules and Fermagate Tablets to constitute part of the foundation for a new and markedly improved standard of care for CKD patients having SHPT and/or hyperphosphatemia.

We believe that our up-regulating oligonucleotide therapeutics technology, or AntagoNAT, has the potential to create new drugs for the treatment of a wide variety of illnesses, including cancer, heart disease, metabolic disorders and a range of genetic disorders. We have a variety of therapeutic agents for respiratory disorders in clinical development, including products for asthma, chronic obstructive pulmonary disease (COPD), and chronic cough. We are also developing a protein-based influenza vaccine designed to offer multi-season and multi-strain protection, that we believe will offer more effective and longer lasting protection against influenza, in addition to more rapid and efficient production than existing influenza vaccine technologies. In addition to these development programs, we have pharmaceutical businesses in Chile, Mexico, Israel, and Spain and recently entered the Brazilian market.

We have a highly experienced management team that we believe has demonstrated an ability to successfully build and manage pharmaceutical businesses. Our Chairman and Chief Executive Officer, Dr. Phillip Frost, founded and served as Chairman and Chief Executive Officer of IVAX Corporation (IVAX), a multi-national pharmaceutical company, from 1987 until the acquisition of IVAX by Teva Pharmaceutical Industries, Limited (Teva) in January 2006. Dr. Frost currently serves as Chairman of the Board of Teva. Prior to IVAX, Dr. Frost founded and served as Chairman of the Board of Directors of Key Pharmaceuticals, Inc. from 1972 until the acquisition of Key Pharmaceuticals by Schering Plough Corporation in 1986. Our other senior executive officers, including Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer and Steven Rubin, our Executive Vice President, Administration, are former executive officers of IVAX. Our Senior Vice President and Chief Financial Officer, Juan F. Rodriguez, is a former executive officer of Kos Pharmaceuticals, Inc., a publicly traded, specialty pharmaceutical company engaged in the development and commercialization of proprietary products, which was sold to Abbott Laboratories in late 2006. Based on their experience in the industry, we believe that our management team has extensive development, regulatory and commercialization expertise and relationships that provide access to commercial opportunities.

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GROWTH STRATEGY

We expect our future growth to come from leveraging our proprietary technology and development strengths, and opportunistically pursuing complementary, accretive, or strategic acquisitions and investments.

We have under development a broad and diversified portfolio of diagnostic tests, vaccines and small molecules, targeting a broad range of unmet medical needs. We intend to continue to leverage our proprietary technology and our strengths in all phases of research and development to further develop and commercialize our portfolio of proprietary pharmaceutical and diagnostic products. In support of our strategy, we intend to:

- obtain requisite regulatory approval and compile clinical data for our most advanced product candidates;
- develop a focused commercialization capability in the United States; and
- expand into other medical markets which provide significant opportunities and which we believe are complementary to and synergistic with our business.

We have and expect to continue to be opportunistic and pursue complementary, or strategic acquisitions, licenses and investments. Our management team has significant experience in identifying, executing and integrating these transactions. We expect to use well-timed, carefully selected acquisitions, licenses and investments to continue to drive our growth, including:

- *Products and technologies*. We intend to pursue product and technology acquisitions and licenses that will complement our existing businesses and provide new product and market opportunities, improve our growth, enhance our profitability, leverage our existing assets, and contribute to our own organic growth.
- *Commercial businesses*. We intend to continue to pursue acquisitions of commercial businesses that will both drive our growth and provide geographically diverse sales and distribution opportunities, particularly outside of the United States.
- *Early stage investments*. We have and may continue to make investments in early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for OPKO as a shareholder.

CORPORATE INFORMATION

We were originally incorporated in Delaware in October 1991 under the name Cytoclonal Pharmaceutics, Inc., which was later changed to eXegenics, Inc. (eXegenics). On March 27, 2007, we were part of a three-way merger with Froptix Corporation (Froptix), a research and development company, and Acuity Pharmaceuticals, Inc. (Acuity), a research and development company. This transaction was accounted for as a reverse merger between Froptix and eXegenics, with the combined company then acquiring Acuity. eXegenics was previously involved in the research, creation, and development of drugs for the treatment and prevention of cancer and infectious diseases; however, eXegenics had been a public shell company without any operations since 2003. On June 8, 2007, we changed our name to OPKO Health, Inc.

Our shares are publicly traded on the NYSE under the ticker OPK . Our principal executive offices are located in leased office space in Miami, Florida. We lease office and lab space in Jupiter, Florida, and Miramar, Florida, which is where our molecular diagnostics research and development and oligonucleotide research and development operations are based, respectively. We lease office, manufacturing, and warehouse space in Woburn, Massachusetts for our point-of-care diagnostics business, and in Nesher, Israel for our API business. We lease laboratory and office space in Nashville, Tennessee and Burlingame, California for our CLIA-certified laboratory business, and we lease office space in Bannockburn, Illinois, and Markham, Ontario and laboratory space in Toronto, Ontario for our Cytochroma business. Our Chilean operations are located in leased offices and leased warehouse facilities in Santiago. Our Spanish operations are based in owned offices in Barcelona and in an owned manufacturing facility in Banyoles. Our Brazilian operation is based in a leased facility in Sao Paulo. Our Mexican operations are based in owned offices, an owned manufacturing facility, and a leased warehouse facility in Guadalajara.

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We currently manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Israel, and Spain through acquisitions in those countries. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired through the acquisition of OURLab in December 2012 and (ii) point-of-care and molecular diagnostics operations. There are no inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

In October 2011, we completed the sale of our ophthalmic instrumentation business to OPTOS, Inc., a subsidiary of Optos plc. Prior to the sale of the business, we had a reporting segment which consisted of ophthalmic instrumentation devices and the activities related to the research, development, manufacture, and commercialization of such products. The assets and liabilities related to our ophthalmic instrumentation business had identifiable cash flows that are independent of the cash flows of other groups of assets and liabilities and we did not have a significant continuing involvement with the related products beyond one year after the closing of the transaction. Therefore, the accompanying Consolidated Balance Sheets report the assets and liabilities related to our ophthalmic instrumentation business as discontinued operations in all periods presented, and the results of operations related to our ophthalmic instrumentation business have been classified as discontinued operations in the accompanying Consolidated Statements of Operations for all periods presented. In connection with the classification of our ophthalmic instrumentation business as discontinued operations, we also reclassified activities related to our Aquashunt development program to our pharmaceutical research and development operating segment.

CURRENT PRODUCT CANDIDATES AND RELATED MARKETS

Diagnostics

Point-of-Care Diagnostics and LDTs

In October 2011, we acquired Claros Diagnostics, Inc. (OPKO Diagnostics), which developed a novel diagnostic instrument system that provides rapid, high performance blood test results and enables tests to be run in point-of-care settings. The instrument, a microfluidics-based diagnostic test system consisting of a disposable test cassette that resembles a credit card and a small but sophisticated desktop analyzer, provides high performance quantitative blood test results within minutes and permits the transition of complex immunoassays and other tests from the centralized reference laboratory to the physician s office or hospital nurses station. The technology requires only a finger stick drop of blood introduced into the cassette, which can simultaneously run, or multiplex, up to 20 separate tests.

We have already obtained a CE Mark for our point-of-care diagnostic test for PSA using this system in Europe, and we plan to launch the PSA test in Europe in the second half of 2013. We expect to submit a 510(k) to the FDA for the PSA test and begin marketing the PSA test in the U.S. in 2014. We are also presently working to add additional panels for our point-of-care system, including testosterone and vitamin D, and we believe that there are many more applications for the technology, including infectious disease, cardiology, women s health, and companion diagnostics. If approved, we intend to market our vitamin D diagnostic test currently in development along with CTAP101 Capsules, our Phase 3 drug candidate for the treatment of SHTP and underlying vitamin D deficiency in pre-dialysis patients. We are also evaluating the ability to use the point-of-care diagnostic system to run our antibody-based tests, and expect to leverage this platform to commercialize these tests.

We are also developing our next generation 4Kscore test for prostate cancer for both our point-of-care system, as well as the laboratory setting in the U.S. The OPKO 4Kscore incorporates four kallikrein biomarkers (PSA, free-PSA, intact-PSA, and hK2) along with a proprietary prediction algorithm. Investigators at the University of Malmo, Sweden, University of Turku, Finland, and Memorial Sloan Kettering Cancer Center, New York, demonstrated that an algorithm integrating these biomarkers along with patient data could predict prostate biopsy results, and that the use of this algorithm to determine whether to biopsy could reduce the number of prostate biopsies performed by over fifty percent (50%). Research results indicate that these markers can predict initial biopsy results in men suspected of having prostate cancer; they have been tested in over 8,000 men and were independently validated in the European Randomized Study of Prostate Cancer Screening (Rotterdam). The value of PSA testing in men who would otherwise not be screened was assessed in the European Randomized Study of Prostate Cancer. Approximately 182,000 men in seven European countries were randomized for PSA screening or to serve as controls. At a median follow-up of approximately 9 years, PSA screening was associated with a 20% reduction in deaths from prostate cancer. Despite this finding, it is noted that 48 men would need to be treated to

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prevent one death from prostate cancer. Although quite specific to the prostate gland, PSA is not specific for prostate cancer. As a result, in the U.S., an estimated 750,000 men receive unnecessary prostate biopsies annually as a result of PSA testing. We believe that our novel 4Kscore test should yield significantly greater accuracy and should provide us with a unique opportunity to greatly improve the value of prostate cancer screening.

In May 2012, we entered into a license agreement with IHT which allows IHT to market our panel of kallikrein biomarkers and associated algorithm for the detection of prostate cancer in a laboratory setting in the United Kingdom, Ireland, Sweden and Denmark; and in October 2012, IHT launched sales of lab services using this panel of biomarkers in the United Kingdom as part of IHT s ProstateCheck program. In December, 2012, we completed the acquisition of OURLab, a Nashville-based CLIA-certified laboratory with 18 phlebotomy sites throughout the U.S and an experienced national sales force calling primarily on urologists. In addition to continuing to operate as a full-service medical laboratory specializing in urologic pathology, OURLab provides us with a commercial platform to support the U.S. commercial launch of the 4Kscore for the detection of prostate cancer as a LDT. We also believe that the OURLab structure will be helpful in speeding the development and introduction of other important tests, including antibody-based tests utilizing our unique molecular diagnostic technology.

Molecular Diagnostics

In June 2009, we acquired exclusive, worldwide rights from the University of Texas Southwestern to an innovative platform technology for the rapid identification of molecules or immunobiomarkers that may be useful in the creation of accurate, easy-to-use diagnostic tests as well as the development of vaccines and highly targeted therapeutic agents for immune system-driven diseases. The technology is based on an innovative method for the identification in small blood samples of disease-specific antibodies that can serve as diagnostic biomarkers for various diseases. We jointly own patent applications covering certain aspects of the technology and hold an exclusive license to the technology.

We believe this innovative technology could have broad applicability for the development of simple and accurate, quantitative blood tests across numerous important diseases, including a number of disease segments where there are no widely accepted or effective screening tests available. The first diagnostic product we are pursuing utilizing this technology is a simple blood test for Alzheimer s disease. The test is designed to detect elevated levels of antibodies that appear to be unique to Alzheimer s disease and could be useful in stratifying patients for ongoing clinical trials of potential Alzheimer s drugs as well as to confirm the diagnosis in a clinical setting and to track the progression of the disease or effectiveness of a therapeutic in a clinical trial. The Alzheimer s disease-specific antibodies were discovered using this novel proprietary platform that we have demonstrated in initial studies to be capable of identifying biomarkers for a wide range of diseases to which the immune system reacts, including Alzheimer s disease, as well as cancers, autoimmune diseases, neurodegenerative diseases and infectious diseases.

Currently it is estimated that over five million people in the United States, and over 35 million people worldwide, have Alzheimer s disease and the national cost of caring for people with Alzheimer s and other dementias was estimated to be $200 billion in 2012 in the United States alone. By 2050, it is estimated that approximately 13 million people in the United States over the age of 65 will have Alzheimer s, and the global prevalence of people living with Alzheimer s and other dementias is expected to be greater than 115 million. Currently there are no specific tests to detect Alzheimer s disease and follow its progression. Current diagnosis tools such as behavioral and cognitive measurements, brain scans and spinal fluid analysis have limited diagnostic accuracy, may not detect early stage disease, and in the case of spinal fluid analysis are highly invasive. Definitive diagnosis can currently be made only from examination of postmortem brain tissue samples. An effective early diagnostic blood test would provide a significant breakthrough in supporting definitive early diagnosis.

As reported in the January 2011 edition of the journal *Cell*, we demonstrated in a preliminary study that we were able to identify unique biomarkers from serum samples of known Alzheimer s disease patients, and then using these biomarkers we were able to distinguish patients with Alzheimer s disease from healthy controls and patients with lupus. In December 2010, we entered into a collaboration agreement with Bristol-Myers Squibb Company (BMS), under which we and BMS are investigating the utility of our novel technology for the diagnosis of Alzheimer s disease and for identifying individuals with early stage cognitive impairment that are likely to progress to Alzheimer s disease. In March 2012, we entered into a license agreement with Laboratory Corporation of America (LabCorp) for LabCorp to develop and commercialize laboratory testing services for Alzheimer s disease. We have ongoing projects for biomarker and platform optimization to support development and launch of a successful commercial test for Alzheimer s disease. In January 2013, we also expanded our collaboration with BMS

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to evaluate use of our technology to identify biomarkers that are predictive of drug response(s) in several other therapeutic areas. In addition to Alzheimer s disease, we are also pursuing the development of diagnostic tests for non-small cell lung cancer, pancreatic and other cancers, tuberculosis and diseases for which early detection could lead to earlier therapy and dramatically improved outcomes. We have conducted preliminary studies in neuromyelitis optica, pancreatic cancer and non-small cell lung cancer patient samples that we believe demonstrate the ability of our technology to identify biomarkers with diagnostic utility for these conditions. We plan to conduct additional studies in larger patient populations to further validate diagnostic tests for these and other conditions.

Along with molecular diagnostic applications, we believe that this same platform technology should permit the development of pharmaceutical agents or other therapeutics which can be delivered directly to the targeted autoimmune cells. Similarly, we believe that the synthetic molecules that we are able to identify through this technology could be used for the formulation of synthetic vaccines to induce an immune response that protects against foreign pathogens.

Pharmaceutical Business

We presently have several pharmaceutical compounds and technologies in research and development for a broad range of indications and conditions. Our product development candidates are in various stages of development and include the following:

Renal Products

In March 2013, we acquired Cytochroma, a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary products to treat vitamin D insufficiency, hyperphosphatemia and SHPT associated with CKD, a condition characterized by progressive decline in renal function. CKD is classified in five stages mild (stage 1) to severe (stage 5) disease. Cytochroma s two lead products, both in phase 3 clinical development, are CTAP101 Capsules, a vitamin D prohormone to treat SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency, and Fermagate Tablets, a new and potent non-absorbed phosphate binder to treat hyperphosphatemia in ESRD patients on chronic hemodialysis.

CTAP101 Capsules have been shown in a phase 2b clinical trial to effectively and safely treat SHPT and the underlying vitamin D insufficiency in pre-dialysis patients. Vitamin D insufficiency arises in CKD due to the abnormal upregulation of CYP24, an enzyme that destroys vitamin D and its metabolites. Studies in CKD patients have demonstrated that currently available over-the-counter and prescription vitamin D products cannot reliably raise blood vitamin D prohormone levels and effectively treat SHPT, a condition commonly associated with CKD in which the parathyroid glands secrete excessive amounts of parathyroid hormone (PTH). Prolonged elevation of blood PTH causes excessive calcium and phosphorus to be released from bone, leading to elevated serum calcium and phosphorus levels, softening of the bones (osteomalacia) and calcification of vascular and renal tissues. SHPT affects 40-60% of patients with stage 3 or 4 CKD and approximately 90% of patients with stage 5. CTAP101 Capsules are currently in phase 3 clinical trials in the U.S.

The new phosphate binder, Fermagate Tablets, has been shown to be safe and effective in treating hyperphosphatemia in phase 2 and 3 trials in CKD patients undergoing chronic hemodialysis. Hyperphosphatemia, or elevated serum phosphorus, is common in dialysis patients and tightly linked to the progression of SHPT. The kidneys provide the primary route of excretion for excess phosphorus absorbed from ingested food. As kidney function worsens, serum phosphorus levels increase and directly stimulate PTH secretion. Stage 5 CKD patients must reduce their dietary phosphate intake and usually require regular treatment with phosphate binding agents to lower serum phosphorus to meet the recommendations of the National Kidney Foundation s Clinical Practice Guidelines that serum phosphorus levels should be maintained at or below 5.5 mg/dL. Hyperphosphatemia contributes to soft tissue mineralization and affects approximately 90% of dialysis patients. Dialysis patients require ongoing phosphate binder treatment to maintain normal serum phosphorus levels. We are working with U.S. and European regulatory authorities to finalize the remaining Phase 3 clinical program for Fermagate Tablets.

We believe the CKD patient population is large and growing as a result of obesity, hypertension and diabetes; therefore this patient population represents a significant market opportunity. According to the National Kidney Foundation, CKD afflicts over 26 million people in the U.S., including more than eight million patients with stage 3 or 4 CKD. In stage 5, kidney function is minimal to absent and patients require regular dialysis or a kidney transplant for survival. An estimated 70-90% of CKD patients have vitamin D insufficiency which can lead to SHPT and its debilitating consequences. CKD continues to be associated with poor outcomes, reflecting the inadequacies of the current standard of care. Vitamin D insufficiency, hyperphosphatemia and SHPT, when inadequately treated, are major contributors to poor CKD outcomes. We intend to develop CTAP101 Capsules and

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Fermagate Tablets to constitute part of the foundation for a new and markedly improved standard of care for CKD patients having SHPT and/or hyperphosphatemia.

APIs

In December 2011, we completed the acquisition of FineTech Pharmaceutical, Ltd. (FineTech), an Israeli company that develops and produces high value, high potency specialty APIs. Through its FDA registered facility in Nesher, Israel, FineTech currently manufactures commercial APIs for sale or license to pharmaceutical companies in the U.S., Canada, Europe and Israel. We believe that FineTech s significant know-how and experience with analytical chemistry and organic syntheses, together with its production capabilities, will play a valuable role in the development of our pipeline of proprietary molecules and compounds for diagnostic and therapeutic products, while providing revenues and profits from its existing API business.

Oligonucleotide Therapeutics

In January 2011, we acquired CURNA, Inc., a privately-held company based in Jupiter, Florida, engaged in the discovery of new drugs for the treatment of a wide variety of illnesses, including cancer, heart disease, metabolic disorders and a range of genetic anomalies. CURNA s broad platform technology utilizes a short, single strand oligonucleotide and is based on the up-regulation of protein production through interference with non-coding RNA s, or natural antisense. This strategy contrasts with established approaches which down-regulate protein production. CURNA has designed a novel type of therapeutic modality, termed AntagoNAT, and has initially demonstrated this approach for up-regulation of several therapeutically relevant proteins in *in vitro* and animal models. We believe that this short, single strand oligonucleotide can be delivered intravenously or subcutaneously without the drug delivery or cell penetration complications typically associated with double stranded siRNA therapeutics. CURNA has identified and developed compounds which increase the production of over 80 key proteins involved in a large number of individual diseases. We have ongoing pre-clinical studies for several of these compounds, with an initial focus on orphan diseases including Dravet Syndrome, Rett Syndrome and MPS-1.

Asthma and COPD

In May 2010, we acquired worldwide rights to a novel heparin-derived oligosaccharide which has significant potential in treating asthma and COPD. Over 22 million people in the United States live with asthma, including nearly 6 million children. Additionally, there are more than 12 million people in the United States who have COPD. The market for asthma and COPD treatments was estimated to be $26 billion in 2009. Currently available therapies often include unwanted side effects and may have limited efficacy. We believe that our product may have an improved efficacy and side effect profile. Our initial studies have demonstrated anti-inflammatory and anti-allergic activity when administered orally or inhaled with inhalers or nebulizers in sheep and mice asthma models. We have also successfully completed human feasibility studies in asthma.

Vaccine Programs

In July 2009, we acquired worldwide rights from Academia Sinica in Taipei, Taiwan, for a new technology to develop protein-based vaccines against influenza and other viral infections. We are developing a proprietary, innovative influenza vaccine designed to provide multi-season and multi-strain protection against many human influenza virus strains, including both seasonal influenza strains as well as global influenza pandemic strains, such as swine flu, or H1N1, and avian flu, or H5N1. The world-wide seasonal influenza market place is projected to increase to $6.3 billion by 2014. Influenza results in approximately 200,000 hospitalizations and more than 36,000

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deaths each year in the United States alone, with estimated economic costs in excess of $87 billion per year. In addition, in March 2010, we acquired worldwide rights from Academia Sinica to certain alpha-galactosyl ceramide analogs which are believed to be useful as vaccines or vaccine adjuvants for a wide variety of disorders including cancer, infectious disease, and autoimmune disease. We are working in conjunction with Academia Sinica to advance and develop products under these technologies.

NK-1 Program

In November 2009, we acquired rolapitant and other neurokinin-1 (NK-1) assets from Schering Plough Corporation. In December 2010, we exclusively out-licensed the development, manufacture and commercialization of our lead NK-1 candidate, rolapitant, to TESARO. Rolapitant, a potent and selective competitive antagonist of the NK-1 receptor, has successfully completed Phase II clinical testing for prevention of chemotherapy induced nausea and vomiting, or CINV, and post-operative induced nausea and vomiting (PONV). In February 2012, TESARO started Phase III clinical testing and expects to report top line results from the trial during the second half of 2013. Under the terms of the license, we are eligible to receive up-front and milestone payments of up to $121 million, double digit tiered royalties on sales of licensed product, as well as a share of future profits from the commercialization of licensed products in Japan, and an option to market the products in Latin America. In addition, we acquired an equity position in TESARO.

Commercial Operations

We also intend to continue to leverage our global commercialization expertise to pursue acquisitions of commercial businesses that will both drive our growth and provide geographically diverse sales and distribution opportunities, particularly outside of the United States. It is estimated that by 2030 emerging markets will account for 60% of global GDP. According to IMS Health, emerging healthcare markets, including markets such as Brazil, Chile, China, India, Mexico, Russia, and Turkey, are projected to grow approximately 15% in total per year through 2014, while developed markets are projected to grow only 3% to 5% over the same period. At a time of slowing pharmaceutical sales growth in many mature countries, this expansion in many emerging markets has led to higher sales growth rates and an increasing contribution to the industry s global performance. As a result we expect that emerging markets will continue to be a growing part of our business strategy, contributing both attractive revenue growth and cash flow to support our development programs.

In February 2013, we completed the acquisition of Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda. (Silcon), a Brazilian entity domiciled in Sao Paulo. We believe that Silcon will expand OPKO s presence in Latin America and complement the business activities of our operations in Chile and Mexico, as well as permit commercialization of OPKO s products in development.

In December 2012, we completed the acquisition of OURLab, a Nashville-based CLIA-certified laboratory with 18 phlebotomy sites throughout the U.S and an experienced national sales force calling primarily on urologists. In addition to continuing to operate as a full-service medical laboratory specializing in urologic pathology, OURLab provides us with a commercial platform to support the U.S. commercial launch of the 4Kscore for the detection of prostate cancer as a LDT and will be helpful in speeding the development and introduction of other important tests, including antibody-based tests utilizing our unique molecular diagnostic technology.

In August 2012, we completed the acquisition of Farmadiet Group Holding, S.L. (Farmadiet), a Spanish company with 20 years of experience engaged in the development, manufacture, marketing, and sale of pharmaceutical, nutraceutical, and veterinary products in Europe.

In April 2012, we completed the acquisition of ALS Distribuidora Limitada (ALS), a privately-held Chilean pharmaceutical company engaged in the business of importation, commercialization and distribution of pharmaceutical products for private markets in Chile. ALS started operations in 2009 as the exclusive product distributor of Arama Laboratorios y Compañía Limitada (Arama), a company with more than 20 years of experience in the pharmaceutical products market. In connection with the transaction, OPKO will also acquire all of the product registrations and trademarks previously owned by Arama, as well as the Arama name.

In February 2010, we completed the acquisition of Pharmacos Exakta S.A. de C.V. (Exakta-OPKO), a Mexican pharmaceutical business engaged in the manufacture, marketing, sale, and distribution of ophthalmic and other pharmaceutical products to private and public customers in Mexico. Exakta-OPKO manufacturers and sells more than 25 products primarily in the generics market in Mexico, although it has recently increased its focus on the development of proprietary products as well.

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In October 2009, we completed the acquisition of Pharma Genexx, S.A. (OPKO Chile). OPKO Chile markets, sells and distributes more than 100 products to the private, hospital and institutional markets in Chile for a wide range of indications, including, cardiovascular products, vaccines, antibiotics, gastro-intestinal products, and hormones, among others.

Strategic Investments

We have and may continue to make investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for OPKO as a shareholder.

In October 2012, we completed the acquisition of a forty-five percent stake in SciGen (I.L.) Ltd (SciGen), an Israeli company that produces a third-generation hepatitis B vaccine in its biologics manufacturing facility in Rehovot, Israel.

In February 2012, we purchased from Biozone Pharmaceuticals, Inc., a publicly-traded company engaged in the manufacture and sale of pharmaceutical and cosmetic products (BZNE), $1.7 million of 10% secured convertible promissory notes (the Notes), convertible into BZNE common stock at a price equal to $0.20 per common share, which Notes are due and payable on February 24, 2014 and ten year warrants (the Warrants) to purchase 8.5 million shares of BZNE common stock at an exercise price of $0.40 per share. In July 2012, we exercised the Warrants using their cashless net exercise feature and received 7,650,000 shares of BZNE common stock. The Notes are secured by a first priority lien in all the assets of BZNE, including the stock of its subsidiaries, pursuant to a security agreement. As further consideration for the purchase of the Notes by us, BZNE granted us exclusive, worldwide distribution rights to its enhanced formulation of propofol, which license was terminated in September 2012. The parties also entered into a license agreement pursuant to which we acquired a world-wide license for the development and commercialization of products utilizing BZNE s proprietary drug delivery technology, including a technology called QuSomes, exclusively for OPKO in the field of ophthalmology and non-exclusive for all other therapeutic fields, subject in each case to certain excluded products.

In February 2012, we made a $1.0 million investment in ChromaDex Corporation (ChromaDex), a publicly-traded company and leading provider of proprietary ingredients and products for the dietary supplement, nutraceutical, food and beverage, functional food, pharmaceutical and cosmetic markets. In connection with our investment, we acquired 1,333,333 shares of ChromaDex common stock, par value $.001, at $0.75 per share. We also entered into a license, supply and distribution agreement with ChromaDex pursuant to which we obtained exclusive distribution rights to certain of its products in Latin America. Our investment was part of a $3.7 million private placement by ChromaDex.

In August 2011, we made a $2.0 million investment in Neovasc Inc. (Neovasc), a medical technology company based in Vancouver, Canada, and a publicly-traded company in Canada. Neovasc is developing devices to treat cardiovascular diseases and is also a leading supplier of tissue components for the manufacturers of replacement heart valves. In connection with our investment, we received two million Neovasc common shares and two-year warrants to purchase an additional one million shares for $1.25 per share. We also entered into an agreement with Neovasc to provide strategic advisory services to Neovasc as it continues to develop and commercialize its novel cardiac devices. As of December 31, 2012, we own approximately 4% of the outstanding common stock of Neovasc.

In December 2010, we acquired a minority equity interest in TESARO, a privately-held oncology-focused biopharmaceutical company, as part of a license agreement with TESARO for the development, manufacture, commercialization and distribution of rolapitant and a related compound. As of December 31, 2012, we owned an approximately 2% equity position in TESARO.

In November 2010, we acquired a minority equity interest in Fabrus, Inc. (Fabrus), a privately-held early-stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities that is using its proprietary antibody screening and engineering approach to discover promising lead compounds against several important oncology targets. As of December 31, 2012, we owned an approximately 13% equity position in Fabrus.

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In September 2009, we acquired a minority equity interest in Cocrystal Discovery, Inc. (Cocrystal), a privately-held biopharmaceutical company focused on the discovery and development of novel small molecule antiviral therapeutics tailored for the treatment of serious and chronic viral diseases. In September 2011, Teva signed a collaboration option to license and share purchase agreements to invest in Cocrystal. Dr. Phillip Frost, our Executive Officer and Chairman of our Board of Directors, is Chairman of the Board of Directors of Teva. Teva agreed to initially invest $7.5 million in Cocrystal, and Cocrystal will develop an antiviral drug targeting the polymerase enzyme of the Hepatitis C virus for Teva. Upon completion of the initial development plan, Teva will have the option to make additional investments under certain milestones. Teva also has the option to further invest in Cocrystal for the development of two additional antiviral or antibacterial drugs. For all such investments, Teva will receive up to approximately 23% holdings in Cocrystal. As of December 31, 2012, we owned approximately 16% of the outstanding capital stock of Cocrystal.

In June 2009, we acquired a minority equity interest in Sorrento Therapeutics, Inc. (Sorrento), a publicly-held development-stage biopharmaceutical company focused on applying its proprietary technology platform for the discovery and development of human therapeutic antibodies for the treatment of a variety of disease conditions, including cancer, inflammation, metabolic disease and infectious disease. As of December 31, 2012, we owned approximately 20% of the outstanding capital stock of Sorrento.

Instrumentation Business

In October 2011, we completed the sale of our ophthalmic instrumentation business to OPTOS, Inc., a subsidiary of Optos plc. In connection with the sale of the business, we received $17.5 million in cash at closing and are eligible to receive royalties on future sales of instrumentation products. Refer to Note 4.

RESEARCH AND DEVELOPMENT EXPENSES

During the years ended December 31, 2012, 2011, and 2010, we incurred $19.5 million, $11.4 million, and $5.9 million, respectively, of research and development expenses from continuing operations related to our various product candidates. During the years ended December 31, 2012 and 2011, our research and development expenses primarily consisted of our molecular diagnostic programs and activities related to the development programs acquired from OPKO Diagnostics and CURNA. During the year ended December 31, 2010, our research and development expense consisted of activities related to the development of our molecular diagnostics program and rolapitant, prior to its divesture.

INTELLECTUAL PROPERTY

We believe that technology innovation is driving breakthroughs in healthcare. We have adopted a comprehensive intellectual property strategy which blends the efforts to innovate in a focused manner with the efforts of our business development activities to strategically in-license intellectual property rights. We develop, protect, and defend our own intellectual property rights as dictated by the developing competitive environment. We value our intellectual property assets and believe we have benefited from early and insightful efforts at understanding diagnostics, as well as the disease and the molecular basis of potential pharmaceutical intervention.

We actively seek, when appropriate and available, protection for our products and proprietary information by means of United States and foreign patents, trademarks, trade secrets, copyrights, and contractual arrangements. Patent protection in the pharmaceutical and diagnostic fields, however, can involve complex legal and factual issues. There can be no assurance that any steps taken to protect such proprietary information will be effective.

Because the patent positions of pharmaceutical, biotechnology, and diagnostics companies are highly uncertain and involve complex legal and factual questions, the patents owned and licensed by us, or any future patents, may not prevent other companies from developing similar or therapeutically equivalent products or ensure that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties. Furthermore, to the extent that any of our future products or methods are not patentable, that such products or methods infringe upon the patents of third parties, or that our patents or future patents fail to give us an exclusive position in the subject matter claimed by those patents, we will be adversely affected. We may be unable to avoid infringement of third party patents and may have to obtain a license, defend an infringement action, or challenge the validity of the patents in court. A license may be unavailable on terms and conditions acceptable to us, if at all. Patent litigation is costly and time consuming, and we may be unable to prevail in any such patent litigation or devote sufficient resources to even pursue such litigation.

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LICENSES AND COLLABORATIVE RELATIONSHIPS

Our strategy is to develop a portfolio of product candidates through a combination of internal development, acquisition, and external partnerships. Collaborations are key to our strategy and we continue to build relationships and forge partnerships in various areas where unmet medical need and commercial opportunities exist. In December 2010 we entered into a non-exclusive collaboration agreement with BMS to investigate the utility of our diagnostic technology for the diagnosis of Alzheimer s disease and for identifying individuals with early stage cognitive impairment that are likely to progress to Alzheimer s disease, and in January 2013, we expanded the collaboration to evaluate use of our technology to identify biomarkers that are predictive of drug response(s) in several other therapeutic areas. In March 2012, we entered into a license agreement with LabCorp to develop and commercialize laboratory testing services for Alzheimer s disease. During 2012, we also entered into a worldwide license for exclusive rights to novel prostate cancer biomarkers. Previously, we completed strategic licensing transactions with the University of Texas Southwestern Medical Center at Dallas, the President and Fellows of Harvard College, Academia Sinica, The Scripps Research Institute, IHT, and TESARO, among others.

COMPETITION

The pharmaceutical and diagnostic industries are highly competitive and require an ongoing, extensive search for technological innovation. The industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. They also require, among other things, the ability to effectively discover, develop, test and obtain regulatory approvals for products, as well as the ability to effectively commercialize, market and promote approved products.

We intend to leverage our technological innovation and proprietary position to effectively compete in the pharmaceutical and biopharmaceutical markets. In addition, we are committed to researching, developing and pursuing the commercialization of our molecular diagnostic tests including tests for Alzheimer s disease and various cancers, among others. We are also seeking to commercialize our 4Kscore product in the U.S. in a laboratory setting and to capitalize on near-term commercialization opportunities for our proprietary diagnostic point-of-care system by transitioning laboratory-based tests, including the 4Kscore , PSA, vitamin D, and testosterone, to our point-of-care system. Numerous companies, however, including major pharmaceutical companies, specialty pharmaceutical companies and specialized biotechnology companies, are engaged in the development, manufacture and marketing of pharmaceutical products competitive with those that we intend to commercialize ourselves and through our partners. Competitors to our diagnostics business are many and include major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and research institutions.

Most of these companies have substantially greater financial and other resources, larger research and development staffs and more extensive marketing and manufacturing organizations than ours. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs, as well as their marketing and promotion costs, over a broader revenue base. This also provides our competitors with a competitive advantage in connection with the highly competitive product acquisition and product in-licensing process, which may include auctions in which the highest bidder wins. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. In addition to product development, testing, approval, and promotion, other competitive factors in the pharmaceutical industry include industry consolidation, product quality and price, product technology, reputation, customer service, and access to technical information.

Our ability to commercialize our pharmaceutical and diagnostic test product candidates and compete effectively will depend, in large part, on:

- our ability to meet all necessary regulatory requirements to advance our product candidates through clinical trials and the regulatory approval process in the U.S. and abroad;
- the perception by physicians and other members of the health care community of the safety, efficacy, and benefits of our products compared to those of competing products or therapies;
- our ability to manufacture products we may develop on a commercial scale;
- the effectiveness of our sales and marketing efforts;

the willingness of physicians to adopt a new diagnostic or treatment regimen represented by our technology;

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our ability to secure reimbursement for our product candidates,

the price of the products we may develop and commercialize relative to competing products;

our ability to accurately forecast and meet demand for our product candidates if regulatory approvals are achieved;

our ability to develop a commercial scale infrastructure either on our own or with a collaborator, which would include expansion of existing facilities, including our manufacturing facilities, development of a sales and distribution network, and other operational and financial systems necessary to support our increased scale;

our ability to maintain a proprietary position in our technologies; and

our ability to rapidly expand the existing information technology infrastructure and configure existing operational, manufacturing, and financial systems (on our own or with third party collaborators) necessary to support our increased scale, which would include existing or additional facilities and or partners.

GOVERNMENT REGULATION

The U.S. government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Federal Food, Drug and Cosmetic Act (FDCA), as well as other relevant laws; (ii) the Centers for Medicare & Medicaid Services (CMS), which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General (OIG), which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Statute, the Physician Self-Referral Law, commonly referred to as the Stark law, the Anti-Inducement Law, the Civil Money Penalty Law, and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996. All of the aforementioned are agencies within the Department of Health and Human Services (HHS). Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Department of Veterans Affairs, especially through the Veterans Health Care Act of 1992, the Public Health Service within HHS under Public Health Service Act § 340B (42 U.S.C. § 256b), the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under the Medicaid and other state sponsored or funded programs and their internal laws regulating all healthcare activities.

The testing, manufacture, distribution, advertising, and marketing of drug and diagnostic products and medical devices are subject to extensive regulation by federal, state, and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any drug, diagnostic, or device product that we develop must receive all relevant regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country.

Drug Development

The regulatory process, which includes overseeing preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and efficacy and confirmation by the FDA that good laboratory, clinical, and manufacturing practices were maintained during testing and manufacturing, can take many years, requires the expenditure of substantial resources, and gives larger companies with greater financial resources a competitive advantage over us. Delays or terminations of clinical trials that we undertake would likely impair our development of product candidates. Delays or terminations could result from a number of factors, including stringent enrollment criteria, slow rate of enrollment, size of patient population, having to compete with other clinical trials for eligible patients, geographical considerations, and others.

The FDA review processes can be lengthy and unpredictable, and we may encounter delays or rejections of our applications when submitted. Generally, in order to gain FDA approval, we must first conduct preclinical studies in a laboratory and in animal models to obtain preliminary information on a compound and to identify any safety problems. The results of these studies are submitted as part of an IND application that the FDA must review before human clinical trials of an investigational drug can commence.

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Clinical trials are normally done in three sequential phases and generally take two to five years or longer to complete. Phase I consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase II usually involves studies in a limited patient population to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated, determine dosage tolerance and optimal dosage, and identify possible common adverse effects and safety risks. Phase III consists of additional controlled testing at multiple clinical sites to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling. Phase IV clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication.

After completion of clinical trials of a new drug product, FDA and foreign regulatory authority marketing approval must be obtained. Assuming that the clinical data support the product s safety and effectiveness for its intended use, a new drug application (NDA), is submitted to the FDA for its review. Generally, it takes one to three years to obtain approval. If questions arise during the FDA review process, approval may take a significantly longer period of time. The testing and approval processes require substantial time and effort and we may not receive approval on a timely basis, if at all, or the approval that we receive may be for a narrower indication than we had originally sought, potentially undermining the commercial viability of the product. Even if regulatory approvals are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or 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. For marketing outside the United States, we also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary widely from country to country.

None of our pharmaceutical products under development have been approved for marketing in the United States or elsewhere. We may not be able to obtain regulatory approval for any such products under development in a timely manner, if at all. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude us, or our licensees or marketing partners, from marketing our products, or limit the commercial use of our products, and thereby would have a material adverse effect on our business, financial condition, and results of operations. See Risk Factors The results of pre-clinical trials and previous clinical trials for our products may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.

Device Development

Devices are subject to varying levels of premarket regulatory control, the most comprehensive of which requires that a clinical evaluation be conducted before a device receives approval for commercial distribution. The FDA classifies medical devices into one of three classes: Class I devices are relatively simple and can be manufactured and distributed with general controls; Class II devices are somewhat more complex and require greater scrutiny; Class III devices are new and frequently help sustain life.

In the United States, a company generally can obtain permission to distribute a new device in one of two ways. The first applies to any device that is substantially equivalent to a device first marketed prior to May 1976, or to another device marketed after that date, but which was substantially equivalent to a pre-May 1976 device. These devices are either Class I or Class II devices. To obtain FDA permission to distribute the device, a company generally must submit a section 510(k) submission, and receive an FDA order finding substantial equivalence to a predicate device (pre-May 1976 or post-May 1976 device that was substantially equivalent to a pre-May 1976 device) and permitting commercial distribution of that device for its intended use. A 510(k) submission must provide information supporting a claim of substantial equivalence to the predicate device. If clinical data from human experience are required to support the 510(k) submission, these data must be gathered in compliance with investigational device exemption (IDE), regulations for investigations performed in the United States. The 510(k) process is normally used for products of the type that the Company proposes distributing. The FDA review process for premarket notifications submitted pursuant to section 510(k) takes, on average, about 90 days, but it can take substantially longer if the FDA has concerns, and there is no guarantee that the FDA will clear the device for marketing, in which case the device cannot be distributed in the United States. There is also no guarantee that the FDA will deem the applicable device subject to the 510(k) process, as opposed to the more time-consuming, resource-intensive and problematic, pre-market approval (PMA) process described below. In 2011 the FDA issued a series of draft guidance documents designed to reform the 510(k) clearance process. To the extent that the FDA finalizes and implements these proposed reforms, the average 510(k) review time may change and devices that

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might previously have been cleared under the 510(k) process may be require approval under the PMA process. Similarly, the Medical User Fee Amendments of 2012 authorized the FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2012, including 510(k)s. These fees are intended to improve the device review process, but the actual impact on the industry is still unknown.

The second, more comprehensive, approval process applies to a new device that is not substantially equivalent to a pre-1976 product or that is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices. For example, most implantable devices are subject to the approval process. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to approval, as opposed to clearance. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device. These regulations permit a company to undertake a clinical study of a non-significant risk device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. Second, the FDA must review the company s PMA application, which contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds there is reasonable assurance that the device is safe and effective for its intended use. The PMA process takes substantially longer than the 510(k) process and it is conceivable that the FDA would not agree with our assessment that a device that we propose to distribute should be a Class I or Class II device. If that were to occur we would be required to undertake the more complex and costly PMA process. However, for either the 510(k) or the PMA process, the FDA could require us to run clinical trials, which would pose all of the same risks and uncertainties associated with the clinical trials of drugs, described above.

Even when a clinical study has been approved by the FDA or deemed approved, the study is subject to factors beyond a manufacturer s control, including, but not limited to the fact that the institutional review board at a given clinical site might not approve the study, might decline to renew approval which is required annually, or might suspend or terminate the study before the study has been completed. Also, the interim results of a study may not be satisfactory, leading the sponsor to terminate or suspend the study on its own initiative or the FDA may terminate or suspend the study. There is no assurance that a clinical study at any given site will progress as anticipated; there may be an insufficient number of patients who qualify for the study or who agree to participate in the study or the investigator at the site may have priorities other than the study. Also, there can be no assurance that the clinical study will provide sufficient evidence to assure the FDA that the product is safe and effective, a prerequisite for FDA approval of a PMA, or substantially equivalent in terms of safety and effectiveness to a predicate device, a prerequisite for clearance under 510(k). Even if the FDA approves or clears a device, it may limit its intended uses in such a way that manufacturing and distributing the device may not be commercially feasible.

After clearance or approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain events, are authorized under various circumstances to withdraw the clearance or approval or require changes to a device, its manufacturing process or its labeling or additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the PMA is not permitted to make changes to the device, which affects its safety or effectiveness without first submitting a supplement application to its PMA and obtaining FDA approval for that supplement. In some instances, the FDA may require clinical trials to support a supplement application. A manufacturer of a device cleared through the 510(k) process must submit another premarket notification if it intends to make a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as a significant change or modification in design, material, chemical composition, energy source or manufacturing process. Any change in the intended uses of a PMA device or a 510(k) device requires an approval supplement or cleared premarket notification. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

A company that intends to manufacture medical devices is required to register with the FDA before it begins to manufacture the device for commercial distribution. As a result, we and any entity that manufactures products on our behalf will be subject to periodic inspection by the FDA for compliance with the FDA s Quality System Regulation requirements and other regulations. In the European Community, we will be required to maintain certain International Organization for Standardization (ISO), certifications in order to sell products and we or our manufacturers undergo periodic inspections by notified bodies to obtain and maintain these certifications. These regulations require us or our manufacturers to manufacture products and maintain documents in a prescribed manner with respect to design, manufacturing, testing and control activities. Further, we are required to comply with various FDA and other agency requirements for labeling and promotion. The Medical Device Reporting regulations require that we provide information to the FDA whenever there is evidence to reasonably suggest that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. In addition, the FDA prohibits us from promoting a medical device for unapproved indications.

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Diagnostic Products

Our diagnostic products in development are subject to regulation by the FDA and similar international health authorities. We have an obligation to adhere to the FDA s cGMP regulations. Additionally, we are subject to periodic FDA inspections, quality control procedures, and other detailed validation procedures. If the FDA finds deficiencies in the validation of our manufacturing and quality control practices, they may impose restrictions on marketing specific products until corrected.

Regulation by governmental authorities in the United States and other countries may be a significant factor in how we develop, test, produce and market our diagnostic products. Certain diagnostic tests like ours do not fall squarely within the regulatory approval process for pharmaceutical or device products as described above, and the regulatory pathway is not as clear. It is possible that diagnostic products developed by us or our collaborators will be regulated as medical devices by the FDA and comparable agencies of other countries and require either premarket approval (PMA) or 510(k) clearance from the FDA prior to marketing. Nevertheless, some companies that have successfully commercialized diagnostic tests for various conditions and disease states have not sought clearance or approval for such tests through the traditional 510(k) or PMA processes, and have instead utilized a process involving LDTs through a laboratory certified under The Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for diagnostic, preventative or treatment purpose. In such instances, the CLIA lab is solely responsible for the development, validation and commercialization of the assay. Such LDT testing is currently under the purview of CMS and state agencies that provide oversight of the safe and effective use of LDTs. Although the FDA has consistently claimed that it has the regulatory authority to regulate LDTs that are validated by the developing laboratory and performed only by that laboratory, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and performed by high complexity CLIA-certified laboratories. The FDA has indicated, however, that it is reviewing the regulatory requirements that will apply to LDTs, and held a two-day public meeting in July 2010 to obtain input from stakeholders on how it should apply its authority to implement a reasonable, risk-based, and effective regulatory framework for LDTs. The FDA has not issued guidance directly addressing the nature of the changes the FDA intends to make with respect to the regulation of LDTs, nor the scope of potential regulation. However, two draft guidance documents relating to *in vitro* diagnostic products, which the FDA does regulate, were issued in 2011 that may have indirect implications for LDTs, and the FDA also indicated the intent to further explore aspects of LDT regulation in both its 2012 and 2013 workplans. We will continue to monitor potential changes as the FDA s LDT policy evolves to ensure our activities are consistent with the FDA s most current policy.

CLIA Laboratories

Our CLIA certified laboratories are subject to CLIA regulations, which are designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. We are also subject to regulation of laboratory operations under state clinical laboratory laws. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, such as California and Florida, each require that we obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. Only Washington and New York State are exempt under CLIA, as these states have established laboratory quality standards at least as stringent as CLIA s. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations.

Impact of Regulation

The FDA in the course of enforcing the FDCA may subject a company to various sanctions for violating FDA regulations or provisions of the FDCA, including requiring recalls, issuing Warning Letters, seeking to impose civil money penalties, seizing devices that the agency believes are non-compliant, seeking to enjoin distribution of a specific type of device or other product, seeking to revoke a clearance or approval, seeking disgorgement of profits and seeking to criminally prosecute a company and its officers and other responsible parties.

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The levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, in the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability and adequacy of reimbursement from third party payers, such as the government or private insurance plans. Third party payers are increasingly challenging established prices, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit. We cannot assure you that any of our products will be considered cost effective, or that reimbursement will be available or sufficient to allow us to sell them competitively and profitably.

State and Federal Security and Privacy Regulations

The privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, HIPAA), establish comprehensive federal standards with respect to the uses and disclosures of protected health information, or PHI, by health plans and health care providers, in addition to setting standards to protect the confidentiality, integrity and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, to obtain payments for services and health care operations activities;
- a patient s rights to access, amend and receive an accounting of certain disclosures of PHI;
- the content of notices of privacy practices for PHI; and
- administrative, technical and physical safeguards required of entities that use or receive PHI electronically.

As a provider of clinical laboratory services and as we launch commercial diagnostic tests, we must continue to implement policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law. The privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties.

Anti-Kickback Laws, Physician Self-Referral Laws, False Claims Act, Civil Monetary Penalties

We are also subject to various federal, state, and international laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. The federal Anti-Kickback Statute prohibits anyone from knowingly and willfully soliciting, receiving, offering, or paying any remuneration with the intent to refer, or to arrange for the referral or order of, services or items payable under a federal health care program, including the purchase or prescription of a particular drug or the use of a service or device. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the U.S. Department of Health and Human Services Office of Inspector General, or OIG, to issue a series of regulations, known as safe harbors. These safe harbors set forth requirements that, if met in their entirety, will assure health care providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal, or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

Violations of the Anti-Kickback Statute are punishable by the imposition of criminal fines, civil money penalties, treble damages, and/or exclusion from participation in federal health care programs. Many states have also enacted similar anti-kickback laws. The Anti-Kickback Statute and similar state laws and regulations are expansive. If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our business, results of operations, financial condition, and our stock price. Even an unsuccessful challenge could

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cause adverse publicity and be costly to respond to, which could have a materially adverse effect on our business, results of operations and financial condition. We will consult counsel concerning the potential application of these and other laws to our business and our sales, marketing and other activities and will make good faith efforts to comply with them. However, given the broad reach of federal and state anti-kickback laws and the increasing attention given by law enforcement authorities, we are unable to predict whether any of our activities will be challenged or deemed to violate these laws.

We are also subject to the physician self-referral laws, commonly referred to as the Stark law, which is a strict liability statute that generally prohibits physicians from referring Medicare patients to providers of designated health services, including clinical laboratories, with whom the physician or the physician s immediate family member has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self-referrals, regardless of the source of the payment for the patient s care. If it is determined that certain of our practices or operations violate the Stark law or similar statutes, we could become subject to civil and criminal penalties, including exclusion from the Medicare programs and loss of government reimbursement. The imposition of any such penalties could harm our business.

Another development affecting the health care industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act s whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. We submit claims for services performed at our laboratories. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal health care program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improper use of Medicare numbers when detailing the provider of services, and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly adversely affect our financial performance.

Federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Entities found in violation may be liable for civil monetary penalties of up to $10,000 for each wrongful act. Although we believe that our sales and marketing practices are in material compliance with all applicable federal and state laws and regulations, relevant regulatory authorities may disagree and violation of these laws, or, our exclusion from such programs as Medicaid and other governmental programs as a result of a violation of such laws, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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Foreign Corrupt Practices Act

We are also subject to the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits corporations and individuals from paying, offering to pay, or authorizing 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 otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls. Our international activities create the risk of unauthorized payments or offers of payments by our employees, consultants, sales agents or distributors, even though they may not always be subject to our control. We discourage these practices by our employees and agents. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Any failure by us to adopt appropriate compliance procedures and ensure that our employees and agents comply with the FCPA and applicable laws and regulations in foreign jurisdictions could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions.

MANUFACTURING AND QUALITY

Other than our facilities in Guadalajara, Mexico, Nesher, Israel, and Banyoles, Spain, we currently have no pharmaceutical manufacturing facilities. We have entered into agreements with various third parties for the formulation and manufacture of our pharmaceutical clinical supplies. These suppliers and their manufacturing facilities must comply with FDA regulations, current good laboratory practices (cGLPs) and current good manufacturing practices (cGMPs). We plan to outsource the manufacturing and formulation of our clinical supplies.

The FDA and similar regulatory bodies may inspect our facilities and the facilities of those whom manufacture on our behalf worldwide. If the FDA or similar regulatory bodies inspecting our facilities or the facilities of our suppliers find regulatory violations in manufacturing and quality control practices or procedures they may require us to cease partial or complete manufacturing operations until the violations are corrected. They may also impose restrictions on distribution of specific products until the violations are corrected.

Our point-of-care diagnostic system consists of a disposable test cassette and an analyzer. We prepare all necessary test reagents and assemble and package the disposable cassettes at our facility in Woburn, Massachusetts. We rely on third parties for the manufacture of the analyzer.

We are committed to providing high quality products to our customers, and we plan to meet this commitment by working diligently to continue implementing updated and improved quality systems and concepts throughout our organization.

SALES & MARKETING

We currently do not have pharmaceutical or diagnostics sales or marketing personnel in the United States other than the sales force for the OURLab business, and we have limited personnel in Chile, Mexico, Israel, Spain, and Brazil. In order to commercialize any pharmaceutical or diagnostic products that are approved for commercial sale, we must either build a sales and marketing infrastructure or collaborate with third parties with sales and marketing experience.

EMPLOYEES

As of December 31, 2012, we had 549 full-time employees worldwide. None of our employees are represented by a collective bargaining agreement.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics. We require all employees, including our principal executive officer and principal accounting officer and other senior officers and our employee directors, to read and to adhere to the Code of Business Conduct and Ethics in discharging their work-related responsibilities. Employees are required to report any conduct that they believe in good faith to be an actual or apparent violation of the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http://www.OPKO.com.

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Available Information

We make available free of charge on or through our web site, at www.opko.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the SEC. Additionally, the public may read and copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Room 1580, Washington, D.C., 20549. Information regarding operation of the Public Reference Room is available by calling the SEC at 1-800-SEC-0330. Information that we file with the SEC is also available at the SEC s Web-site at www.sec.gov.

ITEM 1A. RISK FACTORS.

You should carefully consider the risks described below, as well as other information contained in this report, including the consolidated financial statements and the notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations. The occurrence of any of the events discussed below could significantly and adversely affect our business, prospects, results of operations, financial condition, and cash flows.

RISKS RELATED TO OUR BUSINESS

We have a history of operating losses and we do not expect to become profitable in the near future.

We are a healthcare company with a limited operating history. We are not profitable and have incurred losses since our inception. We do not anticipate that we will generate revenue from the sale of proprietary pharmaceutical products or our molecular diagnostic products for some time and we have generated limited revenue from our pharmaceutical operations in Chile, Mexico, Israel and Spain, and from our ophthalmic instrumentation business, which we sold in October 2011. We have not yet submitted any pharmaceutical products or molecular diagnostic products for marketing approval or clearance by regulatory authorities and we do not currently have rights to any pharmaceutical product candidates that have been approved for marketing, other than those products sold by our Chilean, Mexican, Israeli, and Spanish subsidiaries. We continue to incur research and development and general and administrative expenses related to our operations and, to date, we have devoted most of our financial resources to research and development, including our pre-clinical development activities and clinical trials. We expect to continue to incur losses from our operations for the foreseeable future, and we expect these losses to increase as we continue our research activities and conduct development of, and seek regulatory approvals and clearances for, our product candidates, and prepare for and begin to commercialize any approved or cleared products. If our product candidates fail in clinical trials or do not gain regulatory approval or clearance, or if our product candidates do not achieve market acceptance, we may never become profitable. In addition, if we are required by the U.S. Food and Drug Administration (FDA), to perform studies in addition to those we currently anticipate, our expenses will increase beyond current expectations and the timing of any potential product approval may be delayed. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We may require substantial additional funding, which may not be available to us on acceptable terms, or at all.

We are advancing and intend to continue to advance multiple product candidates through clinical and pre-clinical development. On January 30, 2013, we sold $175 million aggregate principal amount of 3.00% convertible senior notes due 2033. We received approximately $170.5 million in net proceeds from the sale of the notes. We believe we have sufficient cash and cash equivalents on hand or available to us through lines of credit to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We have based this estimate on assumptions that may prove to be wrong or subject to change, and we may be required to use our available capital resources sooner than we currently expect or curtail aspects of our operations in order to preserve our capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on a number of factors, including the continued progress of our research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, or strategic collaborations. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. Disruptions in the United States and global

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financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Economic conditions have been, and continue to be, volatile. Continued instability in these market conditions may limit our ability to replace, in a timely manner, maturing liabilities and access the capital necessary to fund and grow our business. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, which could adversely impact our business, results of operations, liquidity, capital resources and financial condition. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our technologies are in an early stage of development and are unproven.

The effectiveness of our technologies is not well-known in, or accepted generally by, the clinical medical community. There can be no assurance that we will be able to successfully employ our technologies as therapeutic, diagnostic, or preventative solutions for any disease or condition. Our failure to establish the efficacy or safety of our technologies would have a material adverse effect on our business.

In addition, we have a limited operating history. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our pharmaceutical product or molecular diagnostic candidates other than those products sold by our Chilean, Mexican, Israeli and Spanish subsidiaries. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our research and development activities may not result in commercially viable products.

Many of our product candidates are in the early stages of development and are prone to the risks of failure inherent in drug, diagnostic, and medical device product development. These risks further include the possibility that such products would:

- be found to be ineffective, unreliable, or otherwise inadequate or otherwise fail to receive regulatory approval;
- be difficult or impossible to manufacture on a commercial scale;
- be uneconomical to market or otherwise not be effectively marketed;
- fail to be successfully commercialized if adequate reimbursement from government health administration authorities, private health insurers, and other organizations for the costs of these products is unavailable;
- be impossible to commercialize because they infringe on the proprietary rights of others or compete with products marketed by others that are superior; or
- fail to be commercialized prior to the successful marketing of similar products by competitors.

The results of pre-clinical trials and previous clinical trials for our products may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.

Positive results from pre-clinical studies and early clinical trial experience should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. Likewise, there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future study results. We may be required to demonstrate with substantial evidence through

well-controlled clinical trials that our product candidates are either (i) with respect to drugs or Class III devices, safe and effective for use in a diverse population of their intended uses or (ii) with respect to Class I or Class II devices, are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under section 510(k) of the

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Food, Drug and Cosmetic Act. Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other non-U.S. regulatory authorities despite having progressed through initial clinical trials.

Further, our drug candidates may not be approved or cleared even if they achieve their primary endpoints in Phase III clinical trials or registration trials. In addition our diagnostic test candidates may not be approved or cleared, as the case may be, even though clinical or other data are, in our view, adequate to support an approval or clearance. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval or clearance of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA and other non-U.S. regulatory authorities approval. Any of these regulatory authorities may also approve or clear a product candidate for fewer or more limited indications or uses than we request or may grant approval or clearance contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of our product candidates.

The results of our clinical trials may show that our product candidates may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other non-U.S. regulatory authorities.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals, and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Our business is substantially dependent on our ability to develop, launch and generate revenue from our diagnostic programs.

Our business is substantially dependant on our ability to develop and launch simple diagnostic tests based on our molecular diagnostics platform for Alzheimer s disease, cancers and other conditions for which we are developing tests. In addition, our business is dependent on our ability to successfully develop and commercialize various diagnostic tests for our point-of-care platform and various laboratory developed tests (LDTs), including the 4Kscore . We are committing significant research and development resources to the development of diagnostic tests, and there is no guarantee that we will be able to successfully launch these or other diagnostic tests on anticipated timelines or at all. We have limited experience in developing, manufacturing, selling, marketing or distributing diagnostic tests. If we are not able to successfully develop, market or sell diagnostic tests we develop for any reason, including the failure to obtain any required regulatory approvals, we will not generate any revenue from the sale of such tests. Even if we are able to develop effective diagnostic tests for sale in the marketplace, a number of factors could impact our ability to sell such tests or generate any significant revenue from the sale of such tests, including without limitation:

- our ability to establish and maintain adequate infrastructure to support the commercial launch and sale of our diagnostic tests, including establishing adequate laboratory space, information technology infrastructure, sample collection and tracking systems, electronic ordering and reporting systems and other infrastructure and hiring adequate laboratory and other personnel;

- the success of the validation studies for our diagnostic tests under development and our ability to publish study results in peer-reviewed journals;

- the availability of alternative and competing tests or products and technological innovations or other advances in medicine that cause our technologies to be less competitive;

- the accuracy rates of such tests, including rates of false-negatives and/or false-positives;

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concerns regarding the safety or effectiveness or clinical utility of our diagnostic tests;

changes in the regulatory environment affecting health care and health care providers, including changes in laws regulating laboratory testing and/or device manufacturers;

the extent and success of our sales and marketing efforts and ability to drive adoption of our diagnostic tests;

coverage and reimbursement levels by government payors and private insurers;

pricing pressures and changes in third-party payor reimbursement policies; and

intellectual property rights held by others or others infringing our intellectual property rights.

Our ability to successfully develop and commercialize certain of our diagnostic tests and LDTs will depend on our ability to successfully operate our CLIA-certified laboratory and maintain required regulatory licensures.

We recently acquired a CLIA-certified laboratory through our acquisition of OURLab. In order to successfully develop and commercialize certain diagnostic tests and LDTs, we must maintain our CLIA-certified laboratory and comply with all the CLIA requirements.

CLIA is designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency such as CAP, among others. OURLab is also subject to regulation of laboratory operations under state clinical laboratory laws as will be any new CLIA-certified laboratory that we establish or acquire. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, such as California, Florida, Maryland, New York, Pennsylvania and Rhode Island, require that laboratories obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If we are unable to obtain and maintain licenses from states where required, we will not be able to process any samples from patients located in those states. Only Washington and New York States are exempt under CLIA, as these states have established laboratory quality standards at least as stringent as CLIA s. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations.

If we fail to comply with CLIA requirements, HHS or state agencies could require us to cease diagnostic testing. Even if it were possible for us to bring our laboratory back into compliance after failure to comply with such requirements, we could incur significant expenses and potentially lose revenues in doing so. Moreover, new interpretations of current regulations or future changes in regulations under CLIA may make it difficult or impossible for us to comply with the CLIA classification, which would significantly harm our business and materially adversely affect our financial condition.

It is also possible that we do not currently have adequate infrastructure in place for the demand of future LDTs or other diagnostic tests we develop. Failure to expand our current infrastructure and laboratories to support the development and commercialization of certain diagnostic tests could adversely affect our business and results of operations.

If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.

The pharmaceutical and diagnostic industries are highly competitive and require an ongoing, extensive search for technological innovation. Numerous companies, including major pharmaceutical companies, specialty pharmaceutical companies and specialized biotechnology companies, are engaged in the development, manufacture and marketing of pharmaceutical products competitive with those that we intend to commercialize ourselves and through our partners. Competitors to our diagnostics business are many and include major diagnostic companies,

reference laboratories, molecular diagnostic firms, universities and research institutions. Most of these companies have substantially greater financial and other resources, larger research and development staffs and more extensive

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marketing and manufacturing organizations than ours. Large pharmaceutical and diagnostic companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals or clearances for drugs, diagnostic tests, or medical devices. These companies also have significantly greater research and marketing capabilities than we do. Compared to us, many of our potential competitors have substantially greater capital resources, development resources, including personnel and technology, clinical trial experience, regulatory experience, expertise in prosecution of intellectual property rights, manufacturing and distribution experience, and sales and marketing experience.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- the timing and scope of regulatory approvals or clearances;
- our ability to commercialize and market any of our product candidates that may receive regulatory approval or clearance;
- appropriate coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to have our partners manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of future product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer, easier to use or less expensive than our future product candidates, if any, or that reach the market sooner than our future product candidates, if any, we may not achieve commercial success. In addition, the biopharmaceutical, diagnostic, and medical device industries are characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. 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 or less competitive.

Our product development activities could be delayed or stopped.

We do not know whether our current or planned pre-clinical and clinical studies will be completed on schedule, or at all. Furthermore, we cannot guarantee that our planned pre-clinical and clinical studies will begin on time or at all. The commencement of our planned clinical trials could be

substantially delayed or prevented by several factors, including:

- a limited number of, and competition for, suitable patients with the particular types of disease required for enrollment in our clinical trials or that otherwise meet the protocol s inclusion criteria and do not meet any of the exclusion criteria;

- a limited number of, and competition for, suitable serum samples from patients with particular types of disease required for our validation studies;

- a limited number of, and competition for, suitable sites to conduct our clinical trials;

- delay or failure to obtain FDA or other non-U.S. regulatory authorities approval or agreement to commence a clinical trial;

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delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;

requirements to provide the drugs, diagnostic tests, or medical devices required in our clinical trial protocols or clinical trials at no cost or cost, which may require significant expenditures that we are unable or unwilling to make;

delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and

delay or failure to obtain institutional review board (IRB) approval to conduct or renew a clinical trial at a prospective site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

slower than expected rates of patient recruitment and enrollment;

failure of patients to complete the clinical trial;

unforeseen safety issues;

lack of efficacy evidenced during clinical trials;

termination of our clinical trials by one or more clinical trial sites;

inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; and

inability to monitor patients adequately during or after treatment.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB for any given site, or us. Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. Any failure or significant delay in commencing or completing clinical trials for our product candidates could materially harm our results of operations and financial condition, as well as the commercial prospects for our product candidates.

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing, and distribution of drug products, diagnostic products, or medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. In general, we are not permitted to market our product candidates in the United States until we receive approval of a new drug application (NDA), a clearance letter under the premarket notification process, or 510(k) process, or an approval of a pre-market approval (PMA) from the FDA. We have not submitted a NDA or PMA application or premarket notification, nor have we received marketing approval or clearance for any of our proprietary pharmaceutical or diagnostic product candidates, other than a CE Mark for our point-of-care PSA test. Obtaining approval of a NDA or PMA can be a lengthy, expensive, and uncertain process. With respect to medical devices, while the FDA reviews and clears a premarket notification in as little as three months, there is no guarantee that our products will qualify for this more

expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance that even if a device is reviewed under the 510(k) process that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. If the FDA fails to make this finding, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product. Furthermore, we are not permitted to make changes to a device approved through the PMA or 510(k) which affects the safety or efficacy of the device without first submitting a supplement application to the PMA and obtaining FDA approval or cleared premarket notification for that supplement. In some cases, the FDA may require clinical trials to support a supplement application. In addition, failure to comply with FDA, non-U.S. regulatory authorities, or other applicable United States and non-U.S. regulatory requirements may, either before or after product approval or clearance, if any, subject our company to administrative or judicially imposed sanctions, including, but not limited to the following:

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restrictions on the products, manufacturers, or manufacturing process;

adverse inspectional observations (Form 483), warning letters, or non-warning letters incorporating inspectional observations;

civil and criminal penalties;

injunctions;

suspension or withdrawal of regulatory approvals or clearances;

product seizures, detentions, or import bans;

voluntary or mandatory product recalls and publicity requirements;

total or partial suspension of production;

imposition of restrictions on operations, including costly new manufacturing requirements; and

refusal to approve or clear pending NDAs or supplements to approved NDAs, applications or pre-market notifications.

Regulatory approval of an NDA or NDA supplement, PMA, PMA supplement or clearance pursuant to a pre-market notification is not guaranteed, and the approval or clearance process, as the case may be, is expensive and may, especially in the case of an NDA or PMA application, take several years. The FDA also has substantial discretion in the drug and medical device approval and clearance process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval or clearance varies depending on the drug or medical device candidate, the disease or condition that the drug or medical device candidate is designed to address, and the regulations applicable to any particular drug or medical device candidate. The FDA can delay, limit or deny approval or clearance of a drug or medical device candidate for many reasons, including:

a drug candidate may not be deemed safe or effective;

a medical device candidate may not be deemed to be substantially equivalent to a lawfully marketed non-PMA device, in the case of a premarket notification;

the FDA may not find the data from pre-clinical studies and clinical trials sufficient;

the FDA may not approve our or our third-party manufacturer s processes or facilities; or

the FDA may change its approval or clearance policies or adopt new regulations.

Beyond these risks, there is also a possibility that our licensees or collaborators could decide to discontinue a study at any time for commercial, scientific or other reasons.

Regulation by governmental authorities in the United States and other countries may be a significant factor in how we develop, test, produce and market our diagnostic test products. Diagnostic tests like ours may not fall squarely within the regulatory approval process for pharmaceutical or device products as described above, and the regulatory pathway is not as clear. It is possible that the diagnostic products developed by us or our collaborators will be regulated as medical devices by the FDA and comparable agencies of other countries and require either PMA or 510(k) clearance from the FDA prior to marketing. Some companies that have successfully commercialized diagnostic tests for various conditions and disease states have not sought clearance or approval for such tests through the traditional 510(k) or PMA processes, and have instead utilized a process involving LDTs through a CLIA- certified laboratory. CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for diagnostic, preventative or treatment purpose. In such instances, the CLIA lab is solely responsible for the development, validation and commercialization of the

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assay. Such LDT testing is currently under the purview of CMS and state agencies that provide oversight of the safe and effective use of LDTs. Although the FDA has consistently claimed that is has the regulatory authority to regulate LDTs that are validated by the developing laboratory and performed only by that laboratory, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and performed by high complexity CLIA-certified laboratories. The FDA has indicated, however, that it is reviewing the regulatory requirements that will apply to LDTs, and held a two-day public meeting in July 2010 to obtain input from stakeholders on how it should apply its authority to implement a reasonable, risk-based, and effective regulatory framework for LDTs.

The FDA has not issued guidance directly addressing the nature of the changes the FDA may intend to make with respect to the regulation of LDTs, nor the scope of potential regulation. However, two draft guidance documents relating to in vitro diagnostic products, which the FDA does regulate, were issued in 2011 that may have indirect implications for LDTs, and the FDA also indicated the intent to further explore aspects of LDT regulation in both its 2012 and 2013 workplans. We will continue to monitor potential changes as the FDA s LDT policy evolves to ensure our activities are consistent with the FDA s most current policy. Uncertainty regarding the development of new LDTs could materially adversely affect our business, financial condition and results of operations.

Our product candidates may have undesirable side effects and cause our approved products to be taken off the market.

If a product candidate receives marketing approval and we or others later identify undesirable 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;
- regulatory authorities may withdraw their approval of the product and require us to take our approved product off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, or change the labeling of the product;
- we may have limitations on how we promote our products;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

If the validity of an informed consent from a subject was to be challenged, it may negatively impact our product development efforts.

We take steps to ensure that all clinical data and genetic and other biological samples are collected from subjects who provide informed consent for the data and samples and we work to ensure that the subjects from whom our data and samples are collected do not retain any proprietary or commercial rights to the data or samples or any discoveries derived from them. However, because we may collect data and samples from countries that are governed by a number of different regulatory regimes, there are many complex legal questions relating to the adequacy of informed consent that we must continually address. The adequacy of any given subject s informed consent may be challenged in the future, and any given informed consent may prove unlawful or otherwise inadequate for our purposes. Any findings against us, or our clinical collaborators, could obligate us to stop using some of our clinical samples, which in turn may hinder our product development efforts. Such a result would also likely involve legal challenges that may consume our management and financial resources.

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Our business will be heavily dependent on the success of Phase III clinical trials for CTAP101 Capsules and Fermagate Tablets.

There is no assurance that Phase 3 trials for CTAP101 Capsules or Fermagate Tablets will be successful or support marketing approval, or that we will be able to obtain marketing approval for either product or any other product candidate. Before they can be marketed, our products in development must be approved by the FDA or similar foreign governmental agencies. The process for obtaining FDA approval is both time-consuming and costly, with no certainty of a successful outcome. Before obtaining regulatory approval for the sale of any drug candidate, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Although CTAP101 Capsules and Fermagate Tablets have exhibited no serious adverse events associated with the drug administration in the Phase I and II clinical trial, further testing in our Phase III trial may undermine those determinations or unexpected side effects may arise. A failure of any preclinical study or clinical trial can occur at any stage of testing. The results of preclinical and initial clinical testing of these products may not necessarily indicate the results that will be obtained from later or more extensive testing. It also is possible to suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. If Phase III clinical trials for CTAP101 Capsules or Fermagate Tablets are not successful, our business will be significantly adversely impacted, which could have a materially adverse effect on our business, financial condition and results of operations.

Our inability to address quality control issues in a timely manner could delay the production and sale of our products.

We are committed to providing high quality products to our customers, and we plan to meet this commitment by working diligently to continue implementing updated and improved quality systems and concepts throughout our organization. We cannot assure you that we will not have quality control issues in the future, which may result in warning letters and citations from the FDA. If we receive any warning letters from the FDA in the future, there can be no assurances regarding the length of time or cost it will take us to resolve such quality issues to our satisfaction and to the satisfaction of the FDA. If our remedial actions are not satisfactory to the FDA, we may have to devote additional financial and human resources to our efforts, and the FDA may take further regulatory actions against us including, but not limited to, assessing civil monetary penalties or imposing a consent decree on us, which could result in further regulatory constraints, including the governance of our quality system by a third party. Our inability to resolve these issues or the taking of further regulatory action by the FDA may weaken our competitive position and have a material adverse effect on our business, results of operations and financial condition.

We manufacture pharmaceutical products in Mexico, Spain, and Israel. We also prepare necessary test reagants and assemble and package the cassettes for our point-of-care diagnostic system at our facility in Woburn, Massachusetts. Any quality control issues at our facilities may weaken our competitive position and have a material adverse effect on our business results of operations and financial condition.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes, which could have an adverse effect on our business, results of operations and financial condition.

As a medical device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation (QSR) requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. In addition, most international jurisdictions have adopted regulatory approval and periodic renewal requirements for medical devices, and we must comply with these requirements in order to market our products in these jurisdictions. In the European Community, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Further, some emerging markets rely on the FDA s Certificate for Foreign Government (CFG) in lieu of their own regulatory approval requirements. Our, or our manufacturers failure to meet QSR ISO, or any other regulatory requirements or industry standards could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which could, in turn, have a material adverse effect on our business, results of operations, and our financial condition.

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Even if we obtain marketing approvals or clearances for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.

Once regulatory approval has been granted to market a product, the approved or cleared product and its manufacturer are subject to continual review. Any approved or cleared product may only be promoted for its indicated uses. In addition, if the FDA or other non-U.S. regulatory authorities approve any of our product candidates for marketing, the labeling, packaging, adverse event reporting, storage, advertising, and promotion for the product will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with current Good Manufacturing Practices (cGMP) regulations or the FDA s QSR regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which reports are publicly available. Further, regulatory agencies must approve manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions. Furthermore, any limitation on indicated uses for a product candidate or our ability to manufacture and promote a product candidate could significantly and adversely affect our business, results of operations, and financial condition.

In addition, the FDA and other non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay marketing approval or clearance of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future product candidates and we may not achieve or sustain profitability, which would materially impair our ability to generate anticipated revenues.

Even if we receive regulatory approval or clearance to market our product candidates, the market may not be receptive to our products.

Even if our product candidates obtain marketing approval or clearance, our products may not gain market acceptance among physicians, patients, health care payors and/or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;
- safety and efficacy of our product compared to other products;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our products, both in absolute terms and relative to alternative treatments;
- availability of coverage and reimbursement from government and other third-party payors;
- potential product liability claims;

limitations or warnings contained in a product s regulatory authority-approved labeling; and

changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following applicable regulatory authority approval.

In addition, our efforts to educate the medical community and health care payors on the benefits of our product candidates may require significant resources and may never be successful. If our products do not gain market acceptance, it would have a material adverse effect on our business, results of operations, and financial condition.

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If our future product candidates are not covered and eligible for reimbursement from government and third party payors, we may not be able to generate significant revenue or achieve or sustain profitability.

The coverage and reimbursement status of newly approved or cleared drugs and diagnostic tests is uncertain, and failure of our pharmaceutical products or diagnostic tests to be adequately covered by insurance and eligible for adequate reimbursement could limit our ability to market any future product candidates we may develop and decrease our ability to generate revenue from any of our existing and future product candidates that may be approved or cleared.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved or cleared drugs and diagnostic products. The commercial success of our existing and future product candidates in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors. The government and other third-party payors are increasingly attempting to contain health care costs by limiting both insurance coverage and the level of reimbursement for new drugs and diagnostic tests and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective, or less cost-effective than existing or later-introduced products. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our product candidates for insurance coverage and adequate reimbursement. The failure to obtain coverage and adequate or any reimbursement for our product candidates, or health care cost containment initiatives that limit or restrict reimbursement for our product candidates, may reduce any future product revenue. Even though a drug (not administered by a physician) may be approved by the FDA, this does not mean that a Prescription Drug Plan (PDP), a private insurer operating under Medicare Part D, will list that drug on its formulary or will set a reimbursement level. PDPs are not required to make every FDA-approved drug available on their formularies. If our drug products are not listed on sufficient number of PDP formularies or if the PDPs levels of reimbursement are inadequate, the Company s business, results of operations, and financial condition could be materially adversely affected.

Additionally, our failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in our inability to participate in a governmental payor program, our returning funds already paid to us, civil monetary penalties, criminal penalties and/or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payor program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition.

Our success is dependent to a significant degree upon the involvement and efforts of our Chairman and Chief Executive Officer, Phillip Frost, M.D.

Our success is dependent to a significant degree upon the efforts of our Chairman and Chief Executive Officer, Phillip Frost, M.D., who is essential to our business. The departure of our CEO for whatever reason or the inability of our CEO to continue to serve in his present capacity could have a material adverse effect upon our business, financial condition, and results of operations. Our CEO has a highly regarded reputation in the pharmaceutical and medical industry and attracts business opportunities and assists both in negotiations with acquisition targets, investment targets, and potential joint venture partners. Our CEO has also provided financing to the Company, both in terms of a credit agreement and equity investments. If we lost his services, our relationships with acquisition and investment targets, joint ventures, and investors may suffer and could cause a material adverse impact on our operations, financial condition, and the value of our Common Stock.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial, development, and other resources in order to successfully pursue our research, development, and commercialization efforts for our product candidates. Our success depends on our continued ability to attract, retain, and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services or support of any of our senior management, particularly Dr. Phillip Frost, our Chairman of the Board and CEO, could delay or prevent the development and commercialization of our product candidates. We do not maintain key man insurance policies on the lives of any of our employees. We will need to hire additional personnel as we continue to expand our research and development activities and build a sales and marketing function.

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We have scientific and clinical advisors 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. In addition, these advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical, medical device, diagnostic, and other similar businesses. If we are unable to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy, which will adversely affect our business, results of operations and financial condition. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

As we advance our product candidates through clinical trials, research, and development we will need to expand our development, regulatory, manufacturing, marketing, and sales capabilities or contracts with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; implement and manage an effective marketing strategy; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

Furthermore, we may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company, which would have a material adverse effect on our business, results of operations and financial condition.

If we fail to acquire and develop other products or product candidates at all or on commercially reasonable terms, we may be unable to diversify or grow our business.

We intend to continue to rely on acquisitions and in-licensing as the source of our products and product candidates for development and commercialization. The success of this strategy depends upon our ability to identify, select, and acquire pharmaceutical and diagnostic products, drug delivery technologies, and medical device product candidates. Proposing, negotiating, and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biotechnology and medical device companies, and academic research institutions. Our competitors may have stronger relationships with third parties with whom we are interested in collaborating and/or may have more established histories of developing and commercializing products. Most of our competitors also have substantially greater financial and other resources than us. As a result, our competitors may have a competitive advantage in entering into partnering arrangements with such third parties, as such partnering arrangements are often decided in an auction process in which the highest bidder wins. In addition, even if we find promising product candidates, and generate interest in a partnering or strategic arrangement to acquire such product candidates, we may not be able to acquire rights to additional product candidates or approved products on terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and other non-U.S. regulatory authorities. All product candidates are subject to the risks of failure inherent in pharmaceutical, diagnostic test or medical device product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Even if the product candidates

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are approved or cleared for marketing, we cannot be sure that they would be capable of economically feasible production or commercial success. If we fail to acquire or develop other product candidates that are capable of economically feasible production and commercial success, our business, results of operations and financial condition and cash flows may be materially adversely affected.

We have no experience or capability manufacturing large clinical-scale or commercial-scale products and have no pharmaceutical manufacturing facility other than our facilities in Mexico, Israel, and Spain; we therefore rely on third parties to manufacture and supply our pharmaceutical product candidates.

If our manufacturing partners are unable to produce our products in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

Our product candidates require precise, high quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and other non-U.S. regulatory authorities to ensure strict compliance with QSR regulations for devices or cGMPs for drugs, and other applicable government regulations and corresponding standards relating to matters such as testing, quality control, and documentation procedures. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR or cGMPs, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns, or other problems that could seriously harm our business.

Any performance failure on the part of our contract manufacturers could delay clinical development or regulatory approval or clearance of our product candidates or commercialization of our future product candidates, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third party for manufacturing may adversely affect our future profit margins. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can begin manufacturing our product candidates. Such approval would result in additional non-clinical testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

We currently have limited marketing staff and no pharmaceutical or diagnostic sales or distribution capabilities in the United States. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical or diagnostic product candidates in the United States.

We currently have no pharmaceutical or diagnostic test marketing, sales or distribution capabilities other than the sales force for the OURLab business, and through our Mexican, Spanish and Chilean subsidiaries for sales in those countries and for sales of APIs by our Israeli subsidiary. If our pharmaceutical product candidates are approved, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming. Any failure or delay in the development of any of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our products. With respect to our existing and future pharmaceutical product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue and profit is likely to be lower than if we directly marketed or sold our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future product candidates. If we are not successful in commercializing our existing and future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.

We depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees, and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to products that we develop. If independent investigators fail to devote sufficient resources to the development of product candidates or clinical trials, or if their performance is substandard, it will delay the marketing approval or clearance and commercialization of any products that we develop. Further, the FDA requires that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations and good clinical practice procedures could adversely affect the clinical development of our product candidates and harm our business, results of operations, and financial condition.

If we fail to comply with complex and rapidly evolving laws and regulations, we could suffer penalties, be required to pay substantial damages or make significant changes to our operations.

We are subject to numerous federal and state regulations, including, but not limited to, the Anti-Kickback Statute, the Physician Self-Referral Law, the False Claims Act, and HIPAA. If we fail to comply with existing or future applicable laws and regulations, we could suffer civil or criminal penalties, including the loss of our licenses to operate our institutional pharmacies and our ability to participate in federal and state healthcare programs. Although we believe that we are substantially compliant with all existing statutes and regulations applicable to our business, different interpretations and enforcement policies of these laws and regulations could subject our current practices to allegations of impropriety or illegality, or could require us to make significant changes to our operations. In addition, we cannot predict the impact of future legislation and regulatory changes on our business or assure that we will be able to obtain or maintain the regulatory approvals required to operate our business.

As a result of political, economic, and regulatory influences, the healthcare delivery industry in the United States is under intense scrutiny and subject to fundamental changes. We cannot predict which reform proposals will be adopted, when they may be adopted, or what impact they may have on us. The costs associated with complying with federal and state regulations could be significant and the failure to comply with any such legal requirements could have a material adverse effect on our financial condition, results of operations, and liquidity.

The success of our business may be dependent on the actions of our collaborative partners.

We expect to enter into collaborative arrangements with established multi-national pharmaceutical, diagnostic, and medical device companies, which will finance or otherwise assist in the development, manufacture and marketing of products incorporating our technology. We anticipate deriving some revenues from research and development fees, license fees, milestone payments, and royalties from collaborative partners. Our prospects, therefore, may depend to some extent upon our ability to attract and retain collaborative partners and to develop technologies and products that meet the requirements of prospective collaborative partners. In addition, our collaborative partners may have the right to abandon research projects, guide strategy regarding prosecution of relevant patent applications and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed-upon research terms. There can be no assurance that we will be successful in establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before completion of projects, that our collaborative arrangements will result in successful product commercialization, or that we will derive any revenues from such arrangements. To the extent that we are unable to develop and maintain collaborative arrangements, we would need substantial additional capital to undertake research, development, and commercialization activities on our own.

Our license agreement with TESARO, Inc. is important to our business. If TESARO, Inc. does not successfully develop and commercialize rolapitant, our business could be adversely affected.

In December 2010, we exclusively out-licensed the development, manufacture and commercialization of rolapitant to TESARO, Inc. (TESARO), an oncology-focused biopharmaceutical company founded by executives with a demonstrated track record in launching successful products for the chemotherapy induced nausea and

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vomiting, or CINV market. TESARO is initially pursuing development and commercialization of rolapitant for CINV. Under the terms of the license, we are eligible to receive payments of up to $121.0 million, including an up-front payment of $6.0 million we received in December 2010, and additional payments based upon net sales and achievement of specified regulatory and commercialization milestones. In addition, TESARO will pay us double digit tiered royalties on sales of licensed product. Further, we will share with TESARO future profits from the commercialization of licensed products in Japan, and we will have an option to market the products in Latin America. If TESARO fails to successfully develop and commercialize rolapitant, we may not receive any milestone or royalty payments under the license agreement, which could have a material adverse impact on our financial condition.

If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our product candidates. Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date for which nonpublication has been requested, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we may not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability, or infringement of the third-party patent or otherwise circumvent the third-party patent.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. In addition, we will rely on third-party collaborators to file patent applications relating to proprietary technology that we develop jointly during certain collaborations. The process of obtaining patent protection is expensive and time-consuming. If our present or future collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Despite our efforts and the efforts of our collaborators to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, unenforceable, or circumvented. Moreover, the U.S. Patent and Trademark Office (USPTO) may commence interference proceedings involving our patents or patent applications. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology, pharmaceutical, and medical device companies. Any challenge to, finding of unenforceability or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, and could have a material adverse effect on our business, results of operations and financial condition.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical, biotechnology, diagnostic, and medical device companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical, biotechnology, diagnostic, or medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties.

While we believe that our patent rights are enforceable, we cannot assure you that any patents that have issued, that may issue, or that may be licensed to us will be enforceable or valid, or will not expire prior to the commercialization of our product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our product candidates or our future products, which could have a material adverse effect on our business, results of operations, and financial condition.

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We do not have an exclusive arrangement in place with The Scripps Research Institute or Dr. Tom Kodadek with respect to technology or intellectual property that may be material to our business. If any such technology or intellectual property is developed by The Scripps Research Institute or its employees, including Dr. Kodadek, and we are unable to license such technology or intellectual property, or such technology or intellectual property is licensed to or acquired by other parties, our business and competitive position may be materially harmed.

Our success depends, in part, on our ability to develop and protect proprietary methods, products and technologies. Dr. Tom Kodadek, who currently serves as our Director of Chemistry & Molecular Biology is a staff member and employee of The Scripps Research Institute (TSRI), a private, non-profit research organization. Dr. Kodadek, as our consultant, supervises our research and development efforts with respect to our molecular diagnostics program, and the creation of intellectual property that is important to our business. We have entered into a consulting arrangement with Dr. Kodadek with respect to Dr. Kodadek s services to us. We have the right to intellectual property resulting from Dr. Kodadek s services to us under this arrangement. However, we do not have an exclusive arrangement with Dr. Kodadek or TSRI, and Dr. Kodadek also provides services to TSRI and other third parties and may provide services to other third parties in the future. We have entered into a funding arrangement with TSRI pursuant to which we agreed to fund certain research services to be conducted in Dr. Kodadek s TSRI laboratory and have obtained an option to license any inventions or discoveries resulting from the sponsored research. We do not have any rights to any technology or intellectual property that may be developed by TSRI and its employees, including Dr. Kodadek, outside of these arrangements. If TSRI or its employees, including Dr. Kodadek, develops technology or intellectual property that is material to our business and we are unable to license such technology or intellectual property on favorable terms, if at all, or such technology or intellectual property is licensed to or acquired by other parties, our business and competitive position may be harmed.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how, and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants, and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual s relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property.

However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants, or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition, and results of operations.

We will rely heavily on licenses from third parties. Failure to comply with the provisions of these licenses could result in the loss of our rights under the license agreements.

Many of the patents and patent applications in our patent portfolio are not owned by us, but are licensed from third parties. For example, we rely on technology licensed from UT Southwestern, the President and Fellows of Harvard College, The Scripps Research Institute, Arctic Partners, and Academia Sinica, among others. Such license agreements give us rights for the commercial exploitation of the patents resulting from the respective patent applications, subject to certain provisions of the license agreements. Failure to comply with these provisions could result in the loss of our rights under these license agreements. Our inability to rely on these patents and patent applications, which are the basis of our technology, would have a material adverse effect on our business, results of operations and financial condition.

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We license patent rights to certain of our technology from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We have obtained licenses from, among others, UT Southwestern, the President and Fellows of Harvard College, The Scripps Research Institute, Arctic Partners, and Academia Sinica, among others, that are necessary or useful for our business. In addition, we intend to enter into additional licenses of third-party intellectual property in the future. Although our goal is to obtain exclusivity in our licensing transactions, we cannot guarantee that no third parties will step forward and assert inventorship or ownership in our in-licensed patents. In some cases, we may rely on the assurances of our licensors that all ownership rights have been secured and that all necessary agreements are intact or forthcoming.

Our success will depend in part on our ability or the ability of our licensors to obtain, maintain, and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights in our field. We or our licensors may not successfully prosecute the patent applications which are licensed to us. Even if patents issue in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business, results of operations and financial condition.

Some jurisdictions may require us, or those from whom we license patents, to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief from an infringement and may be unable to enjoin infringement, which could materially diminish the value of the patent. If we or those from whom we license patents are required to issue compulsory licenses, it could materially adversely affect our business, results of operation and financial condition.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Other entities may have or obtain patents or proprietary rights that could limit our ability to develop, manufacture, use, sell, offer for sale or import products, or impair our competitive position. In addition, other entities may have or obtain patents or proprietary rights that cover our current research and preclinical studies. While there are statutory exemptions to patent infringement for those who are using third party patented technology in the process of pursuing FDA regulatory approval, the U.S. case law pertaining to such exemptions changes over time. Lawsuits involving such exemptions are very fact intensive and it is currently unclear under U.S. case law whether preclinical studies would always qualify for such an exemption, and whether such exemptions would apply to research tools. To the extent that our current research and preclinical studies may be covered by the patent rights of others, the risk of suit may continue after such patents expire because the statute of limitations for patent infringement runs for six years. To the extent that a third party develops and patents technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent, or circumvent the third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain by license or assignment valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition, and results of operations.

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If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third-party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third-party license agreements, we generally have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management s efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations. Our involvement in patent litigation and other proceedings could have a material adverse effect on our business, results of operations, and financial condition.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

We may become subject to product liability for our diagnostic tests, clinical trials, pharmaceutical products and medical device products.

Our success depends on the market s confidence that we can provide reliable, high-quality pharmaceuticals, medical devices, and diagnostics tests. Our reputation and the public image of our products or technologies may be impaired if our products fail to perform as expected or our products are perceived as difficult to use. Our products are complex and may develop or contain undetected defects or errors. Furthermore, if future product candidate harms people, or is alleged to be harmful, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, corporate partners or others. We have product liability insurance covering commercial sales of current products and our ongoing clinical trials. Any defects or errors could lead to the filing of product liability claims, which could be costly and time-consuming to defend and result in substantial damages. If we experience a sustained material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could materially harm our business. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. A product liability claim could have a serious adverse effect on our business, financial condition and results of operations.

Adverse results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition.

We may from time to time become subject in the ordinary course of business to material legal action related to, among other things, intellectual property disputes, professional liability, contractual and employee-related matters, as well as inquiries from governmental agencies and Medicare or Medicaid carriers requesting comment and information on allegations of billing irregularities and other matters that are brought to their attention through billing audits, third parties or other sources. The health care industry is subject to substantial federal and state government regulation and audit. Legal actions could result in substantial monetary damages as well as damage to the Company s reputation with customers, which could have a material adverse effect upon our results of operations and financial position.

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Medicare legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.

In the United States, there have been a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products and provide our laboratory services profitably. While many of the proposed policy changes require congressional approval to implement, we cannot assure you that reimbursement payments under governmental and private third party payor programs will remain at levels comparable to present levels or will be sufficient to cover the costs allocable to patients eligible for reimbursement under these programs. Any changes that lower reimbursement rates under Medicare, Medicaid or private payor programs could negatively affect our business.

Most significantly, on March 23, 2010, President Obama signed into law both the Patient Protection and Affordable Care Act (the Affordable Care Act) and the reconciliation law known as Health Care and Education Affordability Reconciliation Act (the Reconciliation Act) and, combined we refer to both Acts as the 2010 Health Care Reform Legislation. The constitutionality of the 2010 Health Care Reform Legislation was confirmed on June 28, 2012 by the Supreme Court of the United States (the Supreme Court). Specifically, the Supreme Court upheld the individual mandate and includes changes to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of third-party payors and government programs, such as Medicare and Medicaid, the creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Additionally, restructuring the coverage of medical care in the United States could impact the reimbursement for diagnostic tests. If reimbursement for our diagnostic tests is substantially less than we or our clinical laboratory customers expect, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Beyond coverage and reimbursement changes, the 2010 Health Care Reform Legislation subjects manufacturers of medical devices to an excise tax of 2.3% on certain U.S. sales of medical devices in January 2013. This excise tax will likely increase our expenses in the future.

Further, the 2010 Health Care Reform Legislation includes the Physician Payments Sunshine Act, which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are covered by Medicare and Medicaid to record all transfers of value to physicians and teaching hospitals starting on August 1, 2013 and to begin reporting the same for public disclosure to the Centers for Medicare and Medicaid Services by March 31, 2014. Several other states and a number of countries worldwide have adopted or are considering the adoption of similar transparency laws. The failure to report appropriate data may result in civil or criminal fines and/or penalties.

Regulations under the 2010 Health Care Reform Legislation are expected to continue being drafted, released and finalized throughout the next several years. Pending the promulgation of these regulations, we are unable to fully evaluate the impact of the 2010 Health Care Reform Legislation.

RISKS RELATED TO INTERNATIONAL OPERATIONS

Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.

We intend to market certain of our existing and future product candidates in non-U.S. markets. In order to market our existing and future product candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-U.S. regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or clearance. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authority does not ensure approval by other regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market, which would have a material adverse effect on our business, results of operations and financial condition.

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Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market certain of our existing and future product candidates in both the United States and in non-U.S. jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug or medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our existing and future product candidates to other available products. If reimbursement of our future product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to generate revenues and achieve or sustain profitability, which would have a material adverse effect on our business, results of operations and financial condition.

Potential political, economic and military instability in the State of Israel, where we have office, laboratory and manufacturing operations, may adversely affect our results of operations.

We maintain office, laboratory and manufacturing facilities in the State of Israel. Political, economic and military conditions in Israel may directly affect our ability to conduct business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its neighbors. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations and product development and cause our revenues to decrease.

Due to the international scope of our business activities, our results of operations may be significantly affected by currency fluctuations.

We derive a significant portion of our consolidated net revenues from international sales, subjecting us to risks relating to fluctuations in currency exchange rates. Currency variations can adversely affect margins on sales of our products in countries outside of the United States and margins on sales of products that include components obtained from suppliers located outside of the United States. Through our subsidiaries, we operate in a wide variety of jurisdictions. Certain countries in which we operate or may operate have experienced geopolitical instability, economic problems and other uncertainties from time to time. To the extent that world events or economic conditions negatively affect our future sales to customers in these and other regions of the world, or the collectability of receivables, our future results of operations, liquidity and financial condition may be adversely affected. Although we do not speculate in the foreign exchange market, we may manage exposures arising in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions are hedged with foreign exchange forward contracts whereby exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. However, our subsidiaries receive their income and pay their expenses primarily in their local currencies. To the extent that transactions of these subsidiaries are settled in their local currencies, a devaluation of those currencies versus the U.S. dollar could reduce the contribution from these subsidiaries to our consolidated results of operations as reported in U.S. dollars. For financial reporting purposes, such depreciation will negatively affect our reported results of operations since earnings denominated in foreign currencies would be converted to U.S. dollars at a decreased value. While we have employed economic cash flow and fair value hedges to minimize the risks associated with these exchange rate fluctuations, the hedging activities may be ineffective or may not offset more than a portion of the adverse financial impact resulting from currency variations. Accordingly, we cannot assure you that fluctuations in the values of the currencies of countries in which we operate will not materially adversely affect our future results of operations.

We may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business.

We are subject to the Foreign Corrupt Practice Act (FCPA) and other laws that prohibit U.S. companies or their agents and employees from providing anything of value to a foreign official or political party for the purposes of influencing any act or decision of these individuals in their official capacity to help obtain or retain business, direct business to any person or corporate entity or obtain any unfair advantage. We have operations and agreements with third parties and we generate sales internationally. Our international activities create the risk of unauthorized and illegal payments or offers of payments by our employees, consultants, sales agents or distributors,

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even though they may not always be subject to our control. We discourage these practices by our employees and agents. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Any failure by us to adopt appropriate compliance procedures and ensure that our employees and agents comply with the FCPA and applicable laws and regulations in foreign jurisdictions could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions.

Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the U.S. government may seek to hold our Company liable for successor liability FCPA violations committed by companies in which we invest or that we acquire.

We are subject to risks associated with doing business globally.

Our operations, both within and outside the United States, are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government tenders that are held annually in many cases, nationalization, increasingly complex labor environments, expropriation and other governmental actions, changes in taxation, including legislative changes in U.S. and international taxation of income earned outside of the United States, importation limitations, export control restrictions, violations of U.S. or local laws, including the FCPA, dependence on a few government entities as customers, pricing restrictions, economic destabilization, political and economic instability, disruption or destruction in a significant geographic region due to the location of manufacturing facilities, distribution facilities or customers regardless of cause, including war, terrorism, riot, civil insurrection or social unrest, or natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. Failure to comply with the laws and regulations that affect our global operations, could have an adverse effect on our business, financial condition or results of operations.

RISKS RELATED TO ACQUISITIONS AND INVESTMENTS

Acquisitions, investments and strategic alliances that we have made or may make in the future may use significant resources, result in disruptions to our business or distractions of our management, may not proceed as planned, and could expose us to unforeseen liabilities. We intend to continue to expand our business through the acquisition of, investments in and strategic alliances with companies, technologies, products, and services. Acquisitions, investments and strategic alliances involve a number of special problems and risks, including, but not limited to:

- difficulty integrating acquired technologies, products, services, operations, and personnel with the existing businesses;
- diversion of management s attention in connection with both negotiating the acquisitions and integrating the businesses;
- strain on managerial and operational resources as management tries to oversee larger operations and investments;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire or invest in, particularly if they are not located near our existing operations;
- exposure to unforeseen liabilities of acquired companies or companies in which we invest;
- potential costly and time-consuming litigation, including stockholder lawsuits;
- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our Common Stock, or which may have a dilutive effect on our stockholders;

the need to incur additional debt or use cash; and

the requirement to record potentially significant additional future operating costs for the amortization of intangible assets.

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As a result of these or other problems and risks, businesses we acquire or invest in may not produce the revenues, earnings, or business synergies that we anticipated, and acquired products, services, or technologies might not perform as we expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We may not be able to successfully address these problems and we cannot assure you that the acquisitions or investments will be successfully identified and completed or that, if completed, the acquired businesses, investments, products, services, or technologies will generate sufficient revenue to offset the associated costs or other negative effects on our business.

Any of these risks can be greater if an acquisition or investment is large relative to our size. Failure to manage effectively our growth through acquisitions could adversely affect our growth prospects, business, results of operations, financial condition and cash flows.

Funding may not be available for us to continue to make acquisitions, investments and strategic alliances in order to grow our business.

We have made and anticipate that we may continue to make acquisitions, investments and strategic alliances with complementary businesses, technologies, products and services to expand our business. Our growth plans rely, in part, on the successful completion of future acquisitions. At any particular time, we may need to raise substantial additional capital or to issue additional equity to finance such acquisitions, investments, and strategic alliances. There is no assurance that we will be able to secure additional funding on acceptable terms, or at all, or obtain the stockholder approvals necessary to issue additional equity to finance such acquisitions, investments, and strategic alliances. If we are unsuccessful in obtaining the financing, our business would be adversely impacted.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

The market price of our Common Stock may fluctuate significantly.

The market price of our Common Stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- results of our clinical trials and other development efforts;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our Common Stock is covered by analysts;
- developments in the biotechnology, pharmaceutical, diagnostic, and medical device industry;
- the results of product liability or intellectual property lawsuits;
- future issuances of our Common Stock or other securities, including debt;
- sales of our Common Stock by our officers, directors or affiliates;

the addition or departure of key personnel;

announcements by us or our competitors of acquisitions, investments, or strategic alliances; and

general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for biotechnology, pharmaceutical, diagnostic, and medical device companies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in extreme volatility in the price of our Common Stock, which could cause a decline in the value of our Common Stock.

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Trading of our Common Stock is limited and restrictions imposed by securities regulation and certain lockup agreements may further reduce our trading, making it difficult for our stockholders to sell shares.

Our Common Stock began trading on the American Stock Exchange, now known as the NYSE MKT, in June 2007. In September 2011, we transferred the listing of our Common Stock from the NYSE MKT to the New York Stock Exchange (NYSE). To date, the liquidity of our Common Stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and changes in security analyst and media coverage, if at all.

A substantial amount of the outstanding shares of our Common Stock are restricted securities and/or are subject to lockup agreements which limit sales for a period of time. These factors may result in lower prices for our Common Stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our Common Stock. In addition, without a large float, our Common Stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our Common Stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our Common Stock. Further, the limited liquidity could be an indication that the trading price is not reflective of the actual fair market value of our Common Stock. Trading of a relatively small volume of our Common Stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger

Future sales of our Common Stock could reduce our stock price.

Some or all of the restricted shares of our Common Stock issued to former stockholders of Froptix and Acuity in connection with the acquisition or held by other of our stockholders may be offered from time to time in the open market pursuant to an effective registration statement, or beginning April 2, 2008, pursuant to Rule 144. In addition, as described herein, a substantial number of our shares of Common Stock were subject to lockup agreements which expired on March 27, 2009. We have also issued or agreed to issue a substantial number of securities in private placement transactions with two year lockup restrictions which expired in each of December 2009, August 2010, and February 2011. In connection with our Series D Preferred Stock offering, shares were issued with a three year lockup restriction that expired in September 2012. On March 8, 2013, the Company converted each outstanding share of Series D Preferred Stock into ten shares of Common Stock. In connection with the conversion, the Company issued 11,290,320 shares of Common Stock. In January 2013, we also entered into note purchase agreements with various purchasers (collectively, the Purchasers) for the sale of $175.0 million aggregate principal amount of 3.00% convertible senior notes due 2033 (the Notes). The Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, upon the occurrence of specified events. The Notes will be convertible into cash, shares of the Company s Common Stock, or a combination of cash and shares of Common Stock at an initial conversion rate of 141.4827 shares of Common Stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $7.07 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events. Sales of a substantial number of shares of our Common Stock in the public market pursuant to Rule 144 or after the lockup agreements lapse or the Notes are converted, or the perception that such sales could occur, could adversely affect the price of our Common Stock.

Directors, executive officers, principal stockholders and affiliated entities own a majority of our capital stock, and they may make decisions that you do not consider to be in the best interests of our stockholders.

As of March 8, 2013, our directors, executive officers, principal stockholders, and affiliated entities beneficially owned, in the aggregate a majority of our outstanding voting securities. Frost Gamma Investments Trust (Gamma Trust), of which Phillip Frost, M.D., the Company s Chairman and CEO, is the sole trustee, is deemed to beneficially own in the aggregate approximately 45.9% of our Common Stock as of March 8, 2013. As a result, Dr. Frost acting with other members of management, would have the ability to control the election of our Board of Directors, the adoption or amendment of provisions in the Company s Certificate of Incorporation, the approval of mergers and other significant corporate transactions, and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our Common Stock.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm on the effectiveness of internal control over financial reporting as of December 31, 2012. We are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal control that, or that are reasonably likely to, materially affect internal control over financial reporting. A material weakness is a significant deficiency or combination of significant deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. In connection with our November 2010 restatement of our previously issued consolidated financial statements as of and for the three and nine months ended September 30, 2009, and as of and for the year ended December 31, 2009, we determined that a deficiency in controls relating to the accounting for a beneficial conversion feature on, and the classification of, convertible Preferred Stock existed as of the previous assessment date and further concluded that such a deficiency represented a material weakness as of December 31, 2009. As a result, we concluded that our internal control over financial reporting was not effective as of December 31, 2009. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Although we have determined that our internal controls are effective as of December 31, 2012, we cannot assure you that we will at all times in the future be able to report that our internal controls are effective. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed. Our failure to maintain the effective internal control over financial reporting could cause the cost related to remediation to increase and could cause our stock price to decline. In addition, we may not be able to accurately report our financial results, may be subject to regulatory sanction, and investors may lose confidence in our financial statements.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

There have been changing laws, regulations, and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, regulations promulgated by the Securities and Exchange Commission and rules promulgated by the NYSE and the other national securities exchanges. These new or changed laws, regulations, and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations, and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, Chief Executive Officer, Chief Financial Officer, and Principal Accounting Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed, which could materially adversely affect our business, results of operations and financial condition.

The conversion of shares of our Preferred Stock or exercise of warrants we have issued may result in dilution to the holders of our Common Stock and cause the price of our Common Stock to decline.

As of December 31, 2012, we had 1,129,032 outstanding shares of Series D Preferred Stock, which were convertible as of such date into approximately 10 shares of our Common Stock. In addition, as of December 31, 2012, we had outstanding warrants to purchase 25,841,868 shares of our Common Stock. On March 8, 2013, the Company converted each outstanding share of Series D Preferred Stock into ten shares of Common Stock resulting in the issuance of 11,290,320 shares of Common Stock. The conversion of outstanding shares of our Series D Preferred Stock and the exercise of warrants has, or may, result in substantial dilution to our existing stockholders and could have a material adverse effect on our stock price. The possibility of the issuance of shares of our Common Stock upon the exercise of warrants could cause our stock price to decline as well.

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ITEM 1B. UNRESOLVED STAFF COMMENTS.
None.

ITEM 2. PROPERTIES.
Our principal corporate office is located at 4400 Biscayne Blvd, Miami, Florida. We lease this space from Frost Real Estate Holdings, LLC, an entity which is controlled by Dr. Phillip Frost, our Chairman of the Board and Chief Executive Officer. Pursuant to the lease agreement with Frost Real Estate Holdings, we lease approximately 8,300 square feet, which encompasses space for our corporate offices, administrative services, and project management. The lease was for a five-year term, which expired in August 2012. In August 2012 and again in February 2013, we entered into a six-month extension on the same terms as the expiring lease. The lease currently requires annual rent of approximately $0.3 million.

We lease facilities in Jupiter, Florida, Miramar, Florida and Woburn, Massachusetts, which is where our molecular diagnostics research and development, oligonucleotide research and development, and point-of-care diagnostic operations are based, respectively. OPKO Chile, our Chilean subsidiary, leases office space and warehouse facilities in Santiago. We lease laboratory and office space in Nashville, Tennessee and Burlingame, California for our CLIA-certified laboratory business, and we lease office space in Bannockburn, Illinois and Markham, Ontario and laboratory space in Toronto, Ontario for the Cytochroma business. Through our Mexican subsidiaries, we own a manufacturing facility, laboratory and office space consisting of approximately 38,000 square feet and lease a warehouse facility in Guadalajara. Our Israeli subsidiary leases a manufacturing facility, laboratory and office space in Nesher. Our Spanish operations are based in owned offices in Barcelona and in an owned manufacturing facility in Banyoles. Our Brazilian operation is based in a leased facility in Sao Paulo.

ITEM 3. LEGAL PROCEEDINGS.
Prost-Data, Inc. (OURLab) received a letter dated July 9, 2012 from AdvanceMed Corporation (AdvanceMed) regarding a post-payment review conducted by AdvanceMed (the Post-Payment Review Letter). The Post-Payment Review letter originated with a post payment review audit by AdvanceMed of 183 claims submitted by OURLab to the Medicare program. OURLab believes that its billing practices were appropriate and it is following the appeal process set forth by Medicare. OURLab received a partially favorable determination, which reduced the amount of the alleged overpayment, and it continues to appeal the remaining alleged overpayments. The outcome of the appeal cannot currently be determined.

On November 27, 2012, Adrian Goldstein, M.D., a former employee of OURLab, filed a complaint for declaratory judgment and alleged breach of contract against OURLab in the Chancery Court for Davidson County, Tennessee. Dr. Goldstein asserts in his complaint that OURLab breached his employment agreement and owes him additional compensation and further compensation for the value of OURLab under a compensation for sale provision set forth in his employment agreement. Dr. Goldstein seeks recovery of compensatory damages not to exceed $20 million, plus his attorney s fees and litigation expenses. OURLab believes this action is without merit and is vigorously defending against plaintiff s claims. It is too early to assess the probability of a favorable or unfavorable outcome or the loss or range of loss, if any.

ITEM 4. MINE SAFETY DISCLOSURES.
Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our Common Stock is traded publicly on the New York Stock Exchange (NYSE) under the symbol OPK . In September 2011, we transferred the listing of our Common Stock from the NYSE MKT to the NYSE. The following table sets forth, for the periods indicated, the high and low sales prices per share of our Common Stock during each of the quarters set forth below as reported on the NYSE MKT and NYSE, as applicable:

	High	Low
2012		
First Quarter	$ 5.53	$ 4.63
Second Quarter	5.05	4.22
Third Quarter	4.80	4.00
Fourth Quarter	4.84	4.10
2011		
First Quarter	$ 4.89	$ 3.48
Second Quarter	4.00	3.28
Third Quarter	4.66	3.54
Fourth Quarter	5.66	4.10

As of March 8, 2013, there were approximately 372 holders of record of our Common Stock.

We have not declared or paid any cash dividends on our Common Stock. No cash dividends have been previously paid on our Common Stock and none are anticipated in fiscal 2013. Prior to March 8, 2013, we had shares of Series D Preferred Stock outstanding that had preferential dividend rights over any dividend payments to holders of Common Stock. On March 1, 2013, our Board of Directors declared a cash dividend to all Series D Preferred stockholders as of March 8, 2013. The total cash dividend was approximately $3.0 million. In addition, on March 1, 2013, our Board of Directors also exercised our option to convert all 1,129,032 shares of our outstanding Series D Preferred Stock into 11,290,320 shares of our Common Stock effective on March 8, 2013. Following the conversion there are no outstanding shares of Series D Preferred Stock.

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Stock Performance Graph

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ITEM 6. SELECTED FINANCIAL DATA.

The following selected historical consolidated statement of operations data for the years ended December 31, 2012, 2011, 2010, 2009, and 2008 and the consolidated balance sheet data as of December 31, 2012, 2011, 2010, 2009, and 2008, below are derived from our audited consolidated financial statements and related notes thereto. This data should be read in conjunction with our Management s Discussion and Analysis of Financial Condition and Results of Operation and our consolidated financial statements and the related notes thereto.

	For the years ended December 31,				
(In thousands, except share and per share information)	2012	2011	2010	2009	2008
Statement of operations data:					
Revenues	$ 47,044	$ 27,979	$ 28,494	$ 4,418	$
Cost of revenues, excluding amortization of intangible assets	27,878	17,243	13,495	2,876	
Gross margin	19,166	10,736	14,999	1,542	
Operating expenses:					
Selling, general and administrative	27,795	19,169	18,133	10,372	9,644
Research and development	19,520	11,352	5,949	10,836	19,960
Write-off of acquired in-process research and development				2,000	1,398
Other operating expenses; primarily amortization of intangible assets	9,120	3,404	2,053	481	
Total operating expenses	56,435	33,925	26,135	23,689	31,002
Operating loss from continuing operations	(37,269)	(23,189)	(11,136)	(22,147)	(31,002)
Other income and (expense), net	56	(1,044)	(844)	(1,916)	(1,311)
Loss from continuing operations before income taxes and investment losses	(37,213)	(24,233)	(11,980)	(24,063)	(32,313)
Income tax benefit	9,626	19,358	18	25	
Loss from continuing operations before investment losses	(27,587)	(4,875)	(11,962)	(24,038)	(32,313)
Loss from investments in investees	(2,062)	(1,589)	(714)	(353)	
Loss from continuing operations	(29,649)	(6,464)	(12,676)	(24,391)	(32,313)
Income (loss) from discontinued operation, net of tax	109	5,181	(6,250)	(5,722)	(7,521)
Net loss	(29,540)	(1,283)	(18,926)	(30,113)	(39,834)
Less: Net loss attributable to noncontrolling interests	(492)				
Net loss attributable to common shareholders before preferred stock dividend	(29,048)	(1,283)	(18,926)	(30,113)	(39,834)
Preferred stock dividend	(2,240)	(2,379)	(2,624)	(4,718)	(217)
Net loss attributable to common shareholders	$ (31,288)	$ (3,662)	$ (21,550)	$ (34,831)	$ (40,051)
(Loss) income per share, basic and diluted:					
Loss from continuing operations	$ (0.11)	$ (0.03)	$ (0.06)	$ (0.12)	$ (0.17)
Income (loss) from discontinued operations	$ 0.00	$ 0.02	$ (0.02)	$ (0.03)	$ (0.04)
Net loss per share	$ (0.11)	$ (0.01)	$ (0.08)	$ (0.15)	$ (0.21)

Weighted average number of common shares outstanding basic and diluted:	295,750,077	280,673,122	255,095,586	233,191,617	187,713,041
Balance sheet data:					
Total assets	$ 289,830	$ 229,489	$ 77,846	$ 87,430	$ 21,764
Working capital	$ 26,275	$ 80,804	$ 29,793	$ 50,795	$ 5,754
Long-term liabilities	$ 34,168	$ 25,443	$ 7,908	$ 11,932	$ 11,867
Series D Preferred Stock	$ 24,386	$ 24,386	$ 26,128	$ 26,128	$
Shareholders equity	$ 179,386	$ 160,882	$ 23,052	$ 31,599	$ 359
Total equity	$ 178,894	$ 160,882	$ 23,052	$ 31,599	$ 359

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA), Section 27A of the Securities Act of 1933, as amended, (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, (the Exchange Act), about our expectations, beliefs, or intentions regarding our product development efforts, business, financial condition, results of operations, strategies, or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends, or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those contained in Item 1A Risk Factors of this Annual Report on Form 10-K. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe harbor provisions of PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

OVERVIEW

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including molecular diagnostics tests, laboratory developed tests (LTDs), point-of-care tests and proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets.

We own established pharmaceutical platforms in Spain, Chile and Mexico, which are generating revenue and from which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We also recently established pharmaceutical operations in Brazil. We operate a specialty active pharmaceutical ingredients (APIs) manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products. We operate a CLIA-certified laboratory facility headquartered in Nashville, Tennessee that currently operates as a full-service medical laboratory specializing in urologic pathology, and will provide us with a platform to commercialize certain of our novel diagnostics tests currently in development. During the year ended December 31, 2012, we completed a number of strategic transactions including:

In December 2012, we entered into an agreement with Bristol-Myers Squibb expanding our collaboration related to our molecular diagnostic test technology.

In December 2012, we completed the acquisition of Prost-Data, Inc. (OURLab), a Nashville-based CLIA laboratory with 18 phlebotomy sites throughout the U.S.

In October 2012, we completed the acquisition of a forty-five percent stake in SciGen (I.L.) Ltd (SciGen), an Israeli company that produces a third-generation hepatitis B vaccine in its biologics manufacturing facility in Rehovot, Israel.

In August 2012, we acquired all of the outstanding stock of Farmadiet Group Holding, S.L. (Farmadiet), a Spanish company engaged in the development, manufacture, marketing, and sale of pharmaceutical, nutraceutical, and veterinary products in Europe.

In April 2012, we completed the acquisition of ALS Distribuidora Limitada (ALS), a privately-held Chilean pharmaceutical company, pursuant to a stock purchase agreement.

In March 2012, we announced a collaboration with Laboratory Corporation of America (LabCorp), an S&P 500 company and pioneer in commercializing new diagnostic technologies, for LabCorp to complete the development of and later commercialize laboratory testing for Alzheimer s disease.

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In February 2012, we purchased from Biozone Pharmaceuticals, Inc. (BZNE), a publicly-traded company that specializes in drug development, manufacturing, and marketing, $1.7 million of 10% secured convertible promissory notes (the BZNE Notes), and ten year warrants (the BZNE Warrants) to purchase 8.5 million shares of BZNE common stock. In July 2012, we exercised the BZNE Warrants using their cashless net exercise feature and received 7,650,000 shares of BZNE common stock. We also entered into a license agreement pursuant to which we acquired a world-wide license for the development and commercialization of products utilizing BZNE s proprietary drug delivery technology, including a technology called QuSomes, exclusively for OPKO in the field of ophthalmology and non-exclusive for all other therapeutic fields, subject in each case to certain excluded products.

In February 2012, we made a $1.0 million investment in ChromaDex Corporation (ChromaDex), a publicly-traded company and leading provider of proprietary ingredients and products for the dietary supplement, nutraceutical, food and beverage, functional food, pharmaceutical and cosmetic markets. We also entered into a license, supply and distribution agreement with ChromaDex pursuant to which we obtained exclusive distribution rights to certain of its products in Latin America.

RECENT DEVELOPMENTS

On March 12, 2013, we completed the sale to RXi Pharmaceuticals Corporation (RXi) of substantially all of our assets in the field of RNA interference (the RNAi Assets) (collectively, the Asset Purchase Agreement). As consideration for the RNAi Assets, at the closing of the Asset Purchase Agreement, RXi issued to us 50 million shares of its common stock (the APA Shares). In addition, pursuant to the Asset Purchase Agreement, RXi will be required to pay us up to $50 million in milestone payments upon the successful development and commercialization of each drug developed by RXi, certain of its affiliates or any of its or their licensees or sublicensees utilizing patents included within the RNAi Assets (each, a Qualified Drug). In addition, RXi will be required to pay us royalties equal to: (a) a mid single-digit percentage of Net Sales (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable Royalty Period (as defined in the Asset Purchase Agreement); and (b) a low single-digit percentage of net sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable royalty period.

On March 4, 2013, we acquired Cytochroma Inc., a corporation located in Markham, Canada (Cytochroma), whose lead products, both in Phase 3 development, are CTAP101 Capsules, a vitamin D prohormone to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, and Fermagate Tablets, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the Cytochroma Acquisition).

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In connection with the Cytochroma Acquisition, OPKO IP Holdings, Inc., our indirect wholly-owned subsidiary paid $100.0 million in shares of our Common Stock, par value $0.01 per share, based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the date of the purchase agreement for the Cytochroma Acquisition, or $4.87 per share (the Stock Consideration). In connection with the Cytochroma Acquisition, we issued 20,517,030 shares of our Common Stock at the closing. The Cytochroma Agreement contains customary representations, warranties, conditions to closing, indemnification rights and obligations of the parties.

In addition, the Cytochroma Acquisition requires payments of up to an additional $190.0 million in cash or additional shares of our Common Stock, at our election, upon the achievement of certain milestones relating to development and annual revenue.

On March 1, 2013, our Board of Directors declared a cash dividend to all Series D Preferred stockholders as of March 8, 2013. The total cash dividend paid was approximately $3.0 million. In addition, the Company also exercised its option to convert all 1,129,032 shares of our outstanding Series D Preferred Stock into 11,290,320 shares of our Common Stock effective of March 8, 2013. Following the conversion there are no outstanding shares of Series D Preferred Stock.

On January 29, 2013, we entered into note purchase agreements, dated January 25, 2013, with various purchasers (collectively, the Purchasers) for the sale of $175.0 million aggregate principal amount of 3.00% convertible senior notes due 2033 (the Notes) to qualified institutional buyers and accredited investors (collectively, the Note Purchase Agreement) in a private placement in reliance on exemptions from registration under the Securities Act of 1933 (the Securities Act). The Purchasers of the Notes include Frost Gamma Investments Trust, a trust affiliated with Dr. Phillip Frost, our Chairman and Chief Executive Officer, and Hsu Gamma Investment, L.P., an entity affiliated with Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer. The Notes were issued on January 30, 2013.

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RESULTS OF OPERATIONS

For The Years Ended December 31, 2012 and December 31, 2011

Revenues. Revenues for the year ended December 31, 2012 increased approximately 68% to $47.0 million from $28.0 million for the year ended December 31, 2011. The increase in revenues for the year ended December 31, 2012 was primarily due to $7.1 million of revenue generated by FineTech, which we acquired in December 2011, $6.1 million of revenue generated by Farmadiet, which we acquired in August 2012, an increase of $5.0 million of revenue generated in Chile primarily related to our acquisition of ALS in April 2012 and $0.6 million of revenue generated by SciGen, a consolidated variable interest entity in which we have a forty-five percent stake.

Gross margin. Gross margin for the year ended December 31, 2012 was $19.2 million compared to $10.7 million for the year ended December 31, 2011. Gross margin for the year ended December 31, 2012 increased from the comparable period of 2011 primarily as a result of $3.4 million of gross margin generated by Farmadiet and $5.4 million of gross margin generated by FineTech. The gross margin increase was partially offset by decreased gross margins in our Chilean and Mexican operations primarily as a result of product pricing pressures experienced in those markets.

Selling, general and administrative expenses. Selling, general and administrative expenses for the year ended December 31, 2012 were $27.8 million, compared to $19.2 million for the year ended December 31, 2011. Selling, general and administrative expenses increased primarily as a result of the 2012 full year impact of expenses, of $0.8 million, related to Claros Diagnostics Inc. (OPKO Diagnostics) and FineTech, which were acquired in October and December 2011, respectively, and $5.0 million of expenses related to ALS, Farmadiet, SciGen and OURLab, which were acquired in 2012. Selling, general and administrative expenses consist primarily of personnel expenses, including equity-based compensation of $3.1 million and $3.0 million for the years ended December 31, 2012 and 2011, respectively.

Research and development expenses. Research and development expenses for the year ended December 31, 2012 were $19.5 million, compared to $11.4 million for the year ended December 31, 2011. Research and development expenses for the year ended December 31, 2012 increased primarily due to the 2012 activities related to our molecular diagnostics development programs and for OPKO Diagnostics, of $6.1 million, which we acquired in October 2011. This increase was partially offset by lower equity based compensation expense due to decreased mark to market adjustments for certain of our consultant stock option awards. Equity based compensation expenses included in research and development expenses were $2.0 million and $4.0 million, respectively, for the years ended December 31, 2012 and 2011. During the year ended December 31, 2012, we received $0.3 million in NASA development grants. During the year ended December 31, 2011 we received $0.7 million of grants under the New Qualifying Therapeutic Discovery Project Credit (or Grant) program for expenditures related to certain development programs. In addition, during the years ended December 31, 2012 and 2011, we received $0.2 million and $0.6 million of research and development grants for development programs in Mexico. These grants were recorded as an offset to research and development expenses.

Contingent consideration. Contingent consideration expenses, which represented the change in the fair value of the contingent consideration liabilities due to the time value of money and changes in the timeline of the development milestones being achieved, were $0.8 million for the year ended December 31, 2012, Contingent consideration liabilities relates to potential amounts payable to former stockholders of Farmadiet, FineTech, OPKO Diagnostics, and CURNA, Inc. pursuant to our acquisition agreements in August 2012, December 2011, October 2011, and January 2011, respectively. The comparable period of 2011 did not include any such expenses.

Amortization of intangible assets. Amortization of intangible assets was $8.3 million for the year ended December 31, 2012, compared to $3.4 million for the year ended December 31, 2011. Amortization expenses increased primarily due to the acquisitions of Farmadiet, ALS, FineTech, and OPKO Diagnostics in August 2012, April 2012, December 2011, and October 2011, respectively.

Other income and (expense), net. Other income, net was $56 thousand for the year ended December 31, 2012, compared to other expense, net of $1.0 million for the year ended December 31, 2011. For the year ended December 31, 2012, other income, net included $1.5 million of other income recognized for the change in fair value of the warrants received in connection with our investment in BZNE, partially offset by other expense recognized for the decrease in fair value of the warrants received in connections with our investment in Neovasc Inc. (Neovasc). Other income and (expense), net also included our interest incurred on our lines of credit in Chile and Spain, our interest expense related to the discount amortization of the

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Deferred Payments in Spain, partially offset by interest earned on our cash and cash equivalents and the benefits from our Chilean and Mexico operations functional currencies strengthening during the year ended December 31, 2012. For the year ended December 31, 2011, other expense, net consisted of our interest incurred on our lines of credit in Chile and foreign currency expense, partially offset by interest earned on our cash and cash equivalents.

Loss from investment in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder. We account for five of these investments under the equity method of accounting, resulting in our recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investee s technologies are commercialized, if ever, we anticipate they will continue to report a net loss. During the year ended December 31, 2012, the losses from our strategic investments increased to $2.1 million from $1.6 million in 2011 as the result of increased losses at our investees. As of December 31, 2012, we have $15.6 million, net, of strategic investments recorded on our Consolidated Balance Sheets.

Discontinued operations. Income from discontinued operations was $0.1 million for the year ended December 31, 2012 compared to $5.2 million for the year ended December 31, 2011. The income for the year ended December 31, 2012 reflected the recovery of certain retained accounts receivable from our ophthalmic instrumentation business following the October 2011 sale of such business to Optos, Inc., a subsidiary of Optos plc (collectively, Optos). The income from discontinued operations for the year ended December 31, 2011 reflected a gain of $10.6 million recorded in connection with the sale of our ophthalmic instrumentation business, which included the cash consideration received less the net assets transferred to Optos.

Income taxes. Our income tax benefit from continuing operations for the year ended December 31, 2012 was 9.6 million, compared to $19.4 million for the year ended December 31, 2011. The decrease in income tax benefit for the 2012 period is primarily the result of lower values assigned to the amortizing intangible assets related to the acquisition of OURLab compared to the OPKO Diagnostics acquisition in 2011. We have recorded a full valuation allowance against our net deferred tax assets in the U.S. for the years ended December 31, 2012 and 2011.

For The Years Ended December 31, 2011 and December 31, 2010

Revenues. Revenues for the year ended December 31, 2011 were $28.0 million, compared to $28.5 million for the year ended December 31, 2010. Revenues from our pharmaceutical products increased during 2011 compared to 2010, primarily related to an increase in revenues of $6.1 million in our pharmaceutical business in Chile and Mexico as the number of customers in each country increased. This increase was offset by a decrease in license revenue. In December 2010, we out-licensed our NK-1 development program to TESARO, Inc. (TESARO) for an upfront cash payment of $6.0 million, future milestone payments of up to $115.0 million, 1.5 million shares of TESARO Series O Preferred Stock (TESARO Preferred Stock) and royalty payments on future sales. We recorded the TESARO Preferred Stock at fair value and recognized $6.7 million as license revenue, including $6.0 million in cash for the year ending December 31, 2010.

Gross margin. Gross margin for the year ended December 31, 2011 was $10.7 million, compared to $15.0 million for the year ended December 31, 2010. Gross margin decreased during 2011 from gross margin in 2010. During the year ended December 31, 2010, license revenue included $6.7 million related to TESARO, with no associated cost of revenues. The decrease in gross margin was partially offset by increased gross margin generated by our pharmaceutical business through our operations in Chile and Mexico.

Selling, general and administrative expenses. Selling, general and administrative expenses for the year ended December 31, 2011 were $19.2 million, compared to $18.1 million for the year ended December 31, 2010. Selling, general and administrative expenses increased primarily as a result of expenses related to our pharmaceutical businesses in Chile and Mexico. This increase was partially offset by decreased equity based compensation expense reflecting $3.0 million and $4.8 million of equity based compensation expense for the years ended December 31, 2011 and 2010, respectively.

Research and development expenses. Research and development expenses for the year ended December 31, 2011 were $11.4 million, compared to $5.9 million for the year ended December 31, 2010. Research and development expenses increased during 2011 primarily as a result of personnel costs, including equity based compensation, to support increased activities for our molecular diagnostic programs and development activities related to our CURNA, Inc. and our point-of-care technology acquired from OPKO Diagnostics. Research and development expenses during the year December 31, 2010 included activities related

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to our rolapitant development program prior to its licensure to TESARO. Included in research and development expense were $4.0 million and $1.7 million of equity based compensation expense for the years ended December 31, 2011 and 2010, respectively. During 2011, we received $1.3 million in research and development grants from the Mexican government and under the New Qualifying Therapeutic Discovery Project Credit in the U.S. During 2010, we received $0.3 million in research and development grants from the Mexican government. These grants were recorded as an offset to research and development expenses during both years.

Amortization of intangible assets. Amortization of intangible assets was $3.4 million for the year ended December 31, 2011, compared to $2.1 million for the year ended December 31, 2010. Amortization expense increased primarily due to our acquisitions of CURNA, OPKO Diagnostics, and FineTech.

Other income and (expense), net. Other expense net was $1.0 million for the year ended December 31, 2011, compared to $0.8 million for the year ended December 31, 2010. Other income and (expense), net primarily consisted of interest expense on our Chilean lines of credit and foreign currency expense for the year ended December 31, 2011, partially offset by interest earned on our cash and cash equivalents. For the year ended December 31, 2010, other expense, net primarily reflected the interest incurred on our line of credit with The Frost Group LLC (the Frost Group) as well as interest expense incurred on our Chilean lines of credit. In June 2010, we repaid all amounts outstanding on the Frost Group line of credit including $12.0 million in principal and $4.1 million in interest. The Frost Group members include a trust controlled by Dr. Frost, who is the Company s Chief Executive Officer and Chairman of the Board of Directors, Dr. Jane H. Hsiao, who is the Vice Chairman of the Board of Directors and Chief Technical Officer and Steven D. Rubin who is Executive Vice President Administration and a director of the Company.

Loss from investment in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder. In connection with our investments, we account for these investments under the equity method of accounting, resulting in our recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investee s technologies are commercialized, if ever, we anticipate they will continue to report a net loss. During the year ended December 31, 2011 the losses from our strategic investments increased to $1.6 million from $0.7 million. This increase is principally the result of increased losses at our investees. In addition to our losses from Sorrento and Cocrystal, we invested in Neovasc during 2011, and a full year of losses from Fabrus, which we invested in November 2010. As of December 31, 2011 we have $6.7 million, net, of strategic investments recorded on our balance sheet.

Discontinued operations. Income from discontinued operations was $5.2 million for the year ended December 31, 2011 compared to a loss of $6.3 million for the year ended December 31, 2010. In September 2011, we entered into an agreement with Optos to sell our ophthalmic instrumentation business. Upon closing in October 2011, we received $17.5 million of cash and are eligible to receive royalties up to $22.5 million on future sales. In connection with the sale, we recorded a gain of $10.6 million reflecting the cash consideration received less the net assets transferred to Optos. The loss incurred during the year ended December 31, 2010 primarily reflected the operating results of our ophthalmic instrumentation business.

Income taxes. Our income tax benefit from continuing operations for the year ended December 31, 2011 was $19.4 million, compared to $18 thousand for the year ended December 31, 2010. The increase in income tax benefit for the year ended December 31, 2011 period was primarily the result of recording a deferred tax liability related to the amortizing intangible assets acquired as part of the OPKO Diagnostics transaction. In connection with the recognition of the deferred tax liability, we reduced the amount of valuation allowance recorded against our deferred tax assets for the year ended December 31, 2011.

Liquidity and Capital Resources

At December 31, 2012, we had cash and cash equivalents of approximately $27.4 million, compared to $71.5 million on December 31, 2011. Cash used in operations during 2012 primarily reflects expenses related to selling, general and administrative activities related to our corporate operations, research and development activities and our operations in Chile, Spain, and Mexico, partially offset by cash provided from our operations in Israel. Cash used in investing activities primarily reflects $22.4 million used to acquire ALS, Farmadiet, and OURLab and to invest in BZNE, Chromadex and SciGen. Cash provided by financing activities primarily reflects $2.3 million received from Common Stock option and Common Stock warrant exercises. Since our inception, we have not generated sufficient gross margins to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock and credit facilities available to us.

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In connection with the acquisition of ALS, we paid (i) $2.4 million in cash at the closing, less certain liabilities, and (ii) $0.8 million in cash at the closing into a separate escrow account to satisfy possible indemnity claims. We agreed to pay the remaining $0.8 million of the $4.0 million purchase price, upon the legal registration in the name of ALS of certain trademarks and product registrations previously held by the seller, Arama Laboratorios y Compañía Limitada.

In connection with the acquisition of Farmadiet, we paid 6.8 million (US$8.4 million) at closing and have deferred payments in the amount of 6.8 million (US$ 8.9 million at December 31, 2012) which will be paid, at our option, in cash or shares of our Common Stock, as follows: (x) 3.4 million (US$4.5 million) to be paid on the first anniversary of the closing date; and (y) 3.4 million (US$4.5 million) to be paid 18 months after the closing date. We also entered into two ancillary transactions which require additional payments including the issuance of 125,000 shares of our Common Stock upon achieving certain milestones and 0.75 million (US$1.0 million) will be paid in cash or shares of Common Stock upon achieving other milestones, at our option. In the event we elect to make the payment in shares of our Common Stock, the number of shares issuable shall be calculated using the average closing sales price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the applicable payment date.

In December 2012, we completed the acquisition of OURLab. In connection with the transaction, we paid an aggregate purchase price of $42.3 million, of which $9.4 million was in cash, and issued 7,072,748 shares of Common Stock at closing, of which 1,732,102 shares of our Common Stock are being held in escrow for indemnity claims.

In connection with the March 2013 Cytochroma Acquisition, we paid $100.0 million in shares of our Common Stock, based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the date of the entering into the agreement, or $4.87 per share. We issued 20,517,030 shares of our Common Stock to the seller at the closing. In addition, the agreement provides for the payment of up to an additional $190.0 million in cash or additional shares of our Common Stock, at our election, upon the achievement of certain milestones relating to development and annual revenue. If we elect to pay any portion of the Milestone Consideration in shares of our Common Stock, the amount of shares to be issued will be based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding: (i) the milestone being achieved in the case of development milestones; or (ii) the earlier of the completion of the audit of our financial statements or the 105th day after the end of the applicable calendar year in the case of revenue milestones. In certain circumstances, the payment of the Milestone Consideration shall be made by us in cash, including if payment in shares of our Common Stock would trigger an obligation to obtain the approval of our shareholders under applicable securities laws or NYSE regulations.

On January 29, 2013, we entered into, the Note Purchase Agreement in a private placement in reliance on exemptions from registration under the Securities Act. The Purchasers of the Notes include Frost Gamma Investments Trust, a trust affiliated with Dr. Phillip Frost, our Chairman and Chief Executive Officer, and Hsu Gamma Investment, L.P., an entity affiliated with Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer. The Notes were issued on January 30, 2013. The Notes, which total $175.0 million, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year, beginning August 1, 2013. The Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change (as defined in the Indenture), subject to certain exceptions, the holders may require us to repurchase all or any portion of their Notes for cash at a repurchase price equal to 100% of the principal amount of the Notes being repurchased, plus any accrued and unpaid interest to but not including the fundamental change repurchase date.

The Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, under the following circumstances: (1) conversion based upon satisfaction of the trading price condition relating to the Notes; (2) conversion based on the Common Stock price; (3) conversion based upon the occurrence of specified corporate events; or (4) if we call the Notes for redemption. The Notes will be convertible into cash, shares of our

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Common Stock, or a combination of cash and shares of Common Stock, at our election unless we have made an irrevocable election of net share settlement. The initial conversion rate for the Notes will be 141.4827 shares of Common Stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $7.07 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events. In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their Notes in connection with a make-whole fundamental change (as defined in the Indenture) and holders who convert upon the occurrence of certain specific events prior to February 1, 2017 (other than in connection with a make-whole fundamental change).

We may not redeem the Notes prior to February 1, 2017. On or after February 1, 2017 and before February 1, 2019, we may redeem for cash any or all of the Notes but only if the last reported sale price of our Common Stock exceeds 130% of the applicable conversion price for at least 20 trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date on which we deliver the redemption notice. The redemption price will equal 100% of the principal amount of the Notes to be redeemed, plus any accrued and unpaid interest to but not including the redemption date. On or after February 1, 2019, we may redeem for cash any or all of the Notes at a redemption price of 100% of the principal amount of the Notes to be redeemed, plus any accrued and unpaid interest to but not including the redemption date.

In connection with our acquisitions of CURNA, OPKO Diagnostics and FineTech, we agreed to pay future consideration to the sellers upon the achievement of certain events, including minimum cash payments of $5.0 million to the former stockholder of FineTech upon the achievement of certain sales milestones, and up to an additional $19.1 million in shares of the our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones.

As of December 31, 2012, we had outstanding lines of credit in the aggregate amount of $15.2 million with 16 financial institutions in Chile and Spain, of which $7.7 million is unused. The weighted average interest rate on these lines of credit is approximately 6.5%. These lines of credit are short-term and are generally due within three months. These lines of credit are used primarily as a source of working capital for inventory purchases. The highest balance at any time during the year ended December 31, 2012 was $16.4 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that this or other funding sources will be available to us on acceptable terms, or at all, in the future.

We expect to incur losses from operations for the foreseeable future. We expect to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure.

We believe the cash, cash equivalents and marketable securities on hand at December 31, 2012, the net proceeds of $170.5 million from our January 2013 convertible debt offering, and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

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The following table provides information as of December 31, 2012 with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations

(In thousands)	2013	2014	2015	2016	2017	After 2018	Total
Open purchase orders	$ 4,183	$	$	$	$	$	$ 4,183
Operating leases	2,007	1,750	1,288	1,134	705	1,849	8,733
Mortgages and other debts payable[(1)]	2,208	629	540	415	375	2,080	6,247
Credit lines	15,195						15,195
Total	$ 23,593	$ 2,379	$ 1,828	$ 1,549	$ 1,080	$ 3,929	$ 34,358

(1) Excludes $1.2 million of consolidated liabilities related to SciGen, as to which there is no recourse against us.

The preceding table does not include information where the amounts of the obligations are not currently determinable, including contractual obligations in connection with product license agreements and contingent consideration that includes payments upon achievement of certain milestones.

Critical Accounting Policies and Estimates

Accounting estimates. The preparation of financial statements in conformity with generally accepted accounting principles requires management 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 sales and expenses during the reporting period. Actual results could differ from those estimates.

Equity-based compensation. We recognize equity based compensation as an expense in our financial statements and that cost is measured at the fair value of the awards and expensed over their vesting period. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the Black-Scholes Model and allocate the resulting compensation expense over the corresponding requisite service period associated with each grant. The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform significant analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model. We also perform significant analyses to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates may have a material impact on our Consolidated Financial Statements.

Goodwill and intangible assets. The allocation of the purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

Purchase price allocations and appraisals inherently require significant estimates and assumptions, including but not limited to, determining the timing and estimated costs to complete the in-process research and development projects, projecting regulatory approvals, estimating future cash flows, and developing appropriate discount rates. We believe the estimated fair values assigned to the ALS, Farmadiet, and OURLab assets acquired and liabilities assumed are based on reasonable assumptions. However, the fair value estimates for the purchase price allocation may change during the allowable allocation period, which is up to one year from the acquisition date, if additional information becomes available that would require changes to our estimates.

Inventories. Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost or market.

Allowance for doubtful accounts and revenue recognition. Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns are based upon the historical patterns of products returned matched against the sales from which they originated, and management s evaluation of specific factors that may increase the risk of product returns. We analyze accounts

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receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by management s estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our consolidated balance sheets at December 31, 2012 and 2011 was $0.5 million and $0.4 million, respectively.

Recent accounting pronouncements. On January 1, 2012, we adopted an amendment issued by the Financial Accounting Standards Board (FASB) to the accounting standards related to fair value measurement and disclosure requirements. This amendment revises the existing guidance on the use and application of fair value measurements and maintains a definition of fair value that it is based on the notion of exit price. The adoption of this amendment did not have a material impact on our consolidated financial statements.

On January 1, 2012, we adopted amendments issued by the FASB to the accounting standards related to comprehensive income. These amendments revise the manner in which entities present comprehensive income in their financial statements and remove the option to present items of other comprehensive income in the statement of changes in stockholders equity. These amendments require an entity to report components of comprehensive income in either (1) a continuous statement of comprehensive income, or (2) two separate but consecutive statements of net income and other comprehensive income. We modified our consolidated financial statements presentation using the latter alternative.

On January 1, 2012, we adopted revised guidance issued by the FASB related to the testing of goodwill for impairment. Under the revise guidance, an entity has the option to perform a qualitative assessment of whether it is more-likely-than-not that a reporting unit s fair value is less than its carrying value prior to performing the two-step quantitative goodwill impairment test. If, based on the qualitative factors, an entity determines that the fair value of the reporting unit is greater than its carrying amount, then the entity would not be required to perform the two-step quantitative impairment test for that reporting unit. However, if the qualitative assessment indicates that it is not more-likely-than-not that the reporting unit s fair value exceeds its carrying value, then the quantitative assessment must be performed. An entity is permitted to perform the qualitative assessment on none, some or all of its reporting units and may also elect to bypass the qualitative assessment and begin with the quantitative assessment of goodwill impairment. This amendment did not have a material impact in our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

Foreign Currency Exchange Rate Risk Although we do not speculate in the foreign exchange market, we may from time to time manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions are hedged with foreign exchange forward contracts. As exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated at current spot rates, with gains and losses included in earnings.

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the Consolidated Statement of Operations at maturity, and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. We had $1.3 million in foreign exchange forward contracts outstanding at December 31, 2012 primarily to hedge Chilean-based operating cash flows against U.S. dollars. If Chilean Pesos were to strengthen in relation to the U.S. dollar, our loss or gain on hedged foreign currency cash-flows would be offset by the derivative contracts, with a net effect of zero.

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or other than trading instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price, or equity price risk.

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Interest Rate Risk Our exposure to market risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment. At December 31, 2012, we had cash and cash equivalents of $27.4 million. The weighted average interest rate related to our cash and cash equivalents for the year ended December 31, 2012 was 0.0%. As of December 31, 2012, the principal value of our credit lines was $15.2 million at a weighted average interest rate of approximately 6.5%.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and money market funds that invest in such debt instruments, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of OPKO Health, Inc. and subsidiaries

We have audited the accompanying consolidated balance sheets of OPKO Health, Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, shareholders equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of OPKO Health, Inc. and subsidiaries at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), OPKO Health, Inc. and subsidiaries internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Certified Public Accountants

Miami, Florida

March 18, 2013

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of OPKO Health, Inc. and subsidiaries

We have audited OPKO Health, Inc. and subsidiaries internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). OPKO Health, Inc. and subsidiaries management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed 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. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying Management s Annual Report on Internal Control Over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Farmadiet Group Limited, Prost-Data, Inc. (d/b/a OURLab) or SciGen (I.L.) Ltd., which are included in the December 31, 2012 consolidated financial statements of OPKO Health, Inc. and subsidiaries and constituted, in the aggregate, $90.4 million of total assets and $57.8 million of net assets as of December 31, 2012 and $7.1 million of revenues and $4.9 million of net income included in the Company s net loss for the year then ended. Our audit of internal control over financial reporting of OPKO Health, Inc. and subsidiaries also did not include an evaluation of the internal control over financial reporting of Farmadiet Group Limited, Prost-Data, Inc. or SciGen (I.L.) Ltd.

In our opinion, OPKO Health, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of OPKO Health, Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, shareholders equity and cash flows for each of the three years in the period ended December 31, 2012 of OPKO Health, Inc. and subsidiaries, and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Certified Public Accountants

Miami, Florida

March 18, 2013

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OPKO Health, Inc. and Subsidiaries

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2012[1]	2011
ASSETS		
Current assets		
Cash and cash equivalents	$ 27,361	$ 71,516
Accounts receivable, net	21,162	12,544
Inventory, net	22,261	13,339
Prepaid expenses and other current assets	7,873	2,179
Current assets of discontinued operations		4
Total current assets	78,657	99,582
Property, plant, equipment, and investment properties, net	16,526	5,358
Intangible assets, net	95,784	76,730
Goodwill	80,450	39,815
Investments, net	15,636	6,717
Other assets	2,777	1,287
Total assets	$ 289,830	$ 229,489
LIABILITIES, SERIES D PREFERRED STOCK AND EQUITY		
Current liabilities		
Accounts payable	$ 10,200	$ 4,891
Accrued expenses	24,656	4,956
Current portion of lines of credit and notes payable	17,526	8,757
Current liabilities of discontinued operations		174
Total current liabilities	52,382	18,778
Other long-term liabilities, principally contingent consideration and deferred tax liabilities	34,168	25,443
Total liabilities	86,550	44,221
Commitments and contingencies		
Series D Preferred Stock $0.01 par value, 2,000,000 shares authorized; 1,129,032 and 1,129,032 shares issued and outstanding (liquidation value of $30,595 and $28,355) at December 31, 2012 and 2011, respectively	24,386	24,386
Equity		
Series A Preferred Stock $0.01 par value, 4,000,000 shares authorized; no shares issued or outstanding at December 31, 2012 or 2011		
Series C Preferred Stock $0.01 par value, 500,000 shares authorized; no shares issued or outstanding at December 31, 2012 or 2011		
Common Stock $0.01 par value, 500,000,000 shares authorized; 305,560,763 shares and 297,503,033 shares issued and outstanding at December 31, 2012 and 2011, respectively	3,056	2,975
Treasury stock (2,293,056 shares and 2,488,477 shares at December 31, 2012 and 2011, respectively)	(7,457)	(8,092)
Additional paid-in capital	565,201	524,814
Accumulated other comprehensive income	7,356	907
Accumulated deficit	(388,770)	(359,722)
Total shareholders equity	179,386	160,882
Noncontrolling interests	(492)	

Total equity	178,894	
Total liabilities, Series D Preferred Stock and equity	$ 289,830	$ 229,489

(1) As of December 31, 2012, total assets include $5.6 million and total liabilities include $5.5 million related to SciGen (I.L.) Ltd, (SciGen), a consolidated variable interest entity. SciGen s consolidated assets are owned by SciGen and SciGen s consolidated liabilities are those as to which there is no recourse against us. Refer to Note 3.

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share data)

	For the years ended December 31,		
	2012	2011	2010
Revenues:			
Products	$ 45,295	$ 27,844	$ 21,763
Revenue from services	1,749	135	
License revenue			6,731
Total revenues	47,044	27,979	28,494
Cost of revenues, excluding amortization of intangible assets	27,878	17,243	13,495
Gross margin, excluding amortization of intangible assets	19,166	10,736	14,999
Operating expenses:			
Selling, general and administrative	27,795	19,169	18,133
Research and development	19,520	11,352	5,949
Contingent consideration	785		
Amortization of intangible assets	8,335	3,404	2,053
Total operating expenses	56,435	33,925	26,135
Operating loss from continuing operations	(37,269)	(23,189)	(11,136)
Other income and (expense), net:			
Interest income	188	288	24
Interest expense	(1,405)	(1,005)	(1,215)
Other income (expense), net	1,273	(327)	347
Other income and (expense), net	56	(1,044)	(844)
Loss from continuing operations before income taxes and investment losses	(37,213)	(24,233)	(11,980)
Income tax benefit	9,626	19,358	18
Loss from continuing operations before investment losses	(27,587)	(4,875)	(11,962)
Loss from investments in investees	(2,062)	(1,589)	(714)
Loss from continuing operations	(29,649)	(6,464)	(12,676)
Income (loss) from discontinued operations, net of tax	109	5,181	(6,250)
Net loss	(29,540)	(1,283)	(18,926)
Less: Net loss attributable to noncontrolling interests	(492)		
Net loss attributable to common shareholders before preferred stock dividend	(29,048)	(1,283)	(18,926)
Preferred stock dividend	(2,240)	(2,379)	(2,624)
Net loss attributable to common shareholders	$ (31,288)	$ (3,662)	$ (21,550)
(Loss) income per share, basic and diluted:			
Loss from continuing operations	$ (0.11)	$ (0.03)	$ (0.06)

Income (loss) from discontinued operations	$ 0.00	$ 0.02	$ (0.02)
Net loss per share	$ (0.11)	$ (0.01)	$ (0.08)
Weighted average number of common shares outstanding, basic and diluted	295,750,077	280,673,122	255,095,586

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	For the years ended December 31,		
	2012	2011	2010
Net loss attributable to common shareholders	$ (31,288)	$ (3,662)	$ (21,550)
Other comprehensive income (loss), net:			
Change in foreign currency translation	2,289	(2,398)	1,608
Available for sale investments:			
Change in unrealized gains, net	4,160	384	
Comprehensive loss	$ (24,839)	$ (5,676)	$ (19,942)

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(In thousands, except share and per share data)

For the years ended December 31, 2010, 2011, and 2012

	Series A Preferred Stock		Common Stock		Treasury		Additional Paid-In Capital	Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total
	Shares	Dollars	Shares	Dollars	Shares	Dollars					
Balance at December 31, 2009	1,025,934	$ 10	253,762,552	$ 2,538	(45,154)	$ (61)	$ 367,028	$ 1,313	$ (339,229)	$	$ 31,599
Equity-based compensation expense							6,922				6,922
Exercise of Common Stock options			150,231	2			72				74
Series A Preferred Stock dividend									(224)		(224)
Conversion of Series A Preferred Stock	(128,495)	(1)	128,495	1							
Issuance of Common Stock to acquire Pharmacos Exakta at $1.46 per share			1,371,428	13			1,986				1,999
Net loss attributable to OPKO Health for the year ended December 31, 2010									(18,926)		(18,926)
Cumulative translation adjustment net								1,608			1,608
Balance at December 31, 2010	897,439	$ 9	255,412,706	$ 2,554	(45,154)	$ (61)	$ 376,008	$ 2,921	$ (358,379)	$	$ 23,052
Equity-based compensation expense							7,155				7,155
Exercise of Common Stock options			422,500	4			980				984
Exercise of Common Stock warrants			2,925,894	29			231				260
Series A Preferred Stock dividend									(60)		(60)
Conversion of Series A Preferred Stock	(294,680)	(3)	294,680	3							
Redemption of Series A Preferred Stock	(602,759)	(6)					(1,501)				(1,507)
Series D Preferred Stock conversion			940,141	10			1,732				1,742
Series D Preferred Stock dividend							(4,704)				(4,704)
Issuance of Common Stock at $3.75 per share			29,397,029	294			104,534				104,828
Repurchase of Common Stock at $3.27 per share					(2,398,740)	(7,832)					(7,832)
Issuance of Common Stock in connection with OPKO Diagnostics acquisition at $5.04 per share			4,494,380	45	(44,583)	(199)	22,606				22,452
			3,615,703	36			17,681				17,717

Issuance of Common Stock in connection with FineTech acquisition at $4.90 per share								
Exakta-OPKO purchase price adjustment					92			92
Net loss for the year ended December 31, 2010							(1,283)	(1,283)
Other comprehensive loss						(2,014)		(2,014)
Balance at December 31, 2011	$ 297,503,033	$ 2,975	(2,488,477)	$ (8,092)	$ 524,814	$ 907	$ (359,722)	$ $ 160,882

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OPKO Health, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(In thousands, except share and per share data)

For the years ended December 31, 2010, 2011, and 2012 (continued)

	Series A Preferred Stock		Common Stock		Treasury		Additional Paid-In	Other Comprehensive	Accumulated	Noncontrolling	
	Shares	Dollars	Shares	Dollars	Shares	Dollars	Capital	Income	Deficit	Interests	Total
Balance at December 31, 2011		$	297,503,033	$ 2,975	(2,488,477)	$ (8,092)	$ 524,814	$ 907	$ (359,722)	$	$ 160,882
Equity-based compensation expense							5,131				5,131
Exercise of Common Stock options			1,019,967	10			2,224				2,234
Exercise of Common Stock warrants			65,015	1			44				45
Adjustment of Common Stock			(100,000)	(1)			1				
Issuance of Common Stock from Treasury in connection with Farmadiet acquisition at $4.12 per share					195,421	635	170				805
Issuance of Common Stock in connection with OURLab acquisition at $4.65 per share			7,072,748	71			32,817				32,888
Net loss attributable to common shareholders before preferred stock dividend for the year ended December 31, 2012									(29,048)		(29,048)
Net loss attributable to noncontrolling interests for the year ended December 31, 2012										(492)	(492)
Other comprehensive income								6,449			6,449
Balance at December 31, 2012		$	305,560,763	$ 3,056	(2,293,056)	$ (7,457)	$ 565,201	$ 7,356	$ (388,770)	$ (492)	$ 178,894

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	For the years ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net loss	$ (29,540)	$ (1,283)	$ (18,926)
Income (loss) from discontinued operations, net of tax	(109)	(5,181)	6,250
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	10,160	3,830	2,207
Accretion of debt discount related to notes payable		2	66
Losses from investments in investees	2,062	1,589	714
Equity based compensation employees and non-employees	5,131	6,953	6,519
Provision for (recovery of) bad debts	(95)	257	(89)
Provision for (recovery of) inventory obsolescence	2,688	607	(48)
Revenue from receipt of equity	(159)	(85)	(731)
Unrealized gains on derivative instruments	(1,340)	39	
Change in fair value of contingent consideration	326		
Deferred income tax benefit	(9,958)	(19,749)	(348)
Changes in assets and liabilities of continuing operations, net of the effects of acquisitions:			
Accounts receivable	763	(1,719)	(2,888)
Inventory	(5,807)	2,170	(8,156)
Prepaid expenses and other current assets	(2,877)	57	270
Other assets	(361)	16	13
Accounts payable	1,247	(1,784)	1,498
Foreign currency measurement	86	363	
Accrued expenses	2,361	(21)	(3,510)
Cash used in operating activities from continuing operations	(25,422)	(13,939)	(17,159)
Cash provided by (used in) operating activities from discontinued operations	7	(4,561)	(1,553)
Net cash used in operating activities	(25,415)	(18,500)	(18,712)
Cash flows from investing activities:			
Investments in investees	(3,396)	(2,013)	(650)
Acquisition of businesses, net of cash	(19,092)	(28,186)	(1,323)
Purchase of marketable securities	(25,806)	(100,161)	(14,997)
Maturities of short-term marketable securities	24,997	100,161	14,997
Capital expenditures	(1,472)	(1,953)	(774)
Cash used in investing activities from continuing operations	(24,769)	(32,152)	(2,747)
Cash provided by (used in) investing activities from discontinued operations		17,316	(33)
Net cash used in investing activities	(24,769)	(14,836)	(2,780)
Cash flows from financing activities:			
Issuance of Common Stock, including related parties, net		104,828	
Purchase of Common Stock held in treasury		(7,832)	
Redemption of Series A Preferred Stock including related parties		(1,792)	
Payment of Series D dividends, including to related parties		(4,704)	
Repayments of line of credit with related party			(12,000)

Proceeds from the exercise of Common Stock options and warrants	2,279	1,244	74
Borrowings on lines of credit	36,506	15,300	15,424
Repayments of lines of credit and capital lease obligations	(32,754)	(20,127)	(6,266)
Net cash provided by (used in) financing activities	6,031	86,917	(2,768)
Effect of exchange rate on cash and cash equivalents	(2)	(81)	(382)
Net (decrease) increase in cash and cash equivalents	(44,155)	53,500	(24,642)
Cash and cash equivalents at beginning of year	71,516	18,016	42,658
Cash and cash equivalents at end of year	$ 27,361	$ 71,516	$ 18,016

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Business and Organization

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including molecular diagnostics tests, laboratory developed tests, point-of-care tests, and proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets.

We own established pharmaceutical platforms in Spain, Chile and Mexico, which are generating revenue and which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. In addition, we recently established pharmaceutical operations in Brazil. We also operate a specialty active pharmaceutical ingredients (APIs) manufacturer in Israel, which we expect to play a valuable role in the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products. We operate a laboratory facility headquartered in Nashville, Tennessee, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), has a strong presence in the U.S. urologic pathology market, and will provide us with a platform to commercialize certain of our novel diagnostics tests currently in development. We also own an interest in a biopharmaceutical company that develops, manufactures and markets recombinant human health care biotechnology derived products in Israel and whose principal marketed product is a novel third generation Hepatitis B vaccine currently being commercialized in Israel, India and Hong Kong.

We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida. We lease office and lab space in Jupiter and Miramar, Florida, which is where our molecular diagnostics research and development and oligonucleotide research and development operations are based, respectively. We lease office, manufacturing and warehouse space in Woburn, Massachusetts for our point-of-care diagnostics business, and in Nesher, Israel for our API business. We lease laboratory and office space in Nashville, Tennessee and Burlingame, California for our CLIA-certified laboratory business, and we lease office space in Bannockburn, Illinois, and Markham, Ontario and laboratory space in Toronto, Ontario for the Cytochroma business. Our Chilean operations are located in leased offices and warehouse facilities in Santiago. Our Mexican operations are based in owned offices, an owned manufacturing facility and a leased warehouse facility in Guadalajara. Our Spanish operations are based in owned offices in Barcelona and in an owned manufacturing facility in Banyoles.

Note 2 Summary of Significant Accounting Policies

Basis of Presentation and Reclassifications. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-K and of Regulation S-X. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the 2012 presentation. These reclassifications had no impact on our results of operations. As a result of our change in reportable segments, we restated certain prior year amounts in the consolidated financial statements to conform to the 2012 presentation. Refer to Note 17. As further discussed in Note 4, the results of operations and the assets and the liabilities related to the ophthalmic instrumentation business have been accounted for as discontinued operations. Accordingly, the results of the operations related to the ophthalmic instrumentation business from prior periods have been reclassified to discontinued operations.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management 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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

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Cash and Cash Equivalents. Cash and cash equivalents include short-term, interest-bearing instruments with original maturities of 90 days or less at the date of purchase. We also consider all highly liquid investments with original maturities at the date of purchase of 90 days or less as cash equivalents. These investments include money markets, bank deposits, certificates of deposit and U.S. treasury securities.

Inventories. Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost or market.

Shipping and Handling Costs. We do not charge customers for shipping and handling costs. Shipping and handling costs are classified as Cost of revenues, excluding amortization of intangible assets in the Consolidated Statements of Operations.

Property, Plant, Equipment and Investment Properties. Property, plant, equipment and investment properties are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, generally five to ten years and includes amortization expense for assets capitalized under capital leases. The estimated useful lives by asset class are as follows: software 3 years, machinery and equipment 5-8 years, furniture and fixtures 5-10 years, leasehold improvements the lesser of their useful life or the lease term, buildings and improvements 10-40 years. Expenditures for repairs and maintenance are charged to expense as incurred, while betterments reduce accumulated depreciation. Depreciation expense from continuing operations was $1.8 million, $0.4 million, and $0.2 million for the years ended December 31, 2012, 2011, and 2010, respectively.

Goodwill and Intangible Assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired when accounted for by the purchase method of accounting and arose from our acquisitions of Pharma Genexx, S.A. (OPKO Chile), Pharmacos Exakta S.A. de C.V. (Exakta-OPKO), CURNA, Inc. (CURNA), Claros Diagnostics, Inc. (OPKO Diagnostics), FineTech Pharmaceuticals, Ltd. (FineTech), ALS Distribuidora Limitada (ALS), Farmadiet Group Holding, S.L. (Farmadiet), and Prost-Data, Inc. (OURLab). Goodwill is principally arising from synergies we anticipate from these acquisitions in conjuction with our pharmaceutical and diagnostics programs.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 10 years, and review for impairment at least annually, or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense from continuing operations was $8.3 million, $3.4 million, and $2.1 million for the years ended December 31, 2012, 2011, and 2010, respectively. Amortization expense from continuing operations for our intangible assets is expected to be $10.6 million, $10.6 million, $10.3 million, $9.5 million, and $8.9 million, respectively, for the years ending December 31, 2013, 2014, 2015, 2016, and 2017.

Impairment of Long-Lived Assets. Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value, or carrying amount for cost basis assets, of the asset.

Fair Value Measurements. The carrying amounts of our cash and cash equivalents, accounts receivable and accounts payable approximate their fair value due to the short-term maturities of these instruments. Investments that are considered available for sale as of December 31, 2012 and 2011 are carried at fair value.

Short-term investments, which we invest in from time to time, include bank deposits, corporate notes, U.S. treasury securities and U.S. government agency securities with original maturities of greater than 90 days and remaining maturities of less than one year. Long-term investments include corporate notes, U.S. treasury securities and U.S. government agency securities with maturities greater than one year.

In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts. Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange. Refer to Note 18.

Derivative financial instruments. We record derivative financial instruments on our balance sheet at their fair value and the changes in the fair value are recognized in Other income (expense), net, when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are

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required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At December 31, 2012 and 2011, our forward contracts for inventory purchases (Refer to Note 19) did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values of the forward contracts in Other income (expense), net. Refer to Note 18. Changes in fair value of our Common Stock option and Common Stock warrants holdings of our available for sale investments are recognized in either Other income (expense), net, or Other comprehensive loss. Refer to Note 18.

Research and Development. Research and development costs are charged to expense as incurred. We record expense for in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use. For in-process research and development projects acquired in business combinations, the in-process research and development project is capitalized and evaluated for impairment until the development process has been completed. Once the development process has been completed the asset will be amortized over its remaining useful life.

Income Taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

Loss Per Share. Basic loss per share is computed by dividing our net loss by the weighted average number of shares outstanding during the period. Diluted loss per share is computed by dividing our net loss increased by dividends on preferred stock by the weighted average number of shares outstanding and the impact of all dilutive potential common shares, primarily stock options. The dilutive impact of stock options and warrants is determined by applying the treasury stock method. In the periods in which their effect would be anti-dilutive, no effect has been given to outstanding options, warrants or convertible Preferred Stock in the diluted computation.

The diluted loss per share does not include the weighted average impact of the outstanding options, warrants and other contingent consideration of 26,695,436, 26,661,326, and 20,310,765 shares for the years ended December 31, 2012, 2011, and 2010 respectively, because their inclusion would have been anti-dilutive. As of December 31, 2012, the holders of our Series D Preferred Stock could convert their shares into approximately 12,336,556 shares of our Common Stock, including accrued dividends. During the year ended December 31, 2012, 1,086,361 Common Stock warrants and Common Stock options to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,084,982 shares of our Common Stock. Of the 1,086,361 Common Stock warrants and Common Stock options exercised, 1,379 shares were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements.

Revenue Recognition. Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and management s evaluation of specific factors that may increase the risk of product returns.

Revenue for services is recognized on the accrual basis at the time test results are reported, which approximates when services are provided. Services are provided to certain patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in sales net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue.

Other revenues include revenue related to upfront license payments, license fees and milestone payments received through our license, collaboration and commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. Other revenue for the year ended December 31, 2012 includes $1.4 million of revenue related to our consulting agreement with Neovasc, Inc. (Neovasc) and to revenue related to molecular diagnostics collaboration agreements. Other revenue for the year ended December 31, 2011 includes $0.1 million of revenue related to our consulting agreement with Neovasc. Refer to Note 3. We recognize this revenue on a straight-line basis over the contractual term of the agreements.

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and the fair value of our undelivered obligations, if any, can be determined. If the license is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, the license payments are recognized as revenue over the period of our performance for such undelivered items or

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services. License fees with ongoing involvement or performance obligations are recorded as deferred revenue as Accrued expenses or Other long-term liabilities, when received and generally are recognized ratably over the period of such performance obligation only after both the license period has commenced and we have delivered the technology. The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a quarterly basis.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Other revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone is commensurate with either the vendor s performance to achieve the milestone or the enhancement of the value of the delivered item by the vendor; the milestone relates solely to past performance; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are not considered to be substantive and are, therefore, deferred and recognized as Other revenue over the term of the arrangement as we complete our performance obligations.

Total deferred revenue recorded as Accrued expenses and Other long-term liabilities was $1.9 million and $0.9 million at December 31, 2012 and December 31, 2011, respectively.

Allowance for Doubtful Accounts. We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by our estimate of the collectability of accounts receivable. The amount of allowance for doubtful accounts from continuing operations at December 31, 2012 and 2011 was $0.5 million and $0.4 million, respectively.

Product Warranties. Product warranty expenses are recorded concurrently with the recording of revenue for product sales. The costs of warranties are recorded as a component of cost of sales. We estimate warranty costs based on our estimated historical experience and adjust for any known product reliability issues.

Equity-Based Compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the statement of operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow rather than as a reduction of taxes paid in cash flow from operations. Refer to Note 9. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation is subject to periodic adjustment as the underlying equity instruments vest. During the years ended December 31, 2012, 2011, and 2010, we recorded $5.1 million, $7.0 million, and $6.5 million, respectively, of equity-based compensation expense.

Segment reporting. Our chief operating decision-maker (CODM) is comprised of our executive management with the oversight of our Board of Directors. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a Company-wide or aggregate basis. Due to the acquisition of OURLab in December 2012, we changed our segment presentation to include diagnostics as a reportable segment. Therefore, we currently manage our operations in two reportable segments, pharmaceuticals and diagnostics. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Israel, and Spain. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired in Tennessee through the acquisition of OURLab in October 2012 and (ii) point-of-care and molecular diagnostics operations. Previously, we presented only one reportable segment, pharmaceutical, which included two operating segments, our (i) pharmaceutical research and development segment and (ii) the pharmaceutical operations we acquired in Chile, Mexico and Israel. The change in reportable segment has no effect on our consolidated financial position, results of operations or cash flows for the periods presented. All prior year segment information has been restated to conform with the 2012 presentation. There are no inter-segment sales. We evaluate the performance of each operating segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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Variable interest entities. The consolidation of variable interest entities (VIE) is required when an enterprise has a controlling financial interest. A controlling financial interest in a VIE will have both of the following characteristics: (a) the power to direct the activities of a VIE that most significantly impact the VIE s economic performance and (b) the obligation to absorb losses of the VIE that could potentially be significant to the VIE. Refer to Note 3.

Investments. We have made investments in other early stage companies. We record these investments as equity method investments or investments available for sale based our percentage of ownership and whether we have significant influence over the operations of the investees. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Consolidated Statement of Operations. Refer to Note 3. For investments classified as available for sale, we record changes in their fair value as unrealized gain or loss in Other comprehensive loss. Refer to Note 3.

Recent accounting pronouncements. On January 1, 2012, we adopted an amendment issued by the Financial Accounting Standards Board (FASB) to the accounting standards related to fair value measurement and disclosure requirements. This amendment revises the existing guidance on the use and application of fair value measurements and maintains a definition of fair value that it is based on the notion of exit price. The adoption of this amendment did not have a material impact on our consolidated financial statements.

On January 1, 2012, we adopted amendments issued by the FASB to the accounting standards related to comprehensive income. These amendments revise the manner in which entities present comprehensive income in their financial statements and remove the option to present items of other comprehensive income in the statement of changes in stockholders equity. These amendments require an entity to report components of comprehensive income in either (1) a continuous statement of comprehensive income, or (2) two separate but consecutive statements of net income and other comprehensive income. We modified our consolidated financial statements presentation using the latter alternative.

On January 1, 2012, we adopted revised guidance issued by the FASB related to the testing of goodwill for impairment. Under the revised guidance, an entity has the option to perform a qualitative assessment of whether it is more-likely-than-not that a reporting unit s fair value is less than its carrying value prior to performing the two-step quantitative goodwill impairment test. If, based on the qualitative factors, an entity determines that the fair value of the reporting unit is greater than its carrying amount, then the entity would not be required to perform the two-step quantitative impairment test for that reporting unit. However, if the qualitative assessment indicates that it is not more-likely-than-not that the reporting unit s fair value exceeds its carrying value, then the quantitative assessment must be performed. An entity is permitted to perform the qualitative assessment on none, some or all of its reporting units and may also elect to bypass the qualitative assessment and begin with the quantitative assessment of goodwill impairment. This amendment did not have a material impact in our consolidated financial statements.

Note 3 Acquisitions, Investments, and Licenses

OURLab acquisition

In October 2012, we entered into a definitive merger agreement to acquire OURLab, a Nashville-based CLIA laboratory with 18 phlebotomy sites throughout the U.S. In December 2012, we paid $9.4 million in cash and delivered 7,072,748 shares of our Common Stock at closing valued at $32.9 million based on the closing sales price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $4.65 per share. The number of shares issued was based on the average closing sales price per share of our Common Stock as reported on the NYSE for the 15 trading days immediately preceding the execution of the purchase agreement, or $4.33 per share. Pursuant to the merger agreement, 1,732,102 shares of the stock consideration issued in the transaction are being held in a separate escrow account to secure the indemnification obligations of OURLab.

Farmadiet acquisition

In August 2012, we entered into a stock purchase agreement pursuant to which we acquired all of the outstanding stock of Farmadiet, a Spanish company engaged in the development, manufacture, marketing, and sale of pharmaceutical, nutraceutical, and veterinary products in Europe (the Farmadiet Transaction).

In connection with the Farmadiet Transaction, we agreed to pay an aggregate purchase price of 13.5 million (approximately $16.0 million), of which (i) 50% ($8.4 million) was paid in cash at closing, and (ii) 50% (the Deferred Payments) will be paid, at our option, in cash or shares of our Common Stock as follows: (x) 25% to be paid on the first anniversary of the closing date; and (y) 25% to be paid 18 months after the closing date. On the date of acquisition, we recorded the 6.8 million Deferred Payments at $7.8 million, net of a discount of $0.6 million. The discount will be amortized as interest expense through the respective payment dates. The Deferred

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Payments are required to be paid in Euro and as such, the final U.S. dollar amount to be paid will be based on the exchange rate at the time the Deferred Payments are made. In the event we elect to pay the Deferred Payments in shares of our Common Stock, the number of shares issuable shall be calculated using the average closing sales price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the applicable payment date. We have the right to hold back up to $3.4 million from the Deferred Payment to satisfy indemnity claims.

In connection with the Farmadiet Transaction, we also entered into two ancillary transactions (the Ancillary Transactions). In exchange for a 40% interest held by one of the sellers in one of Farmadiet s subsidiaries, we agreed to issue up to an aggregate of 250,000 shares of our Common Stock, of which (a) 125,000 shares were issued on the closing date, and (b) 125,000 will be issued upon achieving certain milestones. In addition, we acquired an interest held by an affiliate of Farmadiet in a product in development in exchange for which we agreed to pay up to an aggregate of 1.0 million ($1.3 million) payable at our option in cash or shares of our Common Stock, of which (a) 25% ($0.3 million) was paid at closing through delivery of 70,421 shares of our Common Stock, and 75% ($1.0 million) will be paid in cash or shares of our Common Stock upon achieving certain milestones. As a result, we recorded $1.2 million, as contingent consideration for the future consideration. We evaluate the contingent consideration on an ongoing basis and the changes in fair value are recognized in earnings until the milestones are achieved. Refer to Note 18. The final U.S. dollar amount to be paid will be based on the exchange rate at the time the milestones are achieved. The number of shares of our Common Stock issued is determined based on the average closing sales price for our Common Stock on the NYSE for the ten trading days preceding the required payment date.

ALS acquisition

In April 2012, we completed the acquisition of ALS, a privately-held Chilean pharmaceutical company, pursuant to a stock purchase agreement entered into in January 2012. In connection with the transaction, we agreed to pay up to a total of $4.0 million in cash to the sellers. Pursuant to the purchase agreement, we paid (i) $2.4 million in cash at the closing, less certain liabilities, and (ii) $0.8 million in cash at the closing into a separate escrow account to satisfy possible indemnity claims. We agreed to pay the remaining $0.8 million upon the legal registration in the name of ALS of certain trademarks and product registrations previously held by Arama Laboratorios y Compañía Limitada.

The following table summarizes the preliminary fair value of the net assets acquired and liabilities assumed in the acquisitions of OURLab, Farmadiet and ALS at the dates of acquisition, which are subject to change while contingencies that existed on the acquisition date are resolved:

(in thousands)	OURLab	Farmadiet	ALS
Current assets[1][2]	$ 6,020	$ 8,367	$ 767
Intangible assets:			
Customer relationships	3,860	436	
Technology	1,370	3,017	
In-process research and development		1,459	
Product registrations		2,930	2,300
Licenses	70		
Covenants not to compete	6,900	187	
Tradename	1,830	349	680
Total intangible assets	14,030	8,378	2,980
Goodwill	29,629	8,062	458
Property, plant and equipment	2,117	7,205	24
Other assets	37	611	
Accounts payable and accrued expenses[2]	(3,214)	(3,438)	(229)
Deferred tax liability	(6,356)	(3,169)	
Debt assumed		(7,829)	
Total purchase price	$ 42,263	$ 18,187	$ 4,000

(1) Current assets include cash of $1.1 million, $0.2 million and $33 thousand related to the OURLab, Farmadiet and ALS acquisitions, respectively.

(2) Current assets, accounts payable and accrued expenses include $1.9 million, respectively for a contingency loss and offsetting indemnification asset. Refer to Note 14.

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FineTech acquisition

In December 2011, we purchased all of the issued and outstanding shares of FineTech, a privately-held Israeli company focused on the development and production of APIs. At closing, we delivered to the seller $27.7 million, of which $10.0 million was paid in cash and $17.7 million was paid in shares of our Common Stock. The shares delivered at closing were valued at $17.7 million based on the closing sales price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $4.90 per share. The number of shares issued was based on the average closing sales price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the execution of the purchase agreement, or $4.84 per share. Upon finalization of the closing financial statements of FineTech, we accrued an additional $0.5 million purchase price adjustment related to a working capital surplus, as defined in the purchase agreement, which was paid to the seller in February 2012. In addition, the purchase agreement provides for the payment of additional cash consideration subject to the achievement of certain sales milestones. We evaluate the contingent consideration on an ongoing basis and the changes in fair value are recognized in earnings until the contingencies are resolved. Refer to Note 18.

The following table summarizes the estimated fair value allocation of the net assets acquired and liabilities assumed in the acquisition of FineTech at the date of acquisition, which are subject to change while contingencies that existed on the acquisition date are resolved:

(In thousands)	
Current assets (including cash of $2,000)	$ 3,358
Intangible assets:	
Customer relationships	14,200
Technology	2,700
Non-compete	1,500
Tradename	400
Total intangible assets	18,800
Goodwill	11,623
Plant and equipment	1,358
Other assets	1,154
Accounts payable and accrued expenses	(910)
Deferred tax liability	(2,457)
Contingent consideration	(4,747)
Total purchase price	$ 28,179

OPKO Diagnostics acquisition

In October 2011, we acquired OPKO Diagnostics pursuant to an agreement and plan of merger. We paid $10.0 million in cash, subject to certain set-offs and deductions, and $22.5 million in shares of our Common Stock, based on the closing sales price per share of our Common Stock as reported by the NYSE on the closing date of the merger, or $5.04 per share. The number of shares issued was based on the average closing sales price per share of our Common Stock as reported by the NYSE for the ten trading days immediately preceding the date of the merger, or $4.45 per share. Pursuant to the merger agreement, $5.0 million of the stock consideration was held in a separate escrow account until October 2012 to secure the indemnification obligations of OPKO Diagnostics under the OPKO Diagnostics merger agreement. In December 2011, we made a $0.2 million claim against the escrow for certain undisclosed liabilities. In addition, the merger agreement provides for the payment of up to an additional $19.1 million in shares of our Common Stock upon and subject to the achievement of certain milestones. We evaluate the contingent consideration on an ongoing basis and the changes in fair value are recognized in earnings until the milestones are achieved. Refer to Note 18.

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The following table summarizes the estimated fair value allocation of the net assets acquired and liabilities assumed in the acquisition of OPKO Diagnostics at the date of acquisition, which are subject to change while contingencies that existed on the acquisition date are resolved:

(In thousands)	
Current assets (including cash of $351)	$ 378
Technology	44,400
Goodwill	17,977
Equipment	333
Other assets	18
Accounts payable and accrued expenses	(655)
Deferred tax liability	(17,254)
Contingent consideration	(12,745)
Total purchase price	$ 32,452

CURNA acquisition

In January 2011, we acquired all of the outstanding stock of CURNA in exchange for $10.0 million in cash, plus $0.6 million in liabilities, of which, $0.5 million was paid at closing. In addition to the cash consideration, we have agreed to pay to the CURNA sellers a portion of any consideration we receive in connection with certain license, partnership or collaboration agreements we may enter into with third parties in the future relating to the CURNA technology, including, license fees, upfront payments, royalties and milestone payments. As a result, we recorded $0.6 million, as contingent consideration for the future consideration. We evaluate the contingent consideration on an ongoing basis and the changes in fair value are recognized in earnings until the milestones are achieved. Refer to Note 18. CURNA was a privately-held company based in Jupiter, Florida, engaged in the discovery of new drugs for the treatment of a wide variety of illnesses, including cancer, heart disease, metabolic disorders and a range of genetic anomalies.

The following table reflects the estimated fair value allocation of the net assets acquired at the date of acquisition, which are subject to change while contingencies that existed on the acquisition date are resolved:

(In thousands)	
Current assets (including cash of $5)	$ 38
Fixed assets	21
Intangible assets	
In-process research and development	10,000
Patents	290
Total intangible assets	10,290
Goodwill	4,827
Accounts payable and accrued expenses	(54)
Deferred tax liability	(3,999)
Contingent consideration	(580)
Total purchase price	$ 10,543

Pro forma disclosures for acquisitions

The following table includes the pro forma results for the years ended December 31, 2011 and 2010 of the combined companies as though the acquisitions of FineTech and OPKO Diagnostics had been completed as of the beginning of each period, respectively.

(In thousands, except per share amounts)	For the years Ended December 31, 2011	2010
Revenue	$ 36,238	$ 34,102
Loss from continuing operations	$ (20,879)	$ (12,606)
Net loss attributable to common shareholders	$ (1,368)	$ (23,295)
Basic and diluted loss from continuing operations per share	$ (0.00)	$ (0.08)
Basic and diluted loss from discontinued operations per share	$ (0.00)	$ (0.04)
Basic and diluted loss per share	$ (0.00)	$ (0.12)

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This unaudited pro forma financial information is presented for informational purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had we owned and operated each company as of the beginning of the periods presented.

Equity method investments and available for sale investments

In February 2012, we made a $1.0 million investment in ChromaDex Corporation (ChromaDex), a publicly-traded company and leading provider of proprietary ingredients and products for the dietary supplement, nutraceutical, food and beverage, functional food, pharmaceutical and cosmetic markets, in exchange for 1,333,333 shares of ChromaDex common stock, at $0.75 per share. In connection with our investment, we also entered into a license, supply and distribution agreement with ChromaDex pursuant to which we obtained exclusive distribution rights to certain of its products in Latin America. Our investment was part of a $3.7 million private placement by ChromaDex. Other investors participating in the private financing included certain related parties. Refer to Note 12. In connection with a consulting agreement with ChromaDex, we received 500,000 shares of ChromaDex to provide certain consulting services.

We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of ChromaDex and as a result, we account for ChromaDex as an investment, available for sale, and we record changes in the fair value of ChromaDex as an unrealized gain or loss in Other comprehensive loss each reporting period. Refer to Note 18. The closing price of ChromaDex was $0.53 per share on December 31, 2012.

In August 2011, we made an investment in Neovasc, a medical technology company based in Vancouver, Canada, a Canadian publicly-traded company. Neovasc is developing devices to treat cardiovascular diseases and is also a leading supplier of tissue components for the manufacturers of replacement heart valves. We invested $2.0 million and received two-million Neovasc common shares, and two-year warrants to purchase an additional one-million shares for $1.25 a share. We recorded the warrants on the date of the grant at their estimated fair value of $0.7 million using the Black-Scholes-Merton Model. Prior to the warrants being readily convertible into cash, we recorded an unrealized gain of $0.2 million in Other comprehensive loss. We record changes in fair value for the Neovasc warrants in Other income (expense), net in our Consolidated Statement of Operations. We also entered into an agreement with Neovasc to provide strategic advisory services to Neovasc as it continues to develop and commercialize its novel cardiac devices. In connection with the consulting agreement, Neovasc granted us 913,750 common stock options. The options were granted at (Canadian) $1.00 per share and vest annually over three years. We valued the options using the Black-Scholes-Merton Model at $0.8 million on the date of grant and will recognize the revenue over four years as Other revenue. In August 2012, Neovasc granted us an additional 86,250 common stock options. The options were granted at (Canadian) $1.30 per share and vested immediately. We valued the options using the Black-Scholes-Merton Model at $0.1 million on the date of grant and will recognize the revenue over three years as Other revenue. We record changes in the fair value of Neovasc options as an unrealized gain or loss in Other comprehensive loss each reporting period. Refer to Note 18. The closing price of Neovasc was (Canadian) $1.60 per share on December 31, 2012.

In December 2010, we entered into a license agreement (the TESARO License) with TESARO, Inc. (TESARO) granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Under the terms of the TESARO License, we are eligible for payments of up to $121.0 million, including an up-front payment of $6.0 million, which has been received, and additional payments based upon achievement of specified regulatory and commercialization milestones. In addition, TESARO will pay us double digit tiered royalties on sales of licensed products. We will share future profits from the commercialization of licensed products in Japan with TESARO and we will have an option to market the products in Latin America. In connection with the TESARO License, we also acquired an equity position in TESARO. We recorded the equity position at $0.7 million, the estimated fair value based on a discounted cash flow model.

Neither we nor our related parties have the ability to significantly influence TESARO and as such, we accounted for our investment in TESARO under the cost method until June 2012 on which date, TESARO had an initial public offering. As a result of the initial public offering, we determined TESARO had a readily determinable fair value and we changed the accounting for our investment in TESARO from a cost method investment to an investment, available for sale, and we recorded an unrealized gain in Other comprehensive loss of $5.3 million. We record changes in the fair value as an unrealized gain or loss in Other comprehensive loss. Refer to Note 18. The closing price of TESARO was $16.95 per share in December 31, 2012.

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In accounting for the license of rolapitant to TESARO, we determined that we did not have any continuing involvement in the development of rolapitant or any other future performance obligations and, as a result, during the year ended December 31, 2010 recognized the $6.0 million up-front payment and the $0.7 million equity position as license revenue.

In September 2009, we entered into an agreement pursuant to which we invested $2.5 million in cash in Cocrystal Discovery, Inc. (Cocrystal), a privately-held biopharmaceutical company in exchange for 1,701,723 shares of Cocrystal s Convertible Series A Preferred Stock. Cocrystal is focused on the discovery and development of novel antiviral drugs using a combination of protein structure-based approaches. Refer to Note 12. In October 2011, Cocrystal received an investment of $7.5 million from Teva Pharmaceutical Industries Ltd. (Teva). Dr. Phillip Frost, our Chief Executive Officer and Chairman of our Board of Directors, is Chairman of the Board of Directors of Teva. In connection with that investment, we determined Cocrystal no longer meets the definition of a variable interest entity as it had sufficient capital to carry out its principal activities without additional financial support. As a result of our and our related parties ownership interest, we and our related parties have the ability to significantly influence Cocrystal, and we account for our investment under the equity method.

In June 2009, we entered into a stock purchase agreement with Sorrento Therapeutics, Inc. (Sorrento), a publicly-held company with a technology for generating fully human monoclonal antibodies, pursuant to which we invested $2.3 million in Sorrento. The closing stock price for Sorrento s common stock, a thinly traded stock, as quoted on the over-the-counter markets was $0.15 per share on December 31, 2012. Refer to Note 12.

Investments in variable interest entities

We have determined that we hold variable interests in Fabrus, BZNE and SciGen. We made this determination as a result of our assessment that they do not have sufficient resources to carry out their principal activities without additional financial support.

In February 2012, we purchased from Biozone Pharmaceuticals, Inc., a publicly-traded company that specializes in drug development, manufacturing, and marketing (BZNE), $1.7 million of 10% secured convertible promissory notes (the BZNE Notes), convertible into BZNE common stock at a price equal to $0.20 per common share, which BZNE Notes are due and payable on February 24, 2014 and ten year warrants (the BZNE Warrants) to purchase 8.5 million shares of BZNE common stock at an exercise price of $0.40 per share. In July 2012, we exercised the BZNE Warrants utilizing the net exercise feature and received 7,650,000 shares of BZNE common stock. The BZNE Notes are secured pursuant to a security agreement by a first priority lien in the assets of BZNE, including the stock of its subsidiaries. We also entered into a license agreement pursuant to which we acquired a world-wide license for the development and commercialization of products utilizing BZNE s proprietary drug delivery technology, including a technology called QuSomes, exclusively for OPKO in the field of ophthalmology and non-exclusive for all other therapeutic fields, subject in each case to certain excluded products. Refer to Note 12.

We have accounted for the BZNE Notes as an investment, available for sale. We recorded the BZNE Notes and BZNE Warrants at fair value on the date of acquisition. We record changes in fair value for the BZNE Notes as an unrealized gain or loss in Other comprehensive loss for each reporting period and we record changes in fair value for the beneficial conversion feature of the BZNE Notes in Other income (expense), net in our Consolidated Statements of Operations. Refer to Note 18. The stock market trading activity in BZNE does not represent an active market and as such, we determined the fair market value utilizing a business enterprise valuation approach in order to determine the fair value of our investment. Upon the conversion of the BZNE Warrants to BZNE common stock, we account for the common stock as an equity method investment.

In order to determine the primary beneficiary of BZNE, we evaluated our investment and our related parties investments, as well as our investment combined with the related party group s investments to identify if we had the power to direct the activities that most significantly impact the economic performance of BZNE. We determined that power to direct the activities that most significantly impact BZNE s economic performance is conveyed through the board of directors of BZNE and no entity is able to appoint the BZNE governing body that oversees its executive management team. Based on the capital structure, governing documents and overall business operations of BZNE, we determined that, while a VIE, no single entity has the power to direct the activities that most significantly impact BZNE s economic performance. However, we determined that we and our related parties can significantly influence

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the success of BZNE through our voting power. As such, we account for investment in BZNE under the equity method.

In November 2010, we made a $0.7 million investment in Fabrus, Inc. (Fabrus), a privately-held early stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities. Fabrus is using its proprietary antibody screening and engineering approach to discover promising lead compounds against several important oncology targets. Our investment was part of a $2.1 million financing for Fabrus and included other related parties. Refer to Note 12.

In order to determine the primary beneficiary of Fabrus, we evaluated our investment and our related parties investment, as well as our investment combined with the related party group s investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Fabrus. The related party group when considering our investment in Fabrus includes the Company, Frost Gamma Investments Trust, of which Dr. Frost is the sole trustee (the Gamma Trust), Hsu Gamma Investment, L.P., of which Dr. Jane Hsiao is the general partner (Hsu Gamma), and the Richard Lerner Family Trust, of which Dr. Richard Lerner is the general partner. Drs. Frost, Hsiao and Lerner are all members of our Board of Directors. As of December 31, 2012, we own approximately 13% of Fabrus and Drs. Frost, Hsiao and Lerner own a total of 24% of Fabrus voting stock on an as converted basis, including 16% held by the Gamma Trust. Drs. Frost and Hsiao currently serve on the board of directors of Fabrus and represent 40% of its board. Based on this analysis, we determined that neither we nor our related parties have the power to direct the activities of Fabrus. However, we did determine that our related parties can significantly influence the success of Fabrus through our board representation and voting power. Accordingly, as we and our related parties have the ability to exercise significant influence over Fabrus operations, we account for our investment in Fabrus under the equity method.

Consolidated variable interest entities

In June 2012, we entered into a share and debt purchase agreement whereby in exchange for $0.7 million we acquired shares representing a 45% stock ownership in SciGen (I.L.) Ltd (SciGen) from FDS Pharma LLP (FDS). SciGen is a privately-held Israeli company that produces a third-generation hepatitis B-vaccine. In November 2012 and March 2013, we loaned to SciGen a combined of $0.8 million for working capital purposes. We have determined that we hold variable interests in SciGen based on our assessment that SciGen does not have sufficient resources to carry out their principal activities without financial support. In order to determine the fair market value of our investment in SciGen, we have utilized a business enterprise valuation approach.

In order to determine the primary beneficiary of SciGen, we evaluated our investment to identify if we had the power to direct the activities that most significantly impact the economic performance of SciGen. We have determined that the power to direct the activities that most significantly impact the economic performance of SciGen is conveyed through SciGen s board of directors. SciGen s board of directors appoint and oversee SciGen s management team who carryout the activities that most significantly impact the economic performance of SciGen. As part of the share and debt purchase agreement, SciGen s board of directors will be constituted by 5 members, of which 3 members will be appointed by us, representing 60% of SciGen s board. Based on this analysis, we determined that we have the power to direct the activities of SciGen and as such we are the primary beneficiary. As a result of this conclusion, we have consolidated the results of SciGen and record a reduction of equity for the portion of SciGen we do not own.

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The following table represents the consolidated assets and non-recourse liabilities related to SciGen as of December 31, 2012. Those assets are owned by, and those liabilities are obligations of, SciGen, not us.

(In thousands)	December 31, 2012
Assets	
Current assets:	
Cash and cash equivalents	$ 174
Accounts receivable, net	387
Inventories, net	1,092
Prepaid expenses and other current assets	199
Total current assets	1,852
Property, plant and equipment, net	1,539
Intangible assets, net	1,154
Goodwill	796
Other assets	231
Total assets	$ 5,572
Liabilities	
Current liabilities:	
Accounts payable	$ 1,108
Accrued expenses	2,859
Total current liabilities	3,967
Other long-term liabilities	1,529
Total liabilities	$ 5,496

The following table summarizes the estimated fair value allocation of the net assets acquired and liabilities assumed in the consolidation of SciGen at the investment date:

(In thousands)	
Current assets (including cash of $54)	$ 1,493
Intangible assets:	
Customer relationships	40
Technology	1,090
Total intangible assets	1,130
Goodwill	760
Plant and equipment	1,520
Accounts payable and accrued expenses	(1,970)
Deferred tax liability	(283)
Total	$ 2,650

The total assets and liabilities of our equity method investees as of December 31, 2012 were $26.3 million and $12.8 million, respectively. The total assets and liabilities of our equity method investees as of December 31, 2011 were $22.9 million and $1.9 million, respectively. The net losses of our equity method investees for the years ended December 31, 2012 and 2011 were $13.4 million and $9.1 million, respectively. The following tables reflect our maximum exposure, accounting method, ownership interest and underlying equity in net assets of each of our

unconsolidated investments as of December 31, 2012:

(Dollars in thousands) Investee name	Year invested	Accounting method	Ownership at December 31, 2012	Investment	Underlying equity in net assets
Sorrento	2009	Equity method	20%	$ 2,300	$ 1,219
Cocrystal	2009	Equity method	16%	2,500	1,012
Neovasc	2011	Equity method	4%	2,013	144
Fabrus	2010	VIE, equity method	13%	650	11
BZNE common stock	2012	VIE, equity method	12%	1,276	$ (301)
Less accumulated losses in investees				(4,718)	
Total carrying value of equity method investees				$ 4,021	
TESARO	2010	Investment available for sale	2%	$ 731	
Neovasc options	2011	Investment available for sale	N/A	925	
BZNE Note and conversion feature	2012	VIE, investment available for sale	N/A	1,700	
ChromaDex	2012	Investment available for sale	1%	1,320	
Plus unrealized gains on investments, options and warrants, net				6,939	
Total carrying value of investments, available-for-sale				$ 11,615	
Total				$ 15,636	

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Note 4 Discontinued Operations

In September 2011, we announced that we entered into an agreement with Optos, Inc., a subsidiary of Optos plc (collectively Optos) to sell our ophthalmic instrumentation business. Upon closing in October 2011, we received $17.5 million of cash and we are eligible to receive royalties up to $22.5 million on future sales.

The assets and liabilities related to our ophthalmic instrumentation business have identifiable cash flows that are independent of the cash flows of other groups of assets and liabilities and we will not have a significant continuing involvement with the related products beyond one year after the closing of the transactions. Therefore, the accompanying Consolidated Balance Sheets report the assets and liabilities related to our ophthalmic instrumentation business as discontinued operations in all periods presented, and the results of operations related to our ophthalmic instrumentation business have been classified as discontinued operations in the accompanying Consolidated Statements of Operations for all periods presented.

On or around October 30, 2012, we received a letter from counsel to Optos making certain indemnity claims against us in connection with the sale of our instrumentation business. It is too early to assess the likelihood of litigation in this matter or the probability of a favorable or unfavorable outcome. However, we do not currently believe this matter will have a material impact on our results of operations or financial condition.

The following table presents the major classes of assets and liabilities that have been presented as assets of discontinued operations and liabilities of discontinued operations in the accompanying Consolidated Balance Sheets:

(In thousands)	December 31, 2012	December 31, 2011
Other current assets	$	$ 4
Total assets of discontinued operations	$	$ 4
Accounts payable	$	$ 1
Accrued expenses and other liabilities		173
Total liabilities of discontinued operations	$	$ 174

The following table presents summarized financial information for the discontinued operations presented in the Consolidated Statements of Operations:

	For the years ended December 31		
(In thousands)	2012	2011	2010
Total revenue	$	$ 4,254	$ 8,386
Operating income (loss)	177	(3,434)	(6,095)
Gain on sale to Optos		10,597	
Income (loss) before provision for income taxes	177	7,142	(6,092)
Net income (loss)	$ 109	$ 5,181	$ (6,250)

The income from discontinued operations for the year ended December 31, 2012 primarily represents collection of an accounts receivable balance retained as part of the sale to Optos.

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Note 5 Composition of Certain Financial Statement Captions

(In thousands)	December 31, 2012	2011
Accounts receivable, net:		
Accounts receivable	$ 21,636	$ 12,984
Less: allowance for doubtful accounts	(474)	(440)
	$ 21,162	$ 12,544
Inventories, net:		
Finished products	$ 17,963	$ 11,100
Work in-process	688	277
Raw materials (components)	4,923	2,287
Less: inventory reserve	(1,313)	(325)
	$ 22,261	$ 13,339
Prepaid expenses and other current assets:		
Prepaid supplies	$ 443	$ 256
Other receivables	886	288
Prepaid insurance	301	176
Taxes recoverable	1,493	542
Other	4,750	917
	$ 7,873	$ 2,179
Property and equipment, net:		
Machinery and equipment	$ 7,984	$ 4,850
Building	3,457	656
Land	2,619	437
Furniture and fixtures	1,908	313
Software	853	630
Leasehold improvements	2,616	309
Less: accumulated depreciation	(3,732)	(1,837)
	$ 15,705	$ 5,358
Investment properties, net:		
Building	$ 384	$
Land	450	
Less: accumulated depreciation	(13)	
	$ 821	$
Intangible assets, net:		
Technology	$ 52,810	$ 47,100
Customer relationships	23,088	18,386
In-process research and development	11,546	10,000
Product registrations	9,637	3,895
Tradename	3,746	827
Covenants not to compete	8,662	1,560
Other	367	297
Less: accumulated amortization	(14,072)	(5,335)

	$ 95,784	$ 76,730
Accrued expenses:		
Income taxes payable	$ 1,614	$ 484
Deferred revenue	1,518	530
Clinical trials	50	7
Customer deposits		255
Professional fees	675	632
Employee benefits	3,319	907
Deferred acquisition payments, net of discount	6,172	
Contingent consideration	5,126	
Other	6,182	2,141
	$ 24,656	$ 4,956

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(In thousands)		December 31, 2012	2011
Other long-term liabilities:			
Contingent consideration	Farmadiet	$ 532	$
Contingent consideration	OPKO Diagnostics	11,310	12,745
Contingent consideration	FineTech	2,578	4,747
Contingent consideration	CURNA	510	510
Deferred acquisition payments, net of discount		3,931	
Long-term debt		5,150	
Deferred tax liabilities		9,777	6,863
Other, including deferred revenue		380	578
		$ 34,168	$ 25,443

The following table summarizes the fair values assigned to our major intangible asset classes upon each acquisition:

(In thousands)	OPKO Chile[1]	Exakta OPKO	CURNA	OPKO Diagnostics	FineTech	Farmadiet	OURLab	SciGen	Weighted average amortization period
Technology	$	$	$	$ 44,400	$ 2,700	$ 5,437	$ 1,370	$ 1,090	9 years
In-process research and development			10,000			1,459			Indefinite
Customer relationships	3,945	121			14,200	436	3,860	40	6 years
Product registrations	5,829	77				2,930			9 years
Covenants not to compete		70			1,500	187	6,900		5 years
Tradename	1,032	77			400	349	1,830		4 years
Other			290				70		4 years
Total identified intangible assets	10,806	345	10,290	44,400	18,800	10,798	14,030	1,130	
Goodwill	5,441	21	4,827	17,977	11,623	8,062	29,629	760	Indefinite
Total intangible assets acquired	$ 16,247	$ 366	$ 15,117	$ 62,377	$ 30,423	$ 18,860	$ 43,659	$ 1,890	

[1] Includes intangible assets and goodwill related to ALS acquisition.

All of the intangible assets and goodwill acquired relate to our acquisitions of OPKO Chile, including the intangibles assets and goodwill related to the ALS acquisition, Exakta-OPKO, CURNA, OPKO Diagnostics, FineTech, Farmadiet and OURLab. The pharmaceutical, nutraceutical and veterinary products from ALS and Farmadiet do not require ongoing product renewals. We do not anticipate capitalizing the cost of product registration renewals, rather we expect to expense these costs, as incurred. Our goodwill is not tax deductible for income tax purposes in Chile, the U.S., Spain, or Israel.

The change in value of the intangible assets and goodwill are primarily due to the acquisitions of ALS, Farmadiet, and OURLab, as well as the foreign currency fluctuations between the Chilean and Mexican pesos and the Euro against the U.S. dollar at December 31, 2012 and 2011. The purchase price allocation of the assets acquired in the ALS, Farmadiet, and OURLab acquisitions are subject to change while contingencies that existed on the acquisition dates are resolved.

The following table reflects the changes in the allowance for doubtful accounts, provision for inventory reserve and tax valuation allowance accounts for continuing operations:

(In thousands)				Written-off	

	Beginning balance	Charged to expense		Charged to other	Ending balance
2012					
Allowance for doubtful accounts	$ (440)	(86)	86	(34)	$ (474)
Inventory reserve	$ (325)	(2,544)	1,582	(26)	$ (1,313)
Tax valuation allowance	$ (53,255)	9,626		(15,516)	$ (59,145)
2011					
Allowance for doubtful accounts	$ (279)	(257)	96		$ (440)
Inventory reserve	$ (264)	(607)	546		$ (325)
Tax valuation allowance	$ (47,341)	19,358		(25,272)	$ (53,255)

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Note 6 Debt

We have entered into line of credit agreements with sixteen financial institutions in Chile and Spain. These lines of credit are used primarily as a source of working capital for inventory purchases.

The following table summarizes the lines of credit:

(In thousands)			Amount outstanding at December 31	
Lender	Interest rate on borrowings	Credit line capacity	2012	2011
Itau Bank	7.08%	$ 3,000	$ 2,738	$ 1,091
Bank of Chile	6.09%	3,500	2,292	1,749
BICE Bank	5.54%	3,000	2,451	952
Santander Bank	Libor +3.2%	1,796		236
Corp Banca	6.18%	2,000	1,248	420
BBVA Bank	6.38%	3,000	2,823	2,348
Penta Bank	10.10%	1,800	833	
Security Bank	Libor +3.2%	1,500		1,016
BCI	Libor +3.2%	1,500		945
Estado Bank	6.46%	2,000	1,963	
Sabadell Bank	7.60%	198	3	
Bilbao Vizcaya Bank	4.90%	396	377	
Banco Popular	8.25%	396	260	
Santander Bank	6.00%	198		
Banesto	5.80%	172	163	
Banca March	6.25%	264	44	
Total		$ 24,720	$ 15,195	$ 8,757

At December 31, 2012, the weighted average interest rate on our lines of credit was approximately 6.5%.

At December 31, 2012, we had mortgages notes and other debt payables of $6.2 million in Spain of which $2.3 million was recorded within Current portion of lines of credit and notes payable and $3.9 million was recorded within Other long-term liabilities in the accompanying Consolidated Balance Sheets. The mortgages and other debts payable mature at various dates ranging from 2015 through 2024 bearing variable interest rates from 2.7% up to 8.5%. The weighted average interest rate on the mortgage and other debt payable at December 31, 2012 was 4.5%.

Note 7 Equity Offerings

On March 14, 2011, we issued 27,000,000 shares of our Common Stock in a public offering at a price of $3.75 per share. We also granted the underwriters a 30-day option to purchase up to an additional 4,050,000 shares of our Common Stock to cover over-allotments, if any. On March 15, 2011, representatives for the underwriters provided us notice that the underwriters exercised a portion of their 4,050,000 share overallotment option for 2,397,029 additional shares of our Common Stock.

The following table reflects the proceeds received from the issuance of shares:

(Dollars in thousands, except share amounts)	Shares	Dollars
Original issuance	27,000,000	$ 101,250
Over-allotment	2,397,029	8,989
Total	29,397,029	110,239

Underwriters discount and commissions[(1)]	5.5% on 24,064,029 shares	(4,963)
Offering expenses		(448)
Net proceeds		$ 104,828

(1) The underwriters did not receive any underwriting discount or commissions on the sale of 5,333,000 shares of Common Stock to entities associated with certain stockholders, including two of our directors and executive officers. Refer to Note 12.

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Note 8 Shareholders Equity

Our authorized capital stock consists of 500,000,000 shares of Common Stock, par value $0.01 per share, and 10,000,000 shares of Preferred Stock, par value $0.01 per share.

Common Stock

Subject to the rights of the holders of any shares of Preferred Stock currently outstanding or which may be issued in the future, the holders of the Common Stock are entitled to receive dividends from our funds legally available when, as and if declared by our Board of Directors, and are entitled to share ratably in all of our assets available for distribution to holders of Common Stock upon the liquidation, dissolution or winding-up of our affairs subject to the liquidation preference, if any, of any then outstanding shares of Preferred Stock. Holders of our Common Stock do not have any preemptive, subscription, redemption or conversion rights. Holders of our Common Stock are entitled to one vote per share on all matters which they are entitled to vote upon at meetings of stockholders or upon actions taken by written consent pursuant to Delaware corporate law. The holders of our Common Stock do not have cumulative voting rights, which means that the holders of a plurality of the outstanding shares can elect all of our directors. All of the shares of our Common Stock currently issued and outstanding are fully-paid and nonassessable. No dividends have been paid to holders of our Common Stock since our incorporation, and no cash dividends are anticipated to be declared or paid on our Common Stock in the reasonably foreseeable future.

In addition to our equity-based compensation plans, we have issued warrants to purchase our Common Stock. Refer to Note 9 for additional information on our share-based compensation plans. The table below provides additional information for warrants outstanding as of December 31, 2012.

Warrants	Number of warrants	Weighted average exercise price	Expiration date
Outstanding at December 31, 2011	25,908,265	$ 0.95	Various from September 2014 through March 2017
Issued			
Exercised	(66,397)		
Expired			
Outstanding and Exercisable at December 31, 2012	25,841,868	$ 0.95	Various from September 2014 through March 2017

Of the 66,397 Common Stock warrants exercised, 1,379 shares were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements.

Preferred Stock

Under our certificate of incorporation, our Board of Directors has the authority, without further action by stockholders, to designate up to 10 million shares of Preferred Stock in one or more series and to fix or alter, from time to time, the designations, powers and rights of each series of Preferred Stock and the qualifications, limitations or restrictions of any series of Preferred Stock, including dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and the liquidation preference of any wholly issued series of Preferred Stock, any or all of which may be greater than the rights of the Common Stock, and to establish the number of shares constituting any such series.

Series A Preferred Stock

Of the authorized Preferred Stock, 4,000,000 shares were designated Series A Preferred Stock. Dividends were payable on the Series A Preferred Stock in the amount of $0.25 per share, payable annually in arrears. At the option of our Board of Directors, dividends were paid either (i) wholly or partially in cash or (ii) in newly issued shares of Series A Preferred Stock valued at $2.50 per share to the extent a cash dividend was not paid. In June 2011, we redeemed all 602,759 shares outstanding of our Series A Preferred Stock for an aggregate redemption price of

$1.8 million, including accrued dividends.

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Series C Preferred Stock

Of the authorized Preferred Stock, 500,000 shares were designated Series C Preferred Stock. On June 22, 2007, 457,603 shares of Series C Preferred Stock were issued and outstanding and held by 30 stockholders. Cumulative dividends were payable on the Series C Preferred Stock in the amount of $1.54 per share when declared by the Board of Directors. In June 2007, all outstanding shares (457,603 shares) of Series C Preferred Stock automatically converted into shares of Common Stock, on a one-hundred-for-one basis.

8% Series D Cumulative Convertible Preferred Stock

Of the authorized Preferred Stock, 2,000,000 shares were designated 8% Series D Cumulative Convertible Preferred Stock (Series D Preferred Stock). Holders of the Series D Preferred Stock are entitled to receive, when, as and if declared by our Board of Directors, dividends on each share of Series D Preferred Stock at a rate per annum equal to 8.0% of the sum of (a) $24.80, plus (b) any and all declared and unpaid and accrued dividends thereon, subject to adjustment for any stock split, combination, recapitalization or other similar corporate action (the Liquidation Amount). All dividends shall be cumulative, whether or not earned or declared, accruing on an annual basis from the issue date of the Series D Preferred Stock. In October 2011, 80,654 shares of our Series D Preferred Stock were converted into 940,141 shares of our Common Stock, reflecting the liquidation value on the date of conversion. On November 3, 2011 and March 8, 2013, our Board of Directors declared cash dividends to all Series D Preferred Stockholders as of November 3, 2011 and March 8, 2013, respectively. The 2012 and 2011 cash dividend was approximately $3.0 million and $4.7 million, respectively. As of December 31, 2012 and 2011 we had approximately $2.30 and $0.31, respectively, per Series D Preferred Share, or $2.6 million and $0.4 million, respectively, of Series D Preferred Stock dividends in arrears. Refer to Note 21.

The Holders of Series D Preferred Stock have the right to receive notice of any meeting of holders of our Common Stock or Series D Preferred Stock and to vote (on an as-converted into Common Stock basis) upon any matter submitted to a vote of the holders of Common Stock or Series D Preferred Stock. Except as otherwise expressly set forth in the Company s Amended and Restated Certificate of Incorporation, as amended from time to time, the holders of Series D Preferred Stock will vote on each matter submitted to them with the holders of Common Stock and all other classes and series of our capital stock entitled to vote on such matter, taken together as a single class.

With respect to dividend distributions (other than required dividends to the holders of our Series A Preferred Stock) and distributions upon liquidation, winding up or dissolution of the Company, the Series D Preferred Stock ranks senior to all classes of common stock, our Series A Preferred Stock, our Series C Preferred Stock, and to each other class of our capital stock existing now or hereafter created that are not specifically designated as ranking senior to or pari passu with the Series D Preferred Stock.

Upon the occurrence of a Liquidation Event (as defined in the Certificate of Designation), holders of Series D Preferred Stock are entitled to be paid, subject to applicable law, out of our assets available for distribution to our stockholders, an amount in cash (the Liquidation Payment) for each share of Series D Preferred Stock equal to the greater of (x) the Liquidation Amount for each such share of Series D Preferred Stock outstanding plus (i) any declared and unpaid dividends and (ii) accrued dividends or (y) the amount for each share of Series D Preferred Stock the holders would be entitled to receive pursuant to the Liquidation Event if all of the shares of Series D Preferred Stock had been converted into Common Stock as of the date immediately prior to the date fixed for determination of stockholders entitled to receive a distribution in such Liquidation Event. Such Liquidation Payment will be paid before any cash distribution will be made or any other assets distributed in respect of any class of securities junior to the Series D Preferred Stock, including, without limitation, Common Stock and the our Series A Preferred Stock.

The holder of any share of Series D Preferred Stock may at any time and from time to time convert such share into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (A) the Liquidation Amount of the share by (B) the Conversion Price, which is initially $2.48, subject to adjustment as provided in the Certificate of Designation. Initially, the Series D Preferred Stock was convertible into 10 shares of our Common Stock.

We may, at any time, convert the outstanding Series D Preferred Stock into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing (A) the Liquidation Amount of the shares by (B) the Conversion Price, but only if the closing bid price of the Common Stock exceeds $5.00 per share during any thirty (30) consecutive trading days prior to each conversion. Initially, the Series D Preferred Stock was convertible into 10 shares of our Common Stock.

To the extent it is lawfully able to do so, we may redeem all of the then outstanding shares of Series D Preferred Stock by paying in cash an amount per share equal to $24.80 plus all declared or accrued unpaid dividends on such shares, subject to adjustment for any stock dividends or distributions, splits, subdivisions, combinations, reclassifications, stock issuances or similar events with respect to the Common Stock.

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Note 9 Equity-Based Compensation

We maintain three equity-based incentive compensation plans, the 2007 Equity Incentive Plan, the 2000 Stock Option Plan, and the 1996 Stock Option Plan that provide for grants of stock options and restricted stock to our directors, officers, key employees and certain outside consultants. Equity awards granted under our 2007 Equity Incentive Plan are exercisable for a period up to seven years from the date of grant. Equity awards granted under our 2000 Stock Option Plan and the 1996 Stock Option Plan are exercisable for a period of up to 10 years from date of grant. Vesting periods range from immediate to 5 years.

We classify the cash flows resulting from the tax benefit that arises when the tax deductions exceed the compensation cost recognized for those equity awards (excess tax benefits) as financing cash flows. There were no excess tax benefits for the years ended December 31, 2012, 2011, and 2010.

Equity-based compensation arrangements to non-employees are accounted for at their fair value on the measurement date. The measurement of equity-based compensation is subject to periodic adjustment over the vesting period of the equity instruments.

Valuation and Expense Information

We recorded equity based compensation expense from continuing operations of $5.1 million, $7.0 million and $6.5 million for the years ended December 31, 2012, 2011, and 2010, respectively, all of which were reflected as operating expenses. Of the $5.1 million of equity based compensation expense recorded in the year ended December 31, 2012, $3.1 million was recorded as selling, general and administrative expenses and $2.0 million was recorded as research and development expenses. Of the $7.0 million of equity based compensation expense recorded in the year ended December 31, 2011, $3.0 million was recorded as selling, general and administrative expense and $4.0 million was recorded as research and development expenses. Of the $6.5 million of equity based compensation expense recorded in the year ended December 31, 2010, $4.8 million was recorded as selling, general and administrative expense and $1.7 million was recorded as research and development expenses. In addition, during the years ended December 31, 2011 and 2010, we recorded equity based compensation expense from discontinued operations of $0.2 million and $0.4 million, respectively. Refer to Note 4.

We estimate forfeitures of stock options and recognize compensation cost only for those awards expected to vest. Forfeiture rates are determined for all employees and non-employee directors based on historical experience and our estimate of future vesting. Estimated forfeiture rates are adjusted from time to time based on actual forfeiture experience.

As of December 31, 2012, there was $9.6 million of unrecognized compensation cost related to the stock options granted under our stock plans. Such cost is expected to be recognized over a weighted-average period of approximately 2.2 years.

Stock Options

We estimate the fair value of each stock option on the date of grant using a Black-Scholes option-pricing formula, applying the following assumptions, and amortize the fair value to expense over the option s vesting period using the straight-line attribution approach for employees and non-employee directors, and for awards issued to non-employees we recognize compensation expense on a graded basis, with most of the compensation expense being recorded during the initial periods of vesting:

	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010
Expected term (in years)	3.0 - 7.0	1.0 - 7.0	0.6 - 7.0
Risk-free interest rate	0.34% - 1.61%	0.09% - 2.61%	1.3% - 2.7%
Expected volatility	41% - 68%	69%	69% - 74%
Expected dividend yield	0%	0%	0%

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Expected Term: The expected term of the stock options granted to employees and non-employee directors was calculated using the shortcut method. We believe this method is appropriate as our equity shares have been publicly-traded for a limited period of time and as such we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The expected term of stock options issued to non-employee consultants is the remaining contractual life of the options issued.

Risk-Free Interest Rate: The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the option.

Expected Volatility: The expected volatility for options with an expected life of 5 years or less was based on our historical volatility of our stock. The expected volatility for options with an expected life of 6 years and over was based on a peer group of publicly-traded stocks historical trading, which we believe will be representative of the volatility over the expected term of the options. We believe the peer group s historical volatility is appropriate as our equity shares have been publicly-traded for a limited period of time.

Expected Dividend Yield: We do not intend to pay dividends on Common Stock for the foreseeable future. Accordingly, we used a dividend yield of zero in the assumptions.

We maintain incentive stock plans that provide for the grants of stock options to our directors, officers, employees and non-employee consultants. As of December 31, 2012, there were 6,630,600 shares of Common Stock reserved for issuance under our 2007 Incentive Plan. We intend to issue new shares upon the exercise of options. Stock options granted under these plans have been granted at an option price equal to the closing market value of the stock on the date of the grant. Options granted under these plans to employees typically become exercisable over four years in equal annual installments after the date of grant, and options granted to non-employee directors become exercisable in full one-year after the grant date, subject to, in each case, continuous service with us during the applicable vesting period. We assumed options to grant Common Stock as part of the mergers with Acuity Pharmaceuticals, Inc. and Froptix, Inc., which reflected various vesting schedules, including monthly vesting to employees and non-employee consultants.

A summary of option activity under our stock plans as of December 31, 2012, and the changes during the year is presented below:

Options	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2011	16,814,521	$ 2.64	4.3	$ 38,092
Granted	2,279,500	$ 4.59		
Exercised	(1,019,967)	$ 2.19		
Forfeited	(327,750)	$ 3.36		
Expired	(4,500)	$ 2.41		
Outstanding at December 31, 2012	17,741,804	$ 2.90	3.8	$ 34,227
Vested and expected to vest at December 31, 2012	15,106,165	$ 2.85	3.8	$ 29,973
Exercisable at December 31, 2012	11,513,890	$ 2.48	2.9	$ 27,080

The total intrinsic value of stock options exercised for the years ended December 31, 2012, 2011, and 2010 was $2.4 million, $0.8 million and $0.3 million, respectively.

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The weighted average grant date fair value of stock options granted for the years ended December 31, 2012, 2011, and 2010 was $2.44, $2.49, and $1.39, respectively. The total fair value of stock options vested during the years ended December 31, 2012, 2011 and 2010 was $3.4 million, $6.4 million and $3.4 million, respectively. The following table provides the grant date fair value for each of the following groups of stock option activity during 2012:

Options	Number of options	Weighted average grant date fair value
Nonvested at December 31, 2011	6,484,875	$ 1.84
Granted	2,279,500	$ 2.44
Forfeited	327,750	$ 1.89
Nonvested at December 31, 2012	6,227,914	$ 1.45

Restricted Stock

In 2009, we issued 30,000 shares of restricted Common Stock to one of our independent board members. The restricted stock was granted under our 2007 Equity Incentive Plan with a term of seven years and vesting occurring five years after the grant date with certain events which would accelerate the vesting of the award. The restricted stock was valued using the grant date fair value which was equivalent to the closing price of our Common Stock on the grant date. We record the cost of restricted stock over the vesting period.

Note 10 Income Taxes

We operate in the following countries in which we are required to file tax returns: U.S., Canada, Israel, Mexico, Taiwan, Chile, and Spain.

The (expense) benefit from continuing operations for incomes taxes consists of the following:

(In thousands)	For the years ended December 31, 2012	2011	2010
Current			
Federal	$	$	$
State			
Foreign	(332)	(391)	(330)
	(332)	(391)	(330)
Deferred			
Federal	8,191	18,043	
State	1,038	1,220	
Foreign	729	486	348
	9,958	19,749	348
Total, net	$ 9,626	$ 19,358	$ 18

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Deferred income tax assets and liabilities from continuing operations as of December 31, 2012 and 2011 are comprised of the following:

(In thousands)	December 31, 2012	December 31, 2011
Deferred income tax assets:		
Federal net operating loss	$ 50,174	$ 40,208
State net operating loss	6,774	7,254
Foreign net operating loss	3,427	2,142
Capitalized research and development expense	2,162	2,884
Research and development tax credit	4,204	3,688
Stock options	6,326	5,283
Accruals	1,556	836
Other	4,094	2,991
Deferred income tax assets	78,717	65,286
Deferred income tax liabilities:		
Intangible assets	(25,738)	(18,788)
Other	(3,277)	(106)
Deferred income tax liabilities	(29,015)	(18,894)
Net deferred income tax assets	49,702	46,392
Valuation allowance	(59,145)	(53,255)
Net deferred income tax liabilities	$ (9,443)	$ (6,863)

The changes in deferred income tax assets, liabilities and valuation allowances at December 31, 2012 reflect the acquisition of various legal entities, including the tax attributes. Certain deferred tax assets and liabilities have been changed to properly reflect their classification. The acquisitions were accounted for under U.S. GAAP as stock acquisitions and business combinations. As of December 31, 2012, we have federal, state and foreign net operating loss carryforwards of approximately $201.8 million, $179.7 million and $13.6 million, respectively, that expire at various dates through 2032. As of December 31, 2012, we have research and development tax credit carryforwards of approximately $4.2 million that expire in varying amounts through 2031. We have determined a full valuation allowance is required against all of our net deferred tax assets that we do not expect to be utilized by the turning of deferred income tax liabilities.

Under Section 382 of the Internal Revenue Code of 1986, as amended, certain significant changes in ownership may restrict the future utilization of our income tax loss carryforwards and income tax credit carryforwards in the United States. The annual limitation is equal to the value of our stock immediately before the ownership change, multiplied by the long-term tax-exempt rate (i.e., the highest of the adjusted Federal long-term rates in effect for any month in the three-calendar-month period ending with the calendar month in which the change date occurs). This limitation may be increased under the IRC§ 338 Approach (IRS approved methodology for determining recognized Built-In Gain). As a result, federal net operating losses and tax credits may expire before we are able to fully utilize them.

During 2008, we conducted a study to determine the impact of the various ownership changes that occurred during 2007 and 2008. As a result, we have concluded that the annual utilization of our net operating loss carryforwards (NOLs) and tax credits is subject to a limitation pursuant to Internal Revenue Code section 382. Under the tax law, such NOLs and tax credits are subject to expiration from 15 to 20 years after they were generated. As a result of the annual limitation that may be imposed on such tax attributes and the statutory expiration period, some of these tax attributes may expire prior to our being able to use them. As we have established a valuation allowance against all of our net deferred tax assets, including such NOLs and tax credits, there is no current impact on these financial statements as a result of the annual limitation. This study did not conclude as to whether eXegenics pre-merger NOLs were limited under Section 382. As such, of the $201.8 million of federal net operating loss carryforwards, at least approximately $39.7 million may not be able to be utilized.

Uncertain Income Tax Positions

We file federal income tax returns in the U.S., Canada, Israel, Mexico, Taiwan, Chile, and Spain jurisdictions, as well as with various U.S. states and the Ontario province in Canada. We are subject to tax audits in all jurisdictions for which we file tax returns. Tax audits by their very nature are often complex and can require several years to complete. There are currently no tax audits that have commenced with respect to income tax returns in any jurisdiction.

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U.S. Federal: Under the tax statute of limitations applicable to the Internal Revenue Code, we are no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for years before 2009. However, because we are carrying forward income tax attributes, such as net operating losses and tax credits from 2009 and earlier tax years, these attributes can still be audited when utilized on returns filed in the future.

State: Under the statutes of limitation applicable to most state income tax laws, we are no longer subject to state income tax examinations by tax authorities for years before 2009 in states in which we have filed income tax returns. Certain states may take the position that we are subject to income tax in such states even though we have not filed income tax returns in such states and, depending on the varying state income tax statutes and administrative practices, the statute of limitations in such states may extend to years before 2008.

Foreign: Under the statutes of limitations applicable to our foreign operations, we are no longer subject to tax examination for years before 2007 in jurisdictions where we have filed income tax returns.

As of December 31, 2012, December 31, 2011, and December 31, 2010, the total amount of gross unrecognized tax benefits was approximately $9.2 million, $5.3 million, and $5.4 million, respectively. Accrued interest and penalties on such unrecognized tax benefits were $0 in each period. There are no accrued interest and penalties resulting from such unrecognized tax benefits as a result of net operating loss carryforwards. There are no net unrecognized tax benefits that, if recognized, would impact the effective tax rate as of December 31, 2012 as a result of valuation allowances.

Unrecognized Tax Benefits

As of December 31, 2012, the total gross unrecognized tax benefit of $9.2 million consisted of increases of $4.0 million as a result of current year acquisitions. As of December 31, 2012, the total amount of unrecognized tax benefits that, if recognized, would affect our effective income tax rate was $0.3 million. As of December 31, 2011 and 2010, none of the unrecognized tax benefits, if recognized, would have affected our effective income tax rate. We account for any applicable interest and penalties on uncertain tax positions as a component of income tax expense. The Company had an immaterial amount of interest and penalties accrued at December 31, 2012. We believe it is reasonably possible that approximately $0.2 million of unrecognized tax benefits may be recognized within the next twelve months as a result of a lapse of the statute of limitations.

The following summarizes the changes in our gross unrecognized income tax benefits.

	For the years ended December 31,		
(In thousands)	2012	2011	2010
Unrecognized tax benefits at beginning of period	$ 5,250	$ 5,413	$ 6,818
Gross increases tax positions in prior period	4,467	257	
Gross decreases tax positions in prior period	(472)	(420)	(1,405)
Unrecognized tax benefits at end of period	$ 9,245	$ 5,250	$ 5,413

Other Income Tax Disclosures

The significant elements contributing to the difference between the federal statutory tax rate and the effective tax rate for continuing operations are as follows:

	For the years ended December 31,		
	2012	2011	2010
Federal statutory rate	35.0%	35.0%	35.0%
State income taxes, net of federal benefit	3.1	3.6	3.5
Foreign income tax	(0.9)	(1.9)	(1.2)
Research and development tax credits	(0.3)	0.2	8.3
Original issue discount		0.1	5.2

Other items including valuation allowance adjustments and permanent items	(12.1)	37.9	(50.7)
Total	24.8%	74.9%	0.1%

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The following table reconciles our losses from continuing operations before income taxes between U.S. and foreign jurisdictions:

	For the years ended December 31,		
(In thousands)	2012	2011	2010
Pre-tax loss:			
U.S.	$ (34,058)	$ (24,089)	$ (11,213)
Foreign	(4,725)	(1,733)	(767)
Total	$ (38,783)	$ (25,822)	$ (11,980)

The following table reconciles our long-lived assets between U.S. and foreign jurisdictions:

	For the years ended December 31,	
(In thousands)	2012	2011
Long-lived assets:		
U.S.	$ 4,324	$ 2,240
Foreign	12,202	3,118
Total	$ 16,526	$ 5,358

No additional provision has been made for U.S. or foreign income taxes on the undistributed earnings of subsidiaries or for unrecognized deferred tax liabilities for temporary differences related to investments in subsidiaries, as such earnings are expected to be permanently reinvested, the investments are essentially permanent in duration, or the Company has concluded that no additional tax liability will arise as a result of distribution of such earnings. A liability could arise if amounts are distributed by such subsidiaries or if such subsidiaries are ultimately disposed. It is not practicable to estimate the additional income taxes related to permanently reinvested earnings or the basis differences related to investments in subsidiaries.

We may benefit from tax holidays in Israel as a result of our acquisition of FineTech. These tax holidays are on approved investments and are scheduled to expire, in whole or in part, at varying times within the next eight years. Some of these holidays may be extended when certain conditions are met, or terminated if certain conditions are not met. If the tax holidays are not extended, or if we fail to satisfy the conditions of the reduced tax rate, then our effective tax rate would increase in the future.

Note 11 Supplemental Cash Flow Information

Supplemental cash flow information is summarized as follows:

	For the years ended December 31,		
(In thousands)	2012	2011	2010
Interest paid	$ 945	$ 726	$ 4,386
Income taxes paid, net	$ 575	$ 338	$ 235
Non-cash financing:			
Shares issued upon the conversion of:			
Series D Preferred Stock	$	$ 1,742	$
Common Stock warrants, net exercised	$ 7	$ 1,155	$

Issuance of capital stock to acquire:			
Exakta-OPKO	$	$	$ 1,999
OPKO Diagnostics	$	$ 22,452	$
FineTech	$	$ 17,717	$
Farmadiet	$ 805	$	$
OURLab	$ 32,888	$	$

Note 12 Related Party Transactions

In December 2012, we entered into a five year lease with AVI Properties, LLC. (AVI), an entity affiliated with Dr. Jonathan Oppenheimer, OURLab s Chief Executive Officer. The lease is for approximately 44,000 square feet of laboratory and office space in Nashville, Tennessee, where OURLab is based. The lease provides for payments of approximately $18 thousand per month in the first year, increasing annually if the consumer price index exceeds 5%, plus applicable sales tax. In addition to the rent, we pay a portion of operating expenses, property taxes and parking. The rent for the first year was reduced to reflect a $30 thousand credit for the costs of tenant improvements.

During the year ended December 31, 2012, our FineTech subsidiary recorded revenue of $0.2 million for the sale of APIs to Teva. Dr. Frost serves as the Chairman of the Board of Directors of Teva.

In February 2012, we entered into a cooperative research funding and option agreement with The Scripps Research Institute (TSRI) to support research for the development of novel oligomeric compounds relating to our molecular diagnostics technology (the Research Agreement). Pursuant to the Research Agreement, we agreed to provide funding of approximately $0.9 million annually over a five year period. In conjunction with entering into the Research Agreement, we also entered into a license agreement with TSRI for technology relating to libraries of peptide tertiary amides. In addition, we entered into a second license with TSRI for technology relating to highly selective inhibitors of c-Jun-N-Terminal Kinases that may be useful for the treatment of various diseases, including Parkinson s disease. We also entered into a research funding and option agreement to provide funding of approximately $0.2 million annually over three years to support further development of the technology. Dr. Frost serves as a Trustee for TSRI and Dr. Lerner served as its President until December 2011.

In February 2012, we made a $1.0 million investment in ChromaDex. Other investors participating in the private financing included the Gamma Trust, Hsu Gamma, and Dr. Lerner. Following our investment, we own 1.5% of ChromaDex, the Gamma Trust owns approximately 16% of ChromaDex; Hsu Gamma owns approximately 1%; and Dr. Lerner owns less than 1% of ChromaDex. Refer to Note 3.

In February 2012, we purchased the BZNE Notes, convertible into BZNE common stock at a price equal to $0.20 per common share, which BZNE Notes are due and payable on February 24, 2014 and ten year warrants to purchase 8.5 million shares of BZNE common stock at an exercise price of $0.40 per share. Refer to Note 3.

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Mr. Roberto Prego Novo is the Chairman of BZNE and presently serves as a consultant to us. Dr. Frost and Mr. Prego Novo previously invested in BZNE in February and March, 2011. On May 16, 2011, BZNE acquired the assets and assumed the liabilities of Aero Pharmaceuticals, Inc. (Aero) in exchange for which BZNE issued an aggregate of 8,331,396 shares of its restricted common stock to Aero. On September 21, 2011, BZNE issued an additional 13,914 shares to Aero due to the late filing of a registration statement. Prior to the transaction, Dr. Frost, through the Gamma Trust, beneficially owned approximately 46% of Aero s issued and outstanding common stock; Mr. Prego Novo owned approximately 23% of Aero s issued and outstanding common stock through Olyrca Trust; and Dr. Hsiao beneficially owned approximately 12% of Aero s issued and outstanding common stock. Each of Drs. Frost and Hsiao and Mr. Prego Novo beneficially owned approximately 9.2%, 1.7%, and 8.2% of BZNE, respectively, following the purchase of Aero by BZNE. Mr. Rubin beneficially own less than 1% of BZNE as a result of his prior ownership of Aero shares. In April 2012 and June 2012, Dr. Frost, through the Gamma Trust, also made loans to BZNE in the principal amounts of $0.3 million and $0.1 million, respectively, which were initially secured by a first priority lien on particular BZNE receivables. The notes to Gamma Trust were subsequently amended and Gamma Trust no longer holds a security interest in the BZNE receivables.

In August 2011, we made an investment in Neovasc. Refer to Note 3. Dr. Frost and other members of our management are shareholders of Neovasc. Prior to the investment, Dr. Frost beneficially owned approximately 36% of Neovasc, Dr. Hsiao owned approximately 6%, and Mr. Rubin owned less than 1%. Dr. Hsiao and Mr. Rubin also serve on the board of directors for Neovasc.

In March 2011, we issued 27,000,000 shares of our Common Stock. Refer to Note 7. The 27,000,000 shares of our Common Stock issued include an aggregate of 3,733,000 shares of our Common Stock purchased by the Gamma Trust and Hsu Gamma at the public offering price. The Gamma Trust purchased an aggregate of 3,200,000 shares for approximately $12.0 million, and Hsu Gamma purchased an aggregate of 533,000 shares for approximately $1.9 million. Jefferies & Company, Inc. and J.P. Morgan Securities LLC acted as joint book-running managers for the offering. UBS Investment Bank and Lazard Capital Markets LLC acted as co-lead managers for the offering and Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., acted as co-manager for the offering. Dr. Frost is the Chairman of the Board of Directors and principal shareholder of Ladenburg Thalmann Financial Services Inc.

In January 2011, we entered into a definitive agreement with CURNA and each of CURNA s stockholders and option holders, pursuant to which we agreed to acquire all of the outstanding stock of CURNA in exchange for $10.0 million in cash, plus $0.6 million in liabilities, of which $0.5 million was paid at closing. At the time of the transaction, TSRI owned approximately 4% of CURNA.

In November 2010, we made an investment in Fabrus. In exchange for the investment, we acquired approximately 13% of Fabrus on a fully diluted basis. Our investment was part of a $2.1 million financing for Fabrus. Other investors participating in the financing include the Gamma Trust and Hsu Gamma. In connection with the financing, Drs. Frost and Hsiao joined the Fabrus Board of Managers. Dr. Lerner owns approximately 5% of Fabrus. Mr. Vaughn Smider, Founder and CEO of Fabrus, is an Assistant Professor at TSRI. Dr. Frost serves as a Trustee for TSRI, and Dr. Lerner served as President of TSRI until December 2011.

In June 2010, we entered into a cooperative research and development agreement with Academia Sinica, Taipei, Taiwan (Academia Sinica), for pre-clinical work for a compound against various forms of cancer. Dr. Alice Yu, a member of our Board of Directors, is a Distinguished Research Fellow and Associate Director at the Genomics Research Center, Academia Sinica (Genomics Research Center). In connection with the Academia Sinica Agreement, we are required to pay Academia Sinica approximately $0.2 million over the term of the agreement.

In July 2009, we entered into a worldwide exclusive license agreement with Academia Sinica for a new technology to develop protein vaccines against influenza and other viral infections. Effective in March 2010, the Frost Group assigned two license agreements with Academia Sinica to us. The license agreements pertain to alpha-galactosyl ceramide analogs and their use as immunotherapies and peptide ligands in the diagnosis and treatment of cancer. In connection with the assignment of the two licenses, we agreed to reimburse the Frost Group for the licensing fees previously paid by the Frost Group to Academia Sinica in the amounts of $50 thousand and $75 thousand, respectively, as well as reimbursement of certain expenses of $50 thousand.

Effective in September 2009, we entered into an agreement pursuant to which we invested $2.5 million in Cocrystal in exchange for 1,701,723 shares of Cocrystal s Convertible Series A Preferred Stock. A group of investors, led by the Frost Group (the Cocrystal Investors), previously invested $5.0 million in Cocrystal, and agreed to invest an additional $5.0 million payable in two equal installments in September 2009 and March 2010. As a result of an amendment to the Cocrystal Investors agreements dated June 9, 2009, we, rather than the Cocrystal Investors, made the first installment investment ($2.5 million) on September 21, 2009. Refer to Note 3.

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In June 2009, we entered into a stock purchase agreement with Sorrento, pursuant to which we invested $2.3 million in Sorrento. Refer to Note 3. In exchange for the investment, we acquired approximately one-third of the outstanding common shares of Sorrento and received a fully-paid, exclusive license to the Sorrento antibody library for the discovery and development of therapeutic antibodies in the field of ophthalmology. On September 21, 2009, Sorrento entered into a merger transaction with Quikbyte Software, Inc. (Quikbyte). Prior to the merger transaction, certain investors, including Dr. Frost and other members of our management group, made an investment in Quikbyte. Dr. Lerner serves as a consultant and scientific advisory board member to Sorrento and owns less than one percent of its shares.

On February 23, 2009, we entered into a Stock Purchase Agreement with the Gamma Trust, of which Dr. Frost is the sole trustee. Refer to Note 7.

In November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC (Frost Holdings), an entity affiliated with Dr. Frost. The lease is for approximately 8,300 square feet of space in an office building in Miami, Florida, where our principal executive offices are located. The lease provides for payments of approximately $18 thousand per month in the first year increasing annually to $24 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking. The rent for the first year was reduced to reflect a $30 thousand credit for the costs of tenant improvements. In August 2012, we entered into a six-month extension on the same terms as the 2007 expiring lease and in February 2013, we agreed to extend the lease on a month-to-month basis for up to an additional six months.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost in an amount equal to the cost of a first class airline ticket between the travel cities for each executive, including Dr. Frost, traveling on the airplane for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive; nor do we pay for any other fixed or variable operating costs of the airplane. For the fiscal years ending December 31, 2012, 2011, and 2010, we reimbursed Dr. Frost approximately $203 thousand, $170 thousand, and $46 thousand, respectively, for Company-related travel by Dr. Frost and other executives.

Note 13 Employee Benefit Plans

Effective January 1, 2007, the OPKO Health Savings and Retirement Plan (the Plan) permits employees to contribute up to 50% of qualified pre-tax annual compensation up to annual statutory limitations. The discretionary company match for employee contributions to the Plan is 100% up to the first 4% of the participant s earnings contributed to the Plan. Our matching contributions to the Plan were approximately $0.3 million and $0.2 million for the years ended December 31, 2012 and 2011, respectively.

Note 14 Commitments and Contingencies

In connection with our acquisitions of CURNA, OPKO Diagnostics, FineTech, and Farmadiet, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, for the year ended December 31, 2012, we recorded $20.0 million as contingent consideration, with $5.1 million recorded within Accrued expenses and $14.9 million recorded within Other long-term liabilities in the accompanying Consolidated Balance Sheets. For the year ended December 31, 2011, we recorded $18.0 million as contingent consideration within Other long-term liabilities in the accompanying Consolidated Balance Sheets. Refer to Note 3.

Prost-Data, Inc. (OURLab) received a letter dated July 9, 2012 from AdvanceMed Corporation (AdvanceMed) regarding a post-payment review conducted by AdvanceMed (the Post-Payment Review Letter). The Post-Payment Review Letter originated with a post payment review audit by AdvanceMed of 183 claims submitted by OURLab to the Medicare program. OURLab believes that its billing practices were appropriate and it is following the appeal process set forth by Medicare. OURLab received a partially favorable determination, which reduced the amount of the alleged overpayment, and it continues to appeal the remaining alleged overpayments. No assurances can be given about the outcome of the appeal.

On November 27, 2012, Adrian Goldstein, M.D., a former employee of OURLab, filed a complaint for declaratory judgment and alleged breach of contract against OURLab in the Chancery Court for Davidson County, Tennessee. Dr. Goldstein asserts in his complaint that OURLab breached his employment agreement and owes him additional compensation and further compensation for the value of OURLab under a compensation for sale provision set forth in his employment agreement. Dr. Goldstein seeks recovery of compensatory damages not to exceed $20 million, plus his attorney s fees and litigation expenses. OURLab believes this action is without merit and is vigorously defending against plaintiff s claims. It is too early to assess the probability of a favorable or unfavorable outcome or the loss or range of loss, if any.

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On or around October 30, 2012, we received a letter from counsel to Optos making certain indemnity claims against us in connection with the sale of our ophthalmic instrumentation business. Refer to Note 4. It is too early to assess the likelihood of litigation in this matter or the probability of a favorable or unfavorable outcome. However, we do not currently believe this matter will have a material impact on our results of operations or financial condition.

We are a party to other litigation in the ordinary course of business. We do not believe that any such litigation will have a material adverse effect on our business, financial condition, or results of operations.

We expect to incur substantial losses as we continue the development of our product candidates, continue our other research and development activities, and establish a sales and marketing infrastructure in anticipation of the commercialization of our diagnostic and pharmaceutical product candidates. We currently have limited commercialization capabilities, and it is possible that we may never successfully commercialize any of our diagnostic and pharmaceutical product candidates. We do not currently generate revenue from any of our diagnostic and pharmaceutical product candidates. Our research and development activities are budgeted to expand over a period of time and will require further resources if we are to be successful. As a result, we believe that our operating losses are likely to be substantial over the next several years. We may need to obtain additional funds to further develop our research and development programs, and there can be no assurance that additional capital will be available to us on acceptable terms, or at all.

Note 15 Strategic Alliances

We plan to develop a portfolio of product candidates through a combination of internal development and external partnerships. In December 2010, we entered into a definitive agreement granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Refer to Note 3. We have also completed strategic deals with the UT Southwestern, the President and Fellows of Harvard College, and Academia Sinica, among others. In connection with these license agreements, upon the achievement of certain milestones we are obligated to make certain payments and have royalty obligations upon sales of products developed under the license agreements. At this time, we are unable to estimate the timing and amounts of payments as the obligations are based on future development of the licensed products.

Note 16 Leases

We conduct certain of our operations under operating lease agreements. Rent expense under operating leases from continuing operations was approximately $1.3 million, $0.7 million, and $0.8 million for the years ended December 31, 2012, 2011, and 2010, respectively.

As of December 31, 2012, the aggregate future minimum lease payments under all non-cancelable operating leases with initial or remaining lease terms in excess of one year are as follows:

Year Ending	(In thousands)
2013	$ 2,007
2014	1,750
2015	1,288
2016	1,134
2017	705
Thereafter	1,849
Total minimum lease commitments	$ 8,733

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Note 17 Segments

We currently manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Israel, and Spain. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired in Tennessee through the acquisition of OURLab and (ii) point-of-care and molecular diagnostics operations. Refer to Note 1. There are no inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

Information regarding our operations and assets for our operating segments and the unallocated corporate operations as well as geographic information are as follows:

	For the years ended December 31,		
(In thousands)	2012	2011	2010
Product revenues:			
Pharmaceutical	$ 45,295	$ 27,844	$ 21,763
Diagnostics			
Corporate			
	$ 45,295	$ 27,844	$ 21,763
Revenue from services and license revenues:			
Pharmaceutical	$	$	$
Diagnostics	395		
Corporate	1,354	135	6,731
	$ 1,749	$ 135	$ 6,731
Operating loss from continuing operations:			
Pharmaceutical	$ (6,797)	$ (3,668)	$ (3,257)
Diagnostics	(14,259)	(3,984)	(695)
Corporate	(15,628)	(15,537)	(7,184)
Less: Operating loss from noncontrolling interests	(585)		
	$ (37,269)	$ (23,189)	$ (11,136)
Depreciation and amortization:			
Pharmaceutical	$ 6,367	$ 2,804	$ 2,092
Diagnostics	3,614	856	
Corporate	179	170	115
	$ 10,160	$ 3,830	$ 2,207
Net loss from investments in investees:			
Pharmaceutical	$ (2,062)	$ (1,589)	$ (714)
Diagnostics			
Corporate			
	$ (2,062)	$ (1,589)	$ (714)
Revenues:			
United States	$ 1,749	$ 135	$ 6,731
Chile	26,514	21,466	17,977

Mexico	5,002	6,378	3,786
Israel	7,655		
Spain	6,124		
	$ 47,044	$ 27,979	$ 28,494

	As of December 31,	
	2012	2011
Assets:		
Pharmaceutical	$ 142,299	$ 90,409
Diagnostics	112,422	63,317
Corporate	35,109	75,759
Discontinued operations		4
	$ 289,830	$ 229,489
Goodwill:		
Pharmaceutical	$ 32,844	$ 21,838
Diagnostics	47,606	17,977
Corporate		
Discontinued operations		
	$ 80,450	$ 39,815

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During the year ended December 31, 2012, no customers represented more than 10% of our product revenues. During the year ended December 31, 2011, one customer represented 17% of our product revenues. During the year ended December 31, 2010, one customer represented 13% of our revenues. As of December 31, 2012, no customer represented more than 10% of our account receivables balance. As of December 31, 2011, one customer represented 29% of our accounts receivable balance.

Note 18 Fair Value Measurement

We record fair value at an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. We utilize a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

A summary of our investments as of December 31, 2012 and 2011, classified as available for sale, and carried at fair value is as follows:

	As of December 31, 2012				
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Gain/(Loss) in Accumulated Deficit	Fair value
Common stock investments	$ 2,051	$ 6,185	$	$	$ 8,236
BZNE Note and conversion feature	1,700	53		287	2,040
Neovasc common stock options	925	293		176	1,394
Neovasc common stock warrants	659	194		(375)	478
Total assets	$ 5,335	$ 6,725	$	$ 88	$ 12,148

	As of December 31, 2011				
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Gain/(Loss) in Accumulated Deficit	Fair value
Neovasc common stock options	$ 826	$ 205	$	$	$ 1,031
Neovasc common stock warrants	659	194		(39)	814
Total assets	$ 1,485	$ 399	$	$ (39)	$ 1,845

Any future fluctuation in fair value related to these instruments that is judged to be temporary, including any recoveries of previous write-downs, would be recorded in accumulated other comprehensive income or loss. If we determine that any future valuation adjustment was other-than-temporary, we would record a loss during the period that such determination is made.

As of December 31, 2012, we have money market funds that qualify as cash equivalents, forward contracts for inventory purchases (Refer to Note 19) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics, FineTech, and Farmadiet (Refer to Note 13) that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment in Neovasc as well as entering into our consulting agreement with Neovasc, we record our options and warrants at fair value. Refer to Note 3. During the year ended December 31, 2011, we recorded other income of $0.1 million related to a reduction of the contingent consideration related to CURNA.

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Our financial assets and liabilities measured at fair value on a recurring basis are as follows:

	Fair value measurements as of December 31, 2012			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$ 18,716	$	$	$ 18,716
Certificates of deposits		820		820
Forward contracts		10		10
Common stock investments	8,236			8,236
BZNE Note and conversion feature			2,040	2,040
Neovasc common stock options		1,394		1,394
Neovasc common stock warrants		478		478
Total assets	$ 26,952	$ 2,702	$ 2,040	$ 31,694
Liabilities:				
Deferred acquisition payments, net of discount	$	$	$ 10,103	$ 10,103
CURNA contingent consideration			510	510
OPKO Diagnostics contingent consideration			12,974	12,974
FineTech contingent consideration			5,262	5,262
Farmadiet contingent consideration			1,310	1,310
Total Liabilities	$	$	$ 30,159	$ 30,159

	Fair value measurements as of December 31, 2011			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$ 68,089	$	$	$ 68,089
Forward contracts		143		143
Neovasc common stock options		1,031		1,031
Neovasc common stock warrants		814		814
Total assets	$ 68,089	$ 1,988	$	$ 70,077
Liabilities:				
CURNA contingent consideration	$	$	$ 510	$ 510
OPKO Diagnostics contingent consideration			12,745	12,745
FineTech contingent consideration			4,747	4,747
Total Liabilities	$	$	$ 18,002	$ 18,002

As of December 31, 2012 and 2011, the carrying value of our other financial assets and liabilities approximates their fair value due to their short-term nature.

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The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities:

(In thousands)	BZNE Note and conversion feature	Contingent consideration	Deferred acquisition payments, net of discount
Balance at December 31, 2011	$	$ 18,002	$
Additions	1,700	1,234	9,673
Change in fair value included in:			
Operating expenses		785	
Other income and (expenses), net	1,563		204
Other comprehensive loss	53		
Foreign exchange gain (loss)		35	226
Transfer out to equity method investment	(1,276)		
Balance at December 31, 2012	$ 2,040	$ 20,056	$ 10,103

The estimated fair values of the Company s financial instruments have been determined by using available market information and what we believe to be appropriate valuation methodologies. We use the following methods and assumptions in estimating fair values:

BZNE Note and conversion feature The stock market activity in BZNE does not represent an active market and as such, we determined the fair market value utilizing a business enterprise valuation approach in the order to determine the fair value of our investment. The most significant assumptions are the projected revenue growth and operating income (loss). The impact of a change in any of our significant underlying assumptions +/- 1% would not result in a materially different fair value.

Contingent consideration We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues (Finetech transaction). We use several discount rates depending on each type of contingent consideration related to Finetech, OPKO Diagnostics, CURNA and Farmadiet transactions. The discount rates used range from 13% to 27% and were based on the weighted average cost of capital for those businesses. If the discount rates were to increase by 1%, on each transaction, the contingent consideration would decrease by $0.2 million. If estimated future sales were to decrease by 10%, the contingent consideration related to Finetech would decrease by an insignificant amount. As of December 31, 2012, of the $20.0 million of contingent consideration, $14.9 million is recorded in Accrued expenses and $5.1 million is recorded in Other-long-term liabilities. As of December 31, 2011, the contingent consideration of $18.0 million was recorded in Other-long term liabilities.

Deferred payments We estimate the fair value of the deferred payments utilizing a discounted cash flow model for the expected payments.

Note 19 Derivative Contracts

We enter into foreign currency forward exchange contracts to cover the risk of exposure to exchange rate differences arising from inventory purchases on letters of credit. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date.

During 2012 and 2011, we entered into a foreign exchange, fixed interest rate swap contract that provides for us to pay a fixed interest rate on the underlying loan balance denominated in Chilean Pesos. We entered into this agreement in Chile for purchases of inventory denominated in U.S. dollars. A hypothetical 1% interest rate change or 10% foreign exchange rate change will not have a material impact on our results from operations or financial position.

We record derivative financial instruments as Accrued expenses or Other current assets on our Consolidated Balance Sheet at their fair value and the corresponding gain or loss as Other income (expense), net. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At December 31, 2012 and 2011, the forward contracts did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values in income.

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The outstanding contracts at the end of the years ended December 31, 2012 and 2011 have been valued at fair value, and their maturity details are as follows:

(In thousands)

Days until maturity	Contract value	Fair value at December 31, 2012	Decrease of loss
0 to 30	$	$	$
31 to 60	581	577	(4)
61 to 90	341	339	(2)
91 to 120	212	210	(2)
121 to 180	170	168	(2)
More than 180			
Total	$ 1,304	$ 1,294	$ (10)

(In thousands)

Days until maturity	Contract value	Fair value at December 31, 2011	Decrease of loss
0 to 30	$ 1,232	$ 1,241	$ 9
31 to 60	116	126	10
61 to 90	402	415	13
91 to 120	35	37	2
121 to 180	106	109	3
More than 180	35	36	1
Total	$ 1,926	$ 1,964	$ 38

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Note 20 Selected Quarterly Financial Data (Unaudited)

	For the 2012 Quarters Ended			
(In thousands, except per share data)	March 31	June 30	September 30	December 31
Total revenues	$ 8,777	$ 10,211	$ 11,795	$ 16,261
Gross margin, excluding amortization of intangible assets	3,790	3,657	4,308	7,411
Loss from continuing operations	(8,611)	(10,245)	(9,829)	(1,064)
Net loss attributable to common shareholders	(9,171)	(10,805)	(10,206)	(1,106)
(Loss) income per share, basic and diluted:				
Loss from continuing operations	$ (0.03)	$ (0.04)	$ (0.03)	$ (0.00)
Income (loss) from discontinued operations	$	$	$ 0.00	$
Net loss operations	$ (0.03)	$ (0.04)	$ (0.03)	$ (0.00)

	For the 2011 Quarters Ended			
(In thousands), except per share data	March 31	June 30	September 30	December 31
Total revenues	$ 6,950	$ 8,428	$ 6,807	$ 5,794
Gross margin, excluding amortization of intangible assets	2,772	3,538	2,790	1,636
(Loss) income from continuing operations	(4,749)	(5,347)	(6,749)	10,381
Net (loss) income attributable to common shareholders	(6,349)	(6,361)	(8,836)	17,884
(Loss) income per share, basic:				
(Loss) income from continuing operations	$ (0.02)	$ (0.02)	$ (0.02)	$ 0.04
(Loss) income from discontinued operations	$ (0.00)	$ (0.00)	$ (0.01)	$ 0.03
Net (loss) income	$ (0.02)	$ (0.02)	$ (0.03)	$ 0.06
(Loss) income per share, diluted:				
(Loss) income from continuing operations	$ (0.02)	$ (0.02)	$ (0.02)	$ 0.03
(Loss) income from discontinued operations	$ (0.00)	$ (0.00)	$ (0.01)	$ 0.03
Net (loss) income	$ (0.02)	$ (0.02)	$ (0.03)	$ 0.06

Due to rounding, the quarterly per share amounts may not mathematically compute to the annual amount.

In October 2011, we completed the sale of our ophthalmic instrumentation business to Optos and as a result, recorded a gain of $10.6 million. Refer to Note 4. We corrected an immaterial error related to the classification of one of the intangible assets acquired as part of the CURNA acquisition. During the three months ended December 31, 2011, we reversed $0.7 million of amortization expense previously recorded. We previously recorded $0.2 million, $0.2 million and $0.3 million during each of the three month periods ended March 31, 2011, June 30, 2011 and September 30, 2011, respectively.

Note 21 Subsequent Events

On March 1, 2013, our Board of Directors declared a cash dividend to all Series D Preferred Stockholders as of March 8, 2013. The total cash dividend paid was approximately $3.0 million. In addition, the Company also exercised its option to convert all 1,129,032 shares of our outstanding Series D Preferred Stock into 11,290,320 shares of our Common Stock effective of March 8, 2013. Following the conversion there are no outstanding shares of Series D Preferred Stock.

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On March 1, 2013, we entered into an asset purchase agreement (the Asset Purchase Agreement) with RXi Pharmaceuticals Corporation (RXi). On March 12, 2013, pursuant to the Asset Purchase Agreement, we sold to RXi substantially all of our assets in the field of RNA interference (the RNAi Assets). As consideration for the RNAi Assets, at the closing of the Asset Purchase Agreement, RXi issued to us 50 million shares of its common stock (the APA Shares). In addition, pursuant to the Asset Purchase Agreement, RXi will be required to pay us up to $50 million in milestone payments upon the successful development and commercialization of each drug developed by RXi, certain of its affiliates or any of its or their licensees or sublicensees utilizing patents included within the RNAi Assets (each, a Qualified Drug). RXi also will be required to pay us royalties equal to: (a) a mid single-digit percentage of Net Sales (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable Royalty Period (as defined in the Asset Purchase Agreement); and (b) a low single-digit percentage of net sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable royalty period.

In March 2013, we completed the share purchase agreement entered into in January 2013 (the Cytochroma Agreement) to acquire Cytochroma Inc. (Cytochroma), a corporation located in Markham, Canada, whose two lead products, both in Phase 3 development, are coded CTAP101 Capsules, a vitamin D prohormone to treat secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency, and Fermagate Tablets, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the Cytochroma Acquisition). The transaction closed on March 4, 2013.

We entered into the Cytochroma Agreement with OPKO IP Holdings, Inc. a limited company organized under the laws of Cayman Islands, our indirect wholly-owned subsidiary (the Buyer), Cytochroma Inc., a corporation organized under the laws of Ontario (the Seller), Cytochroma Holdings ULC, an unlimited liability company organized under the laws of Alberta (Holdings), Cytochroma Canada Inc., a corporation organized under the laws of Canada (together with Seller and Holdings, the Seller Parties), Cytochroma Development Inc., a corporation organized under the laws of Barbados (Development), Proventiv Therapeutics, LLC, a Delaware limited liability company (Proventiv), and Cytochroma Cayman Islands, Ltd., a limited company organized under the laws of Cayman Islands (Cayman Newco).

Pursuant to the Cytochroma Agreement, the Buyer purchased from the Seller the issued and outstanding equity securities of Cayman Newco and Proventiv for $100.0 million, which was paid in shares of our Common Stock, par value $0.01 per share, based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the date of the Cytochroma Agreement, or $4.87 per share (the Stock Consideration). In connection with the Cytochroma Agreement, we issued 20,517,030 shares of our Common Stock to the Seller Parties at the closing.

In addition, the Cytochroma Agreement provides for the payment of up to an additional $190.0 million to the Seller Parties in cash or additional shares of our Common Stock, at the Buyer s election, upon the achievement of certain milestones relating to development and annual revenue (the Milestone Consideration). If we elect to pay any portion of the Milestone Consideration in shares of our Common Stock, the amount of shares to be issued will be based on the volume-weighted average price per share of our Common Stock as reported on the NYSE or any other exchange system or market quotation system on which we are then listed for the ten trading days immediately preceding: (i) the milestone being achieved in the case of development milestones; or (ii) the earlier of the completion of the audit of the our financial statements or the 105th day after the end of the applicable calendar year in the case of revenue milestones. In certain circumstances, the payment of the Milestone Consideration shall be made by us in cash, including if payment in shares of our Common Stock would trigger an obligation to obtain the approval of our shareholders under applicable securities laws or NYSE regulations. In addition, we have the ability to off-set the payment of any Milestone Consideration by the amount of our potential indemnity claims under the Cytochroma Agreement.

The Cytochroma Agreement contains customary representations, warranties, conditions to closing, indemnification rights and obligations of the parties.

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On January 29, 2013, we entered into note purchase agreements, dated January 25, 2013, with various purchasers (collectively, the Purchasers) for the sale of $175.0 million aggregate principal amount of 3.00% convertible senior notes due 2033 (the Notes) to qualified institutional buyers and accredited investors (collectively, the Note Purchase Agreement) in a private placement in reliance on exemptions from registration under the Securities Act of 1933, as amended (the Securities Act). The Purchasers of the Notes include Gamma Trust and Hsu Gamma. The Notes were issued on January 30, 2013.

We have reviewed all subsequent events and transactions that occurred after the date of our December 31, 2012 consolidated balance sheet date, through the time of filing this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

The Company s management, under the supervision and with the participation of the Company s Chief Executive Officer (CEO) and Chief Financial Officer (CFO), has evaluated the effectiveness of the Company s disclosure controls and procedures as defined in Securities and Exchange Commission (SEC) Rule 13a-15(e) as of December 31, 2012. Based on that evaluation, the CEO and CFO have concluded that the Company s disclosure controls and procedures are effective to ensure that information the Company is required to disclose in reports that it files or submits under the Securities Exchange Act is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms.

Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements according to generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined effective could provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012, based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. As permitted, our management s assessment of and conclusion on the effectiveness of our internal controls did not include the internal controls of Farmadiet Group Holding, S.L., (Farmadiet), SciGen (I.L.) Ltd (SciGen) and Prost-Data, Inc (OURLab), because they were acquired by us in business combinations during the third and fourth quarter of fiscal 2012, respectively.

Based on our evaluation under the framework in Internal Control Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

The effectiveness of the Company s internal control over financial reporting as of December 31, 2012 has been audited by Ernst & Young LLP, our independent registered public accounting firm, who also audited our consolidated financial statements included in this Annual Report on Form 10-K, as stated in their report which appears with our accompanying consolidated financial statements.

Changes to the Company s Internal Control Over Financial Reporting

In connection with the Farmadiet, SciGen and OURLab acquisitions in August 2012, October 2012 and December 2012, respectively, we began implementing standards and procedures at Farmadiet, SciGen and OURLab including upgrading and establishing controls over accounting systems, and adding employees and consultants who are trained and experienced in the preparation of financial statements in accordance with U.S. GAAP to ensure that we have in place appropriate

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internal control over financial reporting at Farmadiet, SciGen and OURLab. Other than as set forth above with respect to Farmadiet, SciGen and OURLab, there have been no changes to the Company s internal control over financial reporting that occurred during the Company s fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Farmadiet s assets constituted $33.1 million and $9.7 million of total and net assets, respectively, as of December 31, 2012. Farmadiet s revenue for the year ended December 31, 2012 constituted $6.1 million of revenue. In addition, Farmadiet s net loss constituted $0.7 million for the year ended December 31, 2012.

SciGen s assets constituted $5.6 million and ($0.2 million) of total and net assets, respectively, as of December 31, 2012. SciGen s revenue for the year ended December 31, 2012 constituted $0.6 million of revenue. In addition, Farmadiet s net loss constituted $0.4 million for the year ended December 31, 2012.

OURLab s assets constituted $51.7 million and $48.3 million of total and net assets, respectively, as of December 31, 2012. OURLab s revenue for the year ended December 31, 2012 constituted $0.4 million. In addition, OURLab s net income constituted $6.0 million for the year ended December 31, 2012.

ITEM 9B. OTHER INFORMATION.

None.

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PART III

The information required in Items 10 (Directors, Executive Officers and Corporate Governance), Item 11 (Executive Compensation), Item 12 (Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters), Item 13 (Certain Relationships and Related Transactions, and Director Independence), and Item 14 (Principal Accounting Fees and Services) is incorporated by reference to the Company s definitive proxy statement for the 2013 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2012.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) (1) Financial Statements: See Part II, Item 8 of this report.

(2) We filed our consolidated financial statements in Item 8 of Part II. Additionally, the financial statement schedule entitled Schedule II Valuation and Qualifying Accounts has been omitted since the information required is included in the consolidated financial statements and notes thereto.

(3) Exhibits: See below.

Exhibit Number	Description
1.1[14]	Underwriting Agreement, dated March 9, 2011, by and among OPKO Health, Inc., Jefferies & Company, Inc. and J.P. Morgan Securities LLC, as representatives for the underwriters named therein.
2.1[1]	Merger Agreement and Plan of Reorganization, dated as of March 27, 2007, by and among Acuity Pharmaceuticals, Inc., Froptix Corporation, eXegenics, Inc., e-Acquisition Company I-A, LLC, and e-Acquisition Company II-B, LLC.
2.2[5]+	Securities Purchase Agreement, dated May 6, 2008, among Vidus Ocular, Inc., OPKO Instrumentation, LLC, OPKO Health, Inc., and the individual sellers and noteholders named therein.
2.3[11]	Purchase Agreement, dated February 17, 2010, among Ignacio Levy García and José de Jesús Levy García, Inmobiliaria Chapalita, S.A. de C.V., Pharmacos Exakta, S.A. de C.V., OPKO Health, Inc., OPKO Health Mexicana S. de R.L. de C.V., and OPKO Manufacturing Facilities S. de R.L. de C.V.
2.4[16]+	Agreement and Plan of Merger, dated January 28, 2011, among CURNA Inc., KUR, LLC, OPKO Pharmaceuticals, LLC, OPKO CURNA, LLC, and certain individuals named therein.
2.5[17]	Agreement and Plan of Merger, dated October 13, 2011, by and among OPKO Health, Inc., Claros Merger Subsidiary, LLC, Claros Diagnostics, Inc., and Ellen Baron, Marc Goldberg and Michael Magliochetti on behalf of the Shareholder Representative Committee.
2.6[19] +	Stock Purchase Agreement, dated December 20, 2011, by and among FineTech Pharmaceutical Ltd., Arie Gutman, OPKO Holdings Israel Ltd., and OPKO Health, Inc.
2.7[20]	Stock Purchase Agreement, dated January 20, 2012, by and among OPKO Health, Inc., OPKO Chile S.A., Samuel Alexandre Arama, Inversiones SVJV Limitada, Bruno Sergiani, Inversiones BS Limitada, Pierre-Yves LeGoff, and Inversiones PYTT Limitada.
2.8[21]+	Stock Purchase Agreement, dated August 2, 2012, by and among Faramdiet Group Holding, S.L., the Sellers party thereto, and Shebeli XXI, S.L.U.
2.9+	Agreement and Plan of Merger, dated October 18, 2012, by and among Prost-Data, Inc. d/b/a OurLab, Our Labs, Endo Labs and Gold Lab, Jonathan Oppenheimer, M.D., OPKO Health, Inc., OPKO Laboratories Inc., and OPKO Labs, LLC.
3.1[2]	Amended and Restated Certificate of Incorporation.
3.2[4]	Amended and Restated By-Laws.
3.3[9]	Certificate of Designation of Series D Preferred Stock.
4.1[1]	Form of Common Stock Warrant.

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4.2[9]	Form of Common Stock Warrant.
10.1[1]	Form of Lockup Agreement.
10.2[1]	License Agreement, dated as of March 31, 2003, by and between the Trustees of the University of Pennsylvania, and Acuity Pharmaceuticals, Inc. (Reich/Tolentino).
10.3[1]	License Agreement, dated as of March 31, 2003, by and between the Trustees of the University of Pennsylvania, and Acuity Pharmaceuticals, Inc. (Reich/Gewirtz).
10.4[1]	First Amendment to License Agreement, dated as of August 1, 2003, by and between the Trustees of the University of Pennsylvania, and Acuity Pharmaceuticals, Inc. (Reich/Tolentino).
10.5[1]	First Amendment to License Agreement, dated as of August 1, 2003, by and between the Trustees of the University of Pennsylvania, and Acuity Pharmaceuticals, Inc. (Gewirtz).
10.6[1]	Credit Agreement, dated as of March 27, 2007, by and among eXegenics, Inc., The Frost Group, LLC, and Acuity Pharmaceuticals, LLC.
10.7[1]	Amended and Restated Subordination Agreement, dated as of March 27, 2007, by and among The Frost Group, LLC, Horizon Technology Funding Company LLC, Acuity Pharmaceuticals, LLC, and eXegenics, Inc.
10.8[4]	Share Purchase Agreement, dated April 11, 2007, by and between Ophthalmic Technologies, Inc., and eXegenics, Inc.
10.9[3]	Lease Agreement dated November 13, 2007, by and between Frost Real Estate Holdings, LLC, and the Company.
10.10[4]	Share Purchase Agreement, dated as of November 28, 2007, by and among Ophthalmic Technologies, Inc., OTI Holdings Limited, and the Shareholders named therein.
10.11[4]	Exchange and Support Agreement, dated as of November 28, 2007, by and among OPKO Health, Inc. and OTI Holdings Limited, and the holders of exchangeable shares named therein.
10.12[4]	Stock Purchase Agreement, dated December 4, 2007, by and between members of The Frost Group, LLC, and the Company.
10.13[4]*	OPKO Health, Inc. 2007 Equity Incentive Plan.
10.14[5]	Form of Director Indemnification Agreement.
10.15[5]	Form of Officer Indemnification Agreement.
10.16[6]	Stock Purchase Agreement, dated August 8, 2008 by and among the Company and the Investors named therein.
10.17[7]	Stock Purchase Agreement, dated February 23, 2009 by and between the Company and Frost Gamma Investments Trust.
10.18[7]	Promissory Note to Frost Gamma Investments Trust, dated March 4, 2009.
10.19[8]	Form of Stock Purchase Agreement for transactions between the Company and Nora Real Estate SA., Vector Group Ltd., Oracle Partners LP, Oracle Institutional Partners, LP., Chung Chia Company Limited, Gold Sino Assets Limited, and Grandtime Associates Limited.

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10.20[8]	Stock Purchase Agreement, dated June 10, 2009, by and among the Company and Sorrento Therapeutics, Inc.
10.21[9]	Form of Securities Purchase Agreement Series D Preferred Stock.
10.22[10]*	Form of Restricted Share Award Agreement (Director).
10.23[10]	Cocrystal Discovery, Inc. Agreements.
10.24[13]	Stock Purchase Agreement, dated October 1, 2009, by and among the OPKO Chile Limitada and Inversones OPKO Limitada, subsidiaries of the Company, and the Sellers named therein.
10.25+[12]	Asset Purchase Agreement, dated October 12, 2009, by and between the Company and Schering Corporation.
10.26[12]	Letter Agreement, dated June 29, 2010, by and between the Company and Schering Corporation.
10.27[18]+	Exclusive License Agreement by and between the Company and TESARO, Inc. dated December 10, 2010.
10.28[15]	Amendment No. 2 to the Credit Agreement dated March 27, 2007, dated February 22, 2011, with The Frost Group, LLC.
10.29[15]	Third Amended and Restated Subordinated Note and Security Agreement, dated February 22, 2011, with The Frost Group, LLC.
10.30[17]+	Asset Purchase Agreement dated as of September 21, 2011, by and among Optos plc, Optos Inc., OPKO Health, Inc., OPKO Instrumentation, LLC, Ophthalmic Technologies, Inc., and OTI (UK) Limited.
21	Subsidiaries of the Company.
23.1	Consent of Ernst & Young LLP.
31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Juan F. Rodriguez, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by Juan F. Rodriguez, 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 Linkbase Document

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* Denotes management contract or compensatory plan or arrangement.
** As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of sections 11 and 12 of the Securities Act of 1933, as amended, or section 18 of the Securities Exchange Act of 1934, as amended.
+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.
(1) Filed with the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 2, 2007, and incorporated herein by reference.
(2) Filed with the Company s Current Report on Form 8-A filed with the Securities and Exchange Commission on June 11, 2007, and incorporated herein by reference.
(3) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2007 for the Company s three-month period ended September 30, 2007, and incorporated herein by reference.
(4) Filed with the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008 and incorporated herein by reference.
(5) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2008 for the Company s three-month period ended June 30, 2008, and incorporated herein by reference.
(6) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2008 for the Company s three-month period ended September 30, 2008, and incorporated herein by reference.
(7) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 8, 2009 for the Company s three-month period ended March 31, 2009, and incorporated herein by reference.
(8) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2009 for the Company s three-month period ended June 30, 2009, and incorporated herein by reference.
(9) Filed with the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009, and incorporated herein by reference.
(10) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2009 for the Company s three-month period ended September 30, 2009, and incorporated herein by reference.
(11) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2010 for the Company s three-month period ended March 31, 2010, and incorporated herein by reference.
(12) Filed with the Company s Amendment to Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 3, 2011.
(13) Filed with the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2010.
(14) Filed with the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 10, 2011, and incorporated herein by reference.
(15) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2011 for the Company s three-month period ended March 31, 2011, and incorporated herein by reference.
(16) Filed with the Company s Quarterly Report on Form 10-Q/A filed with the Securities and Exchange Commission on July 5, 2011, and incorporated herein by reference.
(17) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2011 for the Company s three-month period ended September 30, 2011, and incorporated herein by reference.
(18) Filed with the Company s Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on July 28, 2011.
(19) Filed with the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2012.
(20) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2012 for the Company s three-month period ended March 31, 2012, and incorporated herein by reference.
(21) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2012 for the Company s three-month period ended September 30, 2012, and incorporated herein by reference.

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SIGNATURES

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

OPKO HEALTH, INC.

By: /s/ Dr. Phillip Frost, M.D.
Dr. Phillip Frost, M.D.
Chairman of the Board and
Chief Executive Officer

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

Signature	Title	Date
/s/ Dr. Phillip Frost, M.D. Dr. Phillip Frost, M.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 18, 2013
/s/ Dr. Jane H. Hsiao Dr. Jane H. Hsiao	Vice Chairman and Chief Technical Officer	March 18, 2013
/s/ Steven D. Rubin Steven D. Rubin	Director and Executive Vice President Administration	March 18, 2013
/s/ Juan F. Rodriguez Juan F. Rodriguez	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	March 18, 2013
/s/ Adam Logal Adam Logal	Vice President of Finance, Chief Accounting Officer and Treasurer (Principal Accounting Officer)	March 18, 2013
/s/ Robert Baron Robert Baron	Director	March 18, 2013
/s/ Thomas E. Beier Thomas E. Beier	Director	March 18, 2013
/s/ Dmitry Kolosov Dmitry Kolosov	Director	March 18, 2013
/s/ Richard A. Lerner, M.D. Richard A. Lerner, M.D.	Director	March 18, 2013
/s/ John A. Paganelli John A. Paganelli	Director	March 18, 2013
/s/ Richard C. Pfenniger, Jr.	Director	March 18, 2013

Richard C. Pfenniger, Jr.		
/s/ Alice Lin-Tsing Yu, M.D., Ph.D. Alice Lin-Tsing Yu, M.D., Ph.D.	Director	March 18, 2013

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EXHIBIT INDEX

Exhibit Number	Description
2.9+	Agreement and Plan of Merger, dated October 18, 2012, by and among Prost-Data, Inc. d/b/a OurLab, Our Labs, Endo Labs and Gold Lab, Jonathan Oppenheimer, M.D., OPKO Health, Inc., OPKO Laboratories Inc., and OPKO Labs, LLC.
21	Subsidiaries of the Company.
23.1	Consent of Ernst & Young LLP.
31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Juan F. Rodriguez, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by Juan F. Rodriguez, 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 Linkbase Document

+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

** As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of sections 11 and 12 of the Securities Act of 1933, as amended, or section 18 of the Securities Exchange Act of 1934, as amended.