Opko Health, Inc.
Form 10-K
March 03, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013.
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 (State or Other Jurisdiction of Incorporation or Organization)	75-2402409 (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 ý
No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No ý
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 ý 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 ý 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. ý

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.

(in Rule 12b-2 of the Exchange Act) (Check one):

Large accelerated filer ý	Accelerated filer o
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 ý

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: $1,177,002,323.

As of February 24, 2014 the registrant had 412,922,864 shares of Common Stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2014 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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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, or that of our investees, 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 United States ("U.S.") Food and Drug Administration ("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.
- 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.

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- We have no experience manufacturing our pharmaceutical product candidates other than at our Israeli, Mexican, and Spanish facilities, and we have no experience in manufacturing our diagnostic product candidates. We will therefore likely rely on third parties to manufacture and supply our pharmaceutical and diagnostics product candidates, and we would need to meet various standards to satisfy FDA regulations in order to manufacture on our own.
- We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile, Mexico, Spain, Brazil, and Uruguay 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 and diagnostic product candidates.
- The success of our business will be heavily dependent on the success of ongoing and planned phase 3 clinical trials for Rayaldy™ (CTAP101), Alpharen™ (Fermagate Tablets) and hGH-CTP.
- 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.
- If our products have undesirable effects on patients, we could be subject to litigation or product liability claims that could impair our reputation and 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 adversely affect our ability to sell our products or provide our services profitably.
- Failure to obtain and maintain regulatory approval outside the U.S. will prevent us from marketing our product candidates abroad.
- We may not have the funding available to pursue acquisitions.
- 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 or neighboring countries could adversely impact our operations.
- We are subject to fluctuations in currency exchange rates in connection with our international businesses.

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- We have a large amount of goodwill and other intangible assets as a result of acquisitions and a significant write-down of goodwill and/or other intangible assets would have a material adverse effect on our reported results of operations and net worth.
- 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.
- The conversion and redemption features of our January 2013 convertible senior notes due in 2033 are classified as embedded derivatives and may continue to result in volatility in our financial statements, including having a material impact on our result of operations and derivative liability recorded.
- We have reported a material weakness in our internal control over financing reporting which may cause investors and stockholders to lose confidence in our financial reporting.
- 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 New York Stock Exchange (“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" refer to 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 own established pharmaceutical platforms in Chile, Spain, Mexico, and Uruguay which generate revenue and which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We also have established pharmaceutical operations in Brazil. We own 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. In the U.S., we own a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"), with a urologic focus that generates revenue and we expect will serve as a commercial platform for the U.S. launch of our next generation prostate cancer test to improve cancer risk stratification of patient candidates for prostate biopsy. 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 credit card-sized disposable test cassette that works with 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"), testosterone and vitamin D, 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 intend to submit our application to the Food and Drug Administration (the "FDA") for clearance of a testosterone diagnostic test for our point-of-care system and seek CLIA-waiver for the device in the fourth quarter of 2014. We also intend to seek European certification related to health, safety and environmental legislation, also known as a CE Marking ("CE Mark") for the test in Europe at approximately the same time. We expect to begin marketing the testosterone test in the U.S. and Europe in late 2014 or early 2015.

We have already obtained a CE Mark for our point-of-care diagnostic test for PSA using our system in Europe. We intend to update our CE Mark to reflect recent product improvements and launch the PSA test in Europe in 2014. We intend to submit our application to the FDA for clearance of the PSA test and expect to begin marketing the test in the U.S. in 2015.

We are also presently working to add additional tests for our point-of-care system, including 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 developing our next generation prostate cancer test for both our point-of-care diagnostic system, as well as for use in a laboratory setting, 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. 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 December 2012, we completed the acquisition of Prost-Data, Inc., a CLIA-certified laboratory doing business as OURLab, and now known as OPKO Lab (“OPKO Lab”). In addition to continuing to operate as a full-service medical

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laboratory specializing in urologic pathology, OPKO Lab 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.

On November 4, 2013, we announced the initiation of a multi-center study expected to generate data to support the launch of the 4Kscore™ test as an LDT through OPKO Lab. We are enrolling men at 21 sites across the U.S. and are planning to enroll more than 1,200 men referred for a prostate biopsy. This clinical study is expected to be the last step before our planned commercial launch of the 4Kscore™ in the first quarter of 2014. The data we generate in this clinical study will not only be used for the required CLIA validation, but will also be used in our efforts to secure 4Kscore™ test reimbursement.

Our 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. We are continuing to work on biomarker and platform optimization to support development of a successful commercial test for Alzheimer's disease, as well as diagnostic tests for other diseases for which early detection could lead to earlier therapy and dramatically improved outcomes.

Our product pipeline also includes several pharmaceutical compounds and technologies in research and development for a broad range of indications and conditions. In March 2013, we completed the acquisition of Cytochroma Inc. ("Cytochroma") whose lead products, both in phase 3 development, include Rayaldy™ (CTAP101), 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 Alpharen™ (Fermagate Tablets), a new and potent non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients.

Rayaldy™ (CTAP101) has 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. Rayaldy™ (CTAP101) is currently in phase 3 clinical trials in the U.S. and we expect top-line data from this pivotal program in mid-2014.

The new phosphate binder, Alpharen™ (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 Alpharen™ (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 Rayaldy™ (CTAP101) and Alpharen™ (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.

In August 2013, we completed the acquisition of PROLOR Biotech, Inc. ("PROLOR"), a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins utilizing a platform technology developed at Washington University in St. Louis, Missouri.

Our most advanced product in development using the platform technology is a long-acting version of human growth hormone, known as hGH-CTP, for the long-term treatment of children and adults with growth failure due to inadequate secretion of endogenous growth hormone (a $3.5 billion market opportunity growing 5% annually). The hGH-CTP product has been shown in a phase 2 clinical trial to have the potential to reduce the required dosing

frequency of human growth hormone from the current standard of one injection per day to a single weekly injection. hGH-CTP is currently in a phase 3 trial in adults and a phase 2 trial in children, and has been awarded orphan drug designation in the U.S. and Europe for both adults and children with growth hormone deficiency (“GHD”).

In addition to hGH-CTP, our internal product development program is currently focused on extending the life span of the following biopharmaceuticals in an effort to provide patients with improved therapies that may enhance their quality of life: Factor VIIa for hemophilia and Anti-Obesity Peptide Oxyntomodulin.

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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 that we believe will offer more effective protection against influenza, in addition to more efficient production than existing influenza vaccine technologies.

In addition to these development programs, we have pharmaceutical businesses in Chile, Spain, Mexico, Israel, Uruguay and Brazil.

We have a highly experienced management team that we believe has demonstrated an ability to successfully build and manage pharmaceutical businesses. 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.

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, small molecules, and biologics 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 U.S.; 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 continue 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 U.S.
- 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". Effective as of August 2013, our stock also began trading on the Tel Aviv Stock Exchange. 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, and Nes Ziona, Israel, which is where our molecular diagnostics research and development, oligonucleotide research and development and carboxyl terminal peptide research and

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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 for our pharmaceutical business directed to CKD. Our Chilean and Uruguayan operations are located in leased offices and warehouse facilities in Santiago and Montevideo, respectively. Our Mexican operations are based in owned offices, an owned manufacturing facility, and a leased warehouse facility in Guadalajara and in leased offices in Mexico City. Our Spanish operations are based in owned offices in Barcelona, in an owned manufacturing facility in Banyoles and a leased warehouse facility in Palol de Revardit. Our Brazilian operations are located in leased offices in Sao Paulo.

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, Spain, Mexico, Israel, Spain, Uruguay and Brazil. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired through the acquisition of OPKO Lab 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.

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 credit card-sized disposable test cassette that works with 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 only requires a finger stick drop of blood introduced into the test cassette which can simultaneously run multiple tests (multiplex) on the single droplet of blood.

We intend to submit our application to the FDA for clearance of a testosterone diagnostic test for our point-of-care system and seek CLIA-waiver for the device in the fourth quarter of 2014. We also intend to seek a CE Mark for the test in Europe at approximately the same time. We expect to begin marketing the testosterone test in the U.S. and Europe in late 2014 or early 2015.

We have already obtained a CE Mark for our point-of-care diagnostic test for PSA using this system in Europe. We intend to update our CE Mark to reflect recent product improvements and launch the PSA test in Europe in 2014. 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 2015. We are also presently working to add additional tests for our point-of-care system, including 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 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 developing the OPKO 4Kscore™, our next generation prostate cancer test for both our point-of-care diagnostic 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. 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. Investigators at the University of Malmo, Sweden, University of Turku, Finland, and Memorial Sloan Kettering Cancer Center, New York, have demonstrated that an algorithm integrating these biomarkers along with patient data can predict prostate biopsy results, and that the use of this algorithm to determine whether to biopsy can reduce the number of prostate biopsies performed by over fifty percent (50%), avoiding the frequent complications from biopsies of pain, bleeding, and infection, which sometimes require hospitalization. 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). 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.

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In December, 2012, we completed the acquisition of OPKO Lab, our CLIA-certified laboratory with 13 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, OPKO Lab provides us with a commercial platform to support the U.S. commercial launch of the 4Kscore™ for the detection of prostate cancer as an LDT. We also believe that OPKO Lab will be helpful in speeding the development and introduction of other important tests, including antibody-based tests utilizing our unique molecular diagnostic technology.

On November 4, 2013, we announced the initiation of a multi-center study expected to generate data to support the launch of the 4Kscore™ test as an LDT through OPKO Lab. We are enrolling men at 21 sites across the U.S. and are planning to enroll more than 1,200 men referred for a prostate biopsy. This clinical study is expected to be the last step before our planned commercial launch of the 4Kscore™ in the first quarter of 2014. The data we generate in this clinical study will not only be used for the required CLIA validation, but will also be used in our efforts to secure 4Kscore™ test reimbursement.

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 blood tests across numerous important diseases, including a number of disease segments where there are no widely accepted or effective screening tests available.

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 expanded our collaboration with BMS 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 pursuing the development of diagnostic tests for other diseases for which early detection could lead to earlier therapy and dramatically improved outcomes.

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. Our two lead renal products, both in phase 3 clinical development, are Rayaldy™ (CTAP101), a vitamin D prohormone to treat SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency, and Alpharen™ (Fermagate Tablets), a new and potent non-absorbed phosphate binder to treat hyperphosphatemia in patients on chronic hemodialysis.

Rayaldy™ (CTAP101) has 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

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vascular and renal tissues. SHPT affects 40-60% of patients with stage 3 or 4 CKD and approximately 90% of patients with stage 5.

Rayaldy™(CTAP101) is currently in phase 3 clinical trials in the U.S. We have completed patient enrollment in two identical randomized, double-blind, placebo-controlled, multi-site studies intended to establish the safety and efficacy of Rayaldy™ (CTAP101) as a new treatment for SHPT in the targeted population. The endpoints of both studies, which are being conducted in parallel, include vitamin D status and changes in serum calcium, serum phosphorus and plasma intact parathyroid hormone (PTH). We expect top-line data from this pivotal program in mid-2014.

The new phosphate binder, Alpharen™ (Fermagate Tablets), has been shown to be safe and effective in treating hyperphosphatemia in phase 2 and 3 trials in stage 5 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 controlled serum phosphorus levels. We are working with U.S. and European regulatory authorities to finalize the remaining phase 3 clinical program for Alpharen™ (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 Rayaldy™ (CTAP101) and Alpharen™ (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.

CTP Technology; hGH-CTP

In August 2013, we acquired PROLOR, a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins utilizing a patented platform technology licensed from Washington University in St. Louis, Missouri. The technology uses a short, naturally-occurring amino acid sequence (peptide) that has the effect of slowing the removal from the body of the therapeutic protein to which it is attached. This Carboxyl Terminal Peptide (CTP) can be readily attached to a wide array of existing therapeutic proteins, stabilizing the therapeutic protein in the bloodstream and extending its life span without additional toxicity or loss of desired biological activity. We are using the CTP technology to develop new, proprietary versions of certain existing therapeutic proteins that have longer life spans than therapeutic proteins without CTP. We believe that our products will have greatly improved therapeutic profiles and distinct market advantages.

There are two existing biopharmaceuticals on the market that currently utilize CTP technology. The first product is human Chorionic Gonadotropin (hCG), of which CTP is naturally a part. Besides being present normally in high amounts during pregnancy, it is also given therapeutically to women or men as a fertility treatment (sold by Merck-Serono, Merck & Co. and Ferring). The second product is ELONVA® (FSH-CTP), which is approved for marketing in Europe. The data from the clinical use of these two products gives us confidence that the CTP technology may be able to address the major problems faced by the other attempted approaches to increase protein lifespan. Clinical data from these products reassures us that CTP can be used safely and that it is effective in extending

the serum lifetime and activity. We are now the exclusive licensee for the utilization of CTP technology in all therapeutic proteins, peptides and their modified forms except for human FSH, LH, TSH and hCG.

Our lead product candidate utilizing CTP, hGH-CTP, is a recombinant human growth hormone product under development for the treatment of GHD, which is a pituitary disorder resulting in short stature in children and other physical ailments in both children and adults. GHD occurs when the production of growth hormone, secreted by the pituitary gland, is disrupted. Since growth hormone plays a critical role in stimulating body growth and development, and is involved in the production of muscle protein and in the breakdown of fats, a decrease in the hormone affects numerous body processes. hGH is used for the long-term treatment of children and adults with inadequate secretion of endogenous growth hormone. The primary indications it treats in children are GHD, kidney disease, Prader-Willi Syndrome and Turner’s Syndrome. In adults, the primary indications are replacement of endogenous growth hormone and the treatment of AIDS-induced weight loss. Patients using hGH receive daily

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injections six or seven times a week. This is particularly burdensome for pediatric patients. We believe a significant market opportunity exists for a longer-lasting version of hGH that would require fewer injections.

In June 2013, PROLOR initiated a phase 3 trial of hGH-CTP in adults with GHD. The phase 3 trial is a pivotal, randomized, placebo-controlled study to evaluate the efficacy and safety of hGH-CTP injected weekly in adults with GHD. The primary endpoint is defined as the change in truncal fat mass from baseline to six months after initiation of treatment. The trial is being conducted at clinical centers in the U.S., Europe and Israel. In March 2012, PROLOR initiated a phase 2 trial of hGH-CTP in children with growth hormone deficiency.

hGH has been proven to promote a number of lifestyle benefits including weight loss, increased energy levels, enhanced sexual performance, improved cholesterol, younger, tighter, thicker skin and reduced wrinkles and cellulite. We expect the hGH market to expand significantly as hGH moves beyond therapeutic treatment to include the treatment of lifestyle issues. We believe that the CTP technology will be broadly applicable to other best-selling therapeutic proteins in the market and provide several key advantages over our competitor's existing products: significant reduction in the number of injections required to achieve the same or superior therapeutic effect from the same dosage; faster commercialization with greater chance of success and lower costs than those typically associated with a new therapeutic protein; and manufacturing using industry-standard biotechnology-based protein production processes.

In addition to hGH-CTP, we are focused on products extending the life span of Factor VIIa (hemophilia), and anti-obesity peptide Oxyntomodulin. In February 2013, the FDA granted orphan drug designation to our longer-acting version of clotting Factor VIIa (Factor VIIa-CTP) for the treatment of bleeding episodes in patients with hemophilia A or B with inhibitors to Factor VIII or Factor IX. These patients are currently being treated by commercially-available Factor VIIa, with estimated 2013 worldwide sales of $1.7 billion.

APIs

In December 2011, we acquired 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 U.S. live with asthma, including nearly 6 million children. Additionally, there are more than 12 million people in the U.S. 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.

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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 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 deaths each year in the U.S. 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 an immunotherapeutic agent as an adjuvant treatment of chemotherapy or vaccine adjuvants. 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, Inc. ("TESARO"). Rolapitant, a potent and selective competitive antagonist of the NK-1 receptor, has successfully completed phase 2 clinical testing for prevention of chemotherapy induced nausea and vomiting, or CINV, and post-operative induced nausea and vomiting ("PONV"). In December 2013, TESARO announced successful achievement of the primary endpoint in each of two phase 3 trials of Rolapitant for prevention of chemotherapy-induced nausea and vomiting. 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 U.S. 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 January 2014 and February 2013, we completed the acquisitions of Laboratorio Arama de Uruguay Limitada ("Arama Uruguay"), an Uruguayan entity domiciled in Montevideo, and Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda. ("OPKO Brazil"), a Brazilian entity domiciled in Sao Paulo, respectively. Arama Uruguay and OPKO Brazil will expand our presence in Latin America and complement the business activities of our operations in Chile and Mexico, as well as facilitate future market entry for our products in development.

In December 2012, we completed the acquisition of OPKO Lab, a Nashville-based CLIA-certified laboratory with 13 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, OPKO Lab provides us with a commercial platform to support the U.S. commercial launch of the 4Kscore™ for the detection of prostate cancer as an 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 acquired all of the product registrations and trademarks previously owned by Arama, as well as the Arama name.

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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.

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 2013, we made a $2.0 million investment in Zebra Biologics, Inc. ("Zebra") pursuant to which we acquired shares of Zebra's Series A-2 Preferred Stock. Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Zebra's patented platform is an advanced version of a core technology developed by Richard Lerner, M.D. at The Scripps Institute, underlying the commercial success of AbbVie Inc.'s Humira™.
- In October 2013, we made an investment in ARNO Therapeutics, Inc. ("ARNO"), a clinical stage company focused on the development of oncology drugs. We invested $2.0 million as part of a $30 million private placement by ARNO. We believe ARNO's lead product and cancer therapeutic, onapristone, shows promise in addressing the need for new and effective treatment for breast and prostate cancer. In connection with this investment, we were granted exclusive first rights to negotiate with Arno regarding any potential strategic transactions that Arno elects to pursue.
- In April 2013 and January 2014, we entered into a series of transactions pursuant to which we acquired an approximately seventeen percent stake in OAO Pharmsynthez ("Pharmsynthez"), a Russian pharmaceutical company traded on the Moscow Stock Exchange. Our investment was part of an approximate $60.0 million two-stage financing in Pharmsynthez alongside the Russian Corporation of Nanotechnologies, a Russian state owned company ("RUSNANO"). We also granted Pharmsynthez right to commercialize certain of our technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan.
- In March 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. In addition, RXi will be required to pay us up to $50.0 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"), as well as royalties on net sales of a Qualified Drug. In addition to the Asset Purchase Agreement, we also purchased 17,241,380 shares of RXi, or $2.5 million, as part of a $16.4 million financing for RXi. As of December 31, 2013, we owned an approximately 19% equity position in RXi.
- In October 2012, we completed the acquisition of a forty-five percent stake in Scivac Ltd ("Scivac"), previously known as SciGen (I.L.), an Israeli company that produces a third-generation hepatitis B vaccine in its biologics manufacturing facility in Rehovot.
- 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 "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 "Warrants") to purchase 8.5 million shares of BZNE common stock at an exercise price of $0.40 per share. On January 3, 2014, BZNE finalized its planned merger with Cocrystal Discovery, Inc. ("Cocrystal"), a privately-held biopharmaceutical company in which we made an investment in September 2009 (refer below and to Note 12 for details regarding our investment in Cocrystal). In January 2014, we invested an additional $.5 million in the combined Biozone-Cocrystal entity pursuant to which we acquired 1 million shares of Biozone's common stock and 1 million warrants to acquire

additional Biozone common stock. As of December 31, 2013, we owned an approximately 16% equity position in BZNE.

- 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

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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. As of December 31, 2013, we owned an approximately 1% equity position in 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 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, 2013, we own approximately 6% 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, 2013, we owned an approximately 1% 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, 2013, we owned an approximately 12% equity position in Fabrus.
- In September 2009, we acquired a minority equity interest in 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. As of December 31, 2013, we owned approximately 16% of the outstanding capital stock of Cocrystal. On January 3, 2014, Cocrystal completed its planned merger with BZNE.
- 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. During the year ended December 31, 2013, we completed the sale of our stake in Sorrento and recorded a gain on the sale of $17.2 million and other income of $2.7 million related to an early termination fee under a license agreement with 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. Refer to Note 4.

RESEARCH AND DEVELOPMENT EXPENSES

During the years ended December 31, 2013, 2012, and 2011, we incurred $53.9 million, $19.5 million, and $11.4 million, respectively, of research and development expenses from continuing operations related to our various product candidates. During the year ended December 31, 2013, our research and development expenses primarily consisted of Cytochroma and PROLOR development programs including expenses related to the ongoing phase 3 clinical trials for Rayaldy™ (CTAP101) and hGH-CTP. 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.

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 U.S. and foreign patents, trademarks, trade secrets, copyrights, and contractual arrangements. Patent protection in

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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.

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. In 2013, we entered into a series of transactions pursuant to which we granted Pharmsynthez rights to commercialize certain of our technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan. Previously, we (or entities we have acquired) have 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, TESARO, INEOS Healthcare, and Washington University, 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. We are 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. 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. 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 and laboratory 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.

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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;
- 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 U.S., 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

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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.

Clinical trials are normally done in three sequential phases and generally take two to five years or longer to complete. Phase 1 consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase 2 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 3 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 4 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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. The FDA periodically issues draft guidance documents designed to reform both the 510(k) and PMA clearance and approval processes. To the extent the FDA finalizes and implements these reforms, the average 510(k) and PMA review times may change and devices that might previously have been cleared under the 510(k) process may require approval under the

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PMA process (and vice-versa). Additionally, 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) and PMA applications. These fees are intended to improve the device review process, but it is still too early to assess the actual impact on the industry.

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 U.S. 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 U.S. 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 laboratory developed tests ("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 OIG indicated an intent in its 2013 work plan to determine the extent of the U.S. Department of Health and Human Services agencies' oversight of the clinical effectiveness of LDTs. 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.

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 U.S., 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 U.S. 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

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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 (the "HITECH Act", and 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.

The final "omnibus" rule implementing the HITECH Act took effect on March 26, 2013. The rule is broad in scope, but certain provisions are particularly significant in light of our business operations. For example, the final "omnibus" rule implementing the HITECH Act:

- Makes clear that situations involving impermissible access, acquisition, use or disclosure of protected health information are now presumed to be a breach unless the covered entity or business associate is able to demonstrate that there is a low probability that the information has been compromised;
- Defines the term "business associate" to include subcontractors and agents that receive, create, maintain or transmit protected health information on behalf of the business associate;
- Establishes new parameters for covered entities and business associates on uses and disclosures of PHI for fundraising and marketing; and
- Establishes clear restrictions on the sale of PHI without patient authorization.

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 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

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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, as amended by the Fraud Enforcement and Recovery Act of 2009 and the Patient Protection and Affordable Care Act of 2010, 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.

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.

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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 U.S. other than the sales force for the OPKO Lab business, and we have limited personnel in Chile, Spain, Mexico, Israel, Uruguay 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, 2013, we had 625 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.

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 only limited revenue from our

pharmaceutical operations

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in Chile, Mexico, Israel, Spain, Brazil and Uruguay and from our ophthalmic instrumentation business, which we sold in October 2011. Although we plan to launch certain of our diagnostics products in the near future, we may not generate substantial revenue from the sale of these products for some time or at all. We have not yet submitted any pharmaceutical 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, Spanish, and Uruguayan 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 ("2033 Senior Notes"). We received approximately $170.5 million in net proceeds from the sale of the notes. As of December 31, 2013, we have cash and cash equivalents of $185.8 million. 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 U.S. and global 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.

The conversion and redemption features of our 2033 Senior Notes are classified as embedded derivatives and may continue to result in volatility in our financial statements, including having a material impact on our results of operations and the derivative liability recorded.

The conversion rights and redemption options of our 2033 Senior Notes are classified as embedded derivatives and as a result, are marked-to-market to reflect their fair value at each reporting period. The fair value of the embedded derivatives is influenced by a variety of factors, including the actual and anticipated behavior of the holders of the 2033 Senior Notes, the expected volatility of our Common Stock price and our Common Stock price as of the fair value measurement date. Some of these factors are outside of our control. As a result, changes in these factors may have a material impact on our results of operations and the derivative liability recorded in our Consolidated Balance Sheets. Consequently, our financial statements may vary periodically, based on factors other than our revenues and expenses.

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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, Spanish, and Uruguayan 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 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 3 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.

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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 dependent on our ability to develop and launch diagnostic tests based on our point-of-care and molecular diagnostics platforms. In addition, our business is dependent on our ability to successfully develop and commercialize various 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 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;
- 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.

In December 2012, we acquired a CLIA-certified laboratory through our acquisition of OPKO Lab. 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. OPKO Lab 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

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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 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.

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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 or other 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;
- 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 U.S. 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

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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 U.S. 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:

- 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 U.S. 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 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

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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 OIG indicated an intent in its 2013 work plan to determine the extent of the United States Department of Health and Human Services agencies' oversight of the clinical effectiveness of LDTs. 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.

Our business will be heavily dependent on the success of phase 3 clinical trials for Rayaldy™ (CTAP101), Alpharen™ (Fermagate Tablets) and hGH-CTP.

There is no assurance that phase 3 trials for Rayaldy™ (CTAP101), Alpharen™ (Fermagate Tablets) or hGH-CTP 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 Rayaldy™ (CTAP101), Alpharen™ (Fermagate Tablets) or hGH-CTP have exhibited no serious adverse events associated with the drug administration in the phase 1 and 2

clinical trials, further testing in our phase 3 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 3 clinical trials for Rayaldy™ (CTAP101), Alpharen™ (Fermagate

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Tablets) or hGH-CTP 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 reagents 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 failure, 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.

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 U.S. or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future

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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.

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, our 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

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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.

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.

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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 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 manufacturing our pharmaceutical product candidates other than at our Israeli, Mexican, and Spanish facilities, and we have no experience in manufacturing our diagnostic product candidates; we therefore rely on third parties to manufacture and supply our pharmaceutical and diagnostic 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 U.S. other than our sales force for our laboratory business based in Nashville, Tennessee. 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 U.S.

We currently have no pharmaceutical or diagnostic test marketing, sales or distribution capabilities in the U.S. other than the sales force for the OPKO Lab business, and through our Mexican, Spanish, Chilean, and Uruguayan subsidiaries for sales in those countries and for sales of APIs by our Israeli subsidiary. If our pharmaceutical and diagnostic 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

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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 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.

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 laboratories 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 U.S. 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.

Failure to timely or accurately bill for our services could have a material adverse effect on our business.

Billing for clinical testing services is extremely complicated and is subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payors, such as patients, insurance companies, Medicare, Medicaid, physicians, hospitals and employer groups. Changes in laws and regulations could increase the complexity and cost of our billing process. Additionally, in the U.S., third-party payors generally require billing codes on claims for reimbursement that describe the services provided. For laboratory

services, the American Medical Association establishes most of the billing codes using a data code set called Current Procedural Terminology, or CPT, codes. Each third-party payor generally develops payment amounts and coverage policies for their beneficiaries or members that ties to the CPT code established for the laboratory test and, therefore, coverage and reimbursement may differ by payor even if the same billing code is reported for claims filing purposes. For laboratory tests without a specific billing code, payors often review claims on a claim-by-claim basis and there are increased uncertainties as to coverage and eligibility for reimbursement.

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Incorrect or incomplete documentation and billing information could result in non-payment for services rendered or having to pay back amounts incorrectly billed and collected. Further, the failure to timely or correctly bill could lead to various penalties, including: (1) exclusion from participation in CMS and other government programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate our business, any of which could have a material adverse effect on our results of operations or cash flows.

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 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 U.S. 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

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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 U.S. Therefore, the enforceability or scope of our owned or licensed patents in the U.S. 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.

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

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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. 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.

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, INEOS Healthcare, Washington University, 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

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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.

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 a 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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Several lawsuits have been filed against PROLOR, the members of PROLOR's Board of Directors, and OPKO challenging the merger, and an adverse judgment in any such lawsuit may have a material adverse effect on our financial condition as well as divert the attention of our management and resources generally.

Six putative class action lawsuits have been filed in connection with our acquisition of PROLOR. In July 2013, the individual actions were consolidated for all purposes into an amended class action complaint as part of the In re PROLOR Biotech, Inc. Shareholders' Litigation (Case No. A-13-680860-B). The lawsuit names PROLOR, the members of PROLOR's Board of Directors, and OPKO as defendants. The lawsuit is brought by purported holders of PROLOR's common stock, both individually and on behalf of a putative class of PROLOR's stockholders, asserting claims that (i) PROLOR's Directors breached their fiduciary duties in connection with the proposed Merger by, among other things, purportedly failing to maximize stockholder value, (ii) PROLOR and its Board of Directors failed to disclose material information concerning the proposed Merger, and (iii) OPKO aided and abetted PROLOR's Directors' alleged breach of their fiduciary duties. The lawsuit seeks various damages, an award of all costs, and reasonable attorneys' fees, as well as certain equitable relief, including rescission of the merger. Although we believe that the claims made in these lawsuits are without merit and intend to defend such claims vigorously; there can be no assurance that we will prevail. An unfavorable resolution of any such litigation surrounding the acquisition could have a material adverse impact on our financial condition. In addition, the cost of defending the litigation, even if resolved favorably, could be substantial. Such litigation could also substantially divert the attention of our management and resources in general.

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

In the U.S., 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 U.S. 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.

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RISKS RELATED TO INTERNATIONAL OPERATIONS

Failure to obtain regulatory approval outside the U.S. 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.

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 U.S. 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 U.S. and margins on sales of products that include components obtained from suppliers located outside of the U.S. 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

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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, 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 U.S., 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 U.S., 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

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

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.

We have a large amount of goodwill and other intangible assets as a result of acquisitions and a significant write-down of goodwill and/or other intangible assets would have a material adverse effect on our reported results of operations and net worth.

We have a large amount of goodwill and other intangible assets and we are required to perform an annual, or in certain situations a more frequent, assessment for possible impairment for accounting purposes. At December 31, 2013, we have goodwill and other intangible assets of $1.1 billion, or approximately 79% of our total assets. If we do not achieve our planned operating results, we may be required to incur a non-cash impairment charge. Any impairment charges in the future will adversely affect our results of operations. A significant write down of goodwill and/or other intangible assets would have a material adverse effect on our reported results of operations and net worth.

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;
- purchases and 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.

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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.

Trading of our Common Stock may be limited and restrictions imposed by securities regulation 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"). Historically, the liquidity of our Common Stock has been limited. A substantial amount of the outstanding shares of our Common Stock are restricted securities. 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 2033 Senior Notes. The 2033 Senior 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 2033 Senior Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, upon the occurrence of specified events. The 2033 Senior 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 2033 Senior 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 the 2033 Senior 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 February 24, 2014, 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 40% of our Common Stock as of February 24, 2014. 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.

A significant short position in our stock could have a substantial impact on the trading price of our stock.

Historically, there has been a significant" short" position in our common stock. As of February 14, 2014, investors held a short position of approximately 46.5 million shares of our common stock which represented approximately 19.6 % of our public float. The anticipated downward pressure on our stock price due to actual or anticipated sales of our stock by some institutions or individuals who engage in short sales of our common stock could cause our stock price to decline. Such stock

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price decrease could encourage further short-sales that could place additional downward pressure on our stock price. This could lead to further increases in the already large short position in our common stock and cause volatility in our stock price. The volatility of our stock may cause the value of a stockholder's investment to decline rapidly. Additionally, if our stock price declines, it may be more difficult for us to raise capital and may have other adverse effects on our business.

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 year end. 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. We have identified that we have a material weakness as of December 31, 2013, which related to the Company's financial statement close process at its Chilean subsidiary due to the lack of sufficient controls to assure that inventory and accounts receivable balances are recoded correctly in accordance with U.S. generally accepted accounting principles. As a result, we concluded that our internal control over financial reporting was not effective as of December 31, 2013. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Although we are taking steps to improve the control environment at our Chilean operations, 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 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, 2013, we had outstanding warrants to purchase 24,496,664 shares of our Common Stock. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

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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 ("Frost Real Estate"), 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 11,555 square feet, which encompasses space for our corporate offices and administrative services. The lease is for a five-year term, which commenced effective January 1, 2014. We previously leased the premises from Frost Real Estate pursuant to a five-year lease that originally expired in August 2012, but was extended through December 31, 2013 by agreement by the parties. The lease currently requires annual rent of approximately $0.4 million.

We lease office and laboratory space in Jupiter and Miramar, Florida and Nes Ziona, Israel, which is where our molecular diagnostics research and development, oligonucleotide research and development, and CTP 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, Burlingame, California, and Miramar, Florida for our CLIA-certified laboratory business, and we lease office space in Bannockburn, Illinois and Markham, Ontario for our pharmaceutical business directed to CKD. Our Chilean and Uruguayan operations are located in leased offices and warehouse facilities in Santiago and Montevideo, respectively. Our Mexican operations are based in an owned manufacturing facility and a leased warehouse facility in Guadalajara and in leased offices in Mexico City. Our Spanish operations are based in owned offices in Barcelona, in an owned manufacturing facility in Banyoles and a leased warehouse facility in Palol de Revardit. Our Brazilian operations are located in leased offices in Sao Paulo.

ITEM 3. LEGAL PROCEEDINGS.

In December, 2013, we entered into a settlement agreement with Adrian Goldstein, M.D., a former employee of OPKO Lab, resolving all claims between OPKO Lab and Dr. Goldstein. On November 27, 2012, Dr. Goldstein had filed a complaint for declaratory judgment and alleged breach of contract against OPKO Lab in the Chancery Court for Davidson County, Tennessee, asserting that OPKO Lab breached his employment agreement and owed him additional compensation and further compensation for the value of OPKO Lab under a "compensation for sale" provision set forth in his employment agreement. The settlement did not have a material impact on our results of operations or financial condition.

On April 29, 2013, a putative class action was filed in the Eighth Judicial District Court in and for Clark County, Nevada against PROLOR Biotech, Inc. ("PROLOR"), the members of the PROLOR Board of Directors, individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company. From May 1, 2013 through May 6, 2013, we were named in an additional five putative class actions lawsuits filed in the Eight Judicial District Court in and for Clark County, Nevada against the same defendants. On July 17, 2013, these six suits were consolidated, for all purposes, into an amended class action complaint, and on or around October 25, 2013, the plaintiffs filed a second amended consolidated class action complaint. The lawsuit is brought by purported holders of PROLOR's common stock, both individually and on behalf of a putative class of PROLOR's stockholders, asserting claims that PROLOR's Board of Directors breached its fiduciary duties in connection with the merger by purportedly failing to maximize stockholder value, that PROLOR and its Board of Directors failed to disclose material information to PROLOR's stockholders, and that the Company aided and abetted the alleged breaches of fiduciary duty. The lawsuit seeks monetary damages, including increased consideration to PROLOR's stockholders, equitable relief, including, among other things, rescission of the Merger Agreement along with rescissionary damages, and an award of all costs, including reasonable attorneys' fees. The Company denies the allegations and intends to vigorously defend the actions. 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". Effective in August 2013, our Common stock also began trading on the Tel Aviv Stock Exchange.

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:

	High	Low
2013		
First Quarter	$7.83	$4.83
Second Quarter	7.65	6.14
Third Quarter	10.00	7.13
Fourth Quarter	12.95	8.17
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

As of February 24, 2014, there were approximately 403 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 2014. 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

The following graph compares the five-year cumulative total return of our Common Stock with the S&P 500 Index and the NASDAQ Biotechnology Index. The NYSE Arca Biotechnology Index is no longer published; as a result no total shareholder return comparison to that index is included in the graph.

The graph assumes $100 invested on December 31, 2008 in our Common Stock and in each of the foregoing indices. The stock price performance reflected in the graph below is not necessarily indicative of future price performance.

	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013
OPKO Health, Inc.	$100.00	$112.96	$226.54	$302.47	$296.91	$520.99
S&P 500	100.00	126.46	145.51	148.59	172.37	228.19
NASDAQ Biotechnology	100.00	104.67	112.89	127.04	169.50	288.38

Recent Sales of Unregistered Securities

As previously disclosed, on February 15, 2013, we acquired the assets of Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda. (“OPKO Brazil”), a Brazilian pharmaceutical company, from NNL Consultoria Empresarial Ltda. (the “Seller”). Under the purchase agreement we issued 64,684 shares of our Common Stock to the Seller of the OPKO Brazil business. The issuance of the Company’s Common Stock in connection with the OPKO Brazil transaction was exempt from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act.

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ITEM 6. SELECTED FINANCIAL DATA.

The following selected historical consolidated statement of operations data for the years ended December 31, 2013, 2012, 2011, 2010, and 2009 and the consolidated balance sheet data as of December 31, 2013, 2012, 2011, 2010, and 2009, 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.

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	For the years ended December 31,				
(In thousands, except share and per share information)	2013	2012	2011	2010	2009
Statement of operations data:					
Revenues	$96,530	$47,044	$27,979	$28,494	$4,418
Costs and expenses:					
Cost of revenues	48,860	27,878	17,243	13,495	2,876
Selling, general and administrative	55,320	27,795	19,169	18,133	10,372
Research and development	53,902	19,520	11,352	5,949	10,836
Write-off of acquired in-process research and development	—	—	—	—	2,000
Other operating expenses; primarily amortization of intangible assets	18,080	9,120	3,404	2,053	481
Total costs and expenses	176,162	84,313	51,168	39,630	26,565
Operating loss from continuing operations	(79,632)	(37,269)	(23,189)	(11,136)	(22,147)
Other income and (expense), net	(24,586)	56	(1,044)	(844)	(1,916)
Loss from continuing operations before income(expense) and investment losses	(104,218)	(37,213)	(24,233)	(11,980)	(24,063)
Income tax benefit (provision)	(1,672)	9,626	19,358	18	25
Loss from continuing operations before investment losses	(105,890)	(27,587)	(4,875)	(11,962)	(24,038)
Loss from investments in investees	(11,456)	(2,062)	(1,589)	(714)	(353)
Loss from continuing operations	(117,346)	(29,649)	(6,464)	(12,676)	(24,391)
Income (loss) from discontinued operation, net of tax	—	109	5,181	(6,250)	(5,722)
Net loss	(117,346)	(29,540)	(1,283)	(18,926)	(30,113)
Less: Net loss attributable to noncontrolling interests	(2,939)	(492)	—	—	—
Net loss attributable to common shareholders before preferred stock dividend	(114,407)	(29,048)	(1,283)	(18,926)	(30,113)
Preferred stock dividend	(420)	(2,240)	(2,379)	(2,624)	(4,718)
Net loss attributable to common shareholders	$(114,827)	$(31,288)	$(3,662)	$(21,550)	$(34,831)
(Loss) income per share, basic and diluted:					
Loss from continuing operations	$(0.32)	$(0.11)	$(0.03)	$(0.06)	$(0.12)
Income (loss) from discontinued operations	$—	$—	$0.02	$(0.02)	$(0.03)
Net loss per share	$(0.32)	$(0.11)	$(0.01)	$(0.08)	$(0.15)
Weighted average number of common shares outstanding basic and diluted:	355,095,701	295,750,077	280,673,122	255,095,586	233,191,617
Balance sheet data:					
Total assets	$1,391,516	$289,830	$229,489	$77,846	$87,430

Working capital	$150,878	$26,275	$80,804	$29,793	$50,795
Long-term liabilities	$426,687	$34,168	$25,443	$7,908	$11,932
Series D Preferred Stock	$—	$24,386	$24,386	$26,128	$26,128
Shareholders' equity	$876,410	$179,386	$160,882	$23,052	$31,599
Total equity	$872,979	$178,894	$160,882	$23,052	$31,599

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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 point-of-care 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 own established pharmaceutical platforms in Spain, Chile, Mexico, and Uruguay 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 have 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. In the U.S., we own a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"), with a urologic focus that generates revenue and we expect will serve as a commercial platform for the U.S. launch of our next generation prostate cancer test to improve cancer risk stratification of patient candidates for prostate biopsy.

During the year ended December 31, 2013, we completed a number of strategic acquisitions and investments, including:

- In October 2013, we made an investment in ARNO Therapeutics, Inc., a clinical stage company focused on the development of oncology drugs ("ARNO"). We invested $2.0 million and received 833,333 ARNO common shares, one year warrants to purchase 833,333 shares for $2.40 a share and five-year warrants to purchase an additional 833,333 shares for $4.00 a share. Our investment was part of a private placement by ARNO.
- In October 2013, we made an investment in Zebra Biologics, Inc. ("Zebra") pursuant to which we acquired 840,000 shares of Zebra's Series A-2 Preferred stock for $2.0 million. Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Zebra's patented platform is an advanced version of a core technology developed by Dr. Richard Lerner, M.D., at The Scripps Research Institute. After the closing, OPKO owns 23.5% of the Series A-2 Preferred stock issued and outstanding by Zebra.
- On August 29, 2013, we acquired PROLOR Biotech, Inc. ("PROLOR") pursuant to an Agreement and Plan of Merger dated April 23, 2013 (the "PROLOR Merger Agreement") in an all-stock transaction. PROLOR is an Israeli-based biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins. At closing we delivered 63,670,805 shares of our Common Stock valued at $540.6 million based on the closing price per share of our Common Stock as reported by the NYSE on the closing date of the

acquisition, or $8.49 per share. In addition, each outstanding option and warrant to purchase shares of PROLOR Common Stock that was outstanding and unexercised immediately prior to the closing date, whether vested or not vested, was converted into 7,889,265 options and warrants to purchase OPKO Common Stock at a fair value of $46.1 million.

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In April 2013, we acquired an approximate ten percent stake in OAO Pharmsynthez ("Pharmsynthez"), a Russian pharmaceutical company traded on the Moscow Stock Exchange. We also granted to Pharmsynthez licenses for certain technology rights in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan. In connection with the licenses, Pharmsynthez agreed to issue, at its option, approximately 12.0 million shares of its common stock or pay us Russian Rubles 265.0 million on or before December 31, 2013(the "Pharmsynthez Note Receivable"). In January 2014, we received approximately 12 million shares of Pharmsynthez common stock, taking our ownership percentage to approximately 17%. In addition, Pharmsynthez agreed to pay us $9.5 million under collaboration and funding agreements for the development of the licensed technology rights (the "Pharmsynthez Collaboration Agreements"), of which we have received $8.2 million as of December 31, 2013.

- In March 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, RXi issued to us 50 million shares of its common stock. In addition, 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. 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. In addition to the Asset Purchase Agreement, we also purchased 17,241,380 shares of RXi, for $2.5 million, as part of a $16.4 million financing for RXi, which included certain of our related parties. As a result of these transactions, we own approximately 21% of RXi.

- In March 2013, we completed the acquisition of Cytochroma, Inc., a corporation located in Markham, Canada ("Cytochroma"), whose lead products, both in phase 3 development, are Rayaldy™, a vitamin D prohormone to treat secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease, and Alpharen™, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the "Cytochroma Acquisition"). In connection with the Cytochroma Acquisition, we delivered 20,517,030 of shares of our Common Stock valued at $146.9 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $7.16 per share. The number of shares issued was 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 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.

- In March 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.

- In January 2013, we entered into note purchase agreements, with qualified institutional buyers and accredited investors (collectively, the "Purchasers") for the sale of $175.0 million aggregate principal amount of 3.00% convertible senior notes due 2033 (the "2033 Senior Notes") in a private placement in reliance on exemptions from registration under the Securities Act of 1933 (the "Securities Act"). The Purchasers of the 2033 Senior 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 2033 Senior Notes were issued on January 30, 2013.

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RECENT DEVELOPMENTS

On January 8, 2014, we completed the acquisition of Laboratorio Arama de Uruguay Limitada ("Arama"), a privately-owned company located in Montevideo, Uruguay. Arama will expand our 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 currently commercialized and those in development.

RESULTS OF OPERATIONS

For The Years Ended December 31, 2013 and December 31, 2012

Revenues. Revenues for the year ended December 31, 2013, were $96.5 million, compared with $47.0 million for the year ended December 31, 2012. The increase principally reflected revenues related to the December 2012 acquisition of Prost-Data, Inc. ("OPKO Lab"), the October 2012 acquisition of SciVac Ltd ("SciVac"), and the August 2012 acquisition of Farmadiet Group Holding, S.L. ("Farmadiet"), which contributed $10.8 million, $1.7 million and $18.8 million of revenue, respectively, during the year ended December 31, 2013, as compared with revenues from those units of $0.4 million, $0.6 million and $6.1 million, respectively, during the year ended December 31, 2012. Revenue from our Chilean operations increased $5.1 million during the year ended December 31, 2013, primarily due to increased sales to government agencies. Revenue from FineTech Pharmaceutical, Ltd. ("FineTech"), our Israeli API business, increased $4.6 million during the year ended December 31, 2013, primarily related to increased sales to new and existing customers. Revenues for the year ended December 31, 2013 also reflects the one-time, non–cash revenue of $12.5 million related to the transfer of substantially all of our assets in the field of RNA interference to RXi (the "RXi Revenue"). Revenue related to our molecular diagnostics collaboration agreements and license agreements, excluding the RXi Revenue, increased $3.7 million during the year ended December 31, 2013, compared to the year ended December 31, 2012, primarily related to revenue recorded in connection to the Pharmsynthez Collaboration Agreements.

Cost of revenues. Costs of revenues for the year ended December 31, 2013, were $48.9 million, compared with $27.9 million for the year ended December 31, 2012. Costs of revenues for the year ended December 31, 2013, increased principally as a result of costs of revenue recorded by OPKO Lab, SciVac and Farmadiet of $10.0 million, $3.6 million and $4.3 million, respectively. Costs of revenue recorded by FineTech, our Chilean and Mexican operations increased $1.1 million, $1.9 million and $0.5 million, respectively, during the year ended December 31, 2013, primarily related to higher revenue levels recorded by those businesses.

Selling, general and administrative expenses. Selling, general and administrative expenses for the year ended December 31, 2013, were $55.3 million, compared with $27.8 million for the year ended December 31, 2012. The increase in selling, general and administrative expenses principally resulted from $15.0 million of such expenses recorded during the year ended December 31, 2013, by Farmadiet, SciVac, OPKO Lab, Cytochroma, the January 2013 acquisition of Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda. ("OPKO Brazil") and the August 2013 acquisition of PROLOR (collectively, the "Acquired Businesses"). Excluding the selling, general and administrative expenses of the Acquired Businesses, selling, general and administrative expenses increased by $10.4 million during the year ended December 31, 2013, principally as a result of increased personnel expenses and professional fees associated with our increased operations. Selling, general and administrative expenses during the year ended December 31, 2013 and 2012, include equity-based compensation expense of $7.3 million and $3.1 million, respectively.

Research and development expenses. Research and development expenses for the years ended December 31, 2013 and 2012, were $53.9 million and $19.5 million, respectively. Research and development expenses include external and internal expenses, partially offset by third-party grants and fundings arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program, with phase 3 clinical trials for drug approval and/or Premarket Approvals for diagnostics tests ("PMA") if any. Research and development employee-related expenses include salaries, benefits and stock-based compensation expense. Other unallocated internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and

facilities.

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The following table summarizes the components of our research and development expenses:

	For the years ended December 31,	
	2013	2012
External expenses:		
Phase 3 clinical trials	$13,078	$—
PMA	—	—
Earlier-stage programs	6,364	—
Research and development employee-related expenses	17,215	8,315
Other unallocated internal research and development expenses	18,998	11,497
Third-party grants and funding from collaboration agreements	(1,753)	(292)
Total research and development expenses	$53,902	$19,520

The increase in research and development expenses during the year ended December 31, 2013 as compared with the year ended December 31, 2012, principally resulted from an increase of $28.3 million related to research and development expenses incurred by Cytochroma, which business was acquired in March 2013, and PROLOR, including $13.1 million related to the costs of ongoing phase 3 clinical trials for Rayaldy™ (CTAP101) and hGH-CTP. Research and development expenses for the years ended December 31, 2013 and 2012, include equity-based compensation expense of $3.6 million and $2.0 million, respectively. The increase in equity-based compensation expense during the year ended December 31, 2013, principally reflects the mark to market impact of Common Stock options granted to non-employees and the associated increase in the trading price of our Common Stock during the year ended December 31, 2013. Research and development expenses for the year ended December 31, 2013, includes an offset to research and development expenses of $2.7 million related to the correction of an error related to equity awards granted to non-employees with performance based vesting.

Contingent consideration. Contingent consideration expenses for the years ended December 31, 2013 and 2012, were $6.9 million and $0.8 million, respectively. The increase in contingent consideration expense resulted from changes in the fair value of the contingent consideration liabilities due to the time value of money and the impact of changes in the underlying assumptions, if any, during the period. The contingent consideration liabilities relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, FineTech, Farmadiet and Cytochroma pursuant to our acquisition agreements in January 2011, October 2011, December 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $11.1 million and $8.3 million for the years ended December 31, 2013 and 2012, respectively. Amortization expense increased due to the acquisitions of Farmadiet, OPKO Lab and Cytochroma in August 2012, December 2012 and March 2013, respectively.

Other income and (expense), net. Other income and (expense), net for the years ended December 31, 2013 and 2012, was ($24.6) million and $0.1 million, respectively. During the year ended December 31, 2013, we recorded a $43.1 million non-cash charge, net, related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes and an $8.7 million loss on early partial conversion of the 2033 Senior Notes, partially offset by other income of $6.5 million related to changes in the fair value of the Pharmsynthez Note Receivable, a certain Pharmsynthez purchase option, and warrants and options received in connection with our investment in Neovasc Inc. (“Neovasc”) and ARNO, and by a gain of $29.9 million on the sale of certain of our strategic investments. Other income and (expense), net, for the year ended December 31, 2013, also included $13.8 million of interest expense primarily related to interest incurred on the 2033 Senior Notes and by the amortization of related deferred financing costs related to the 2033 Senior Notes. For the year ended December 31, 2012, other income net, included $1.5 million of other income recognized from the change in fair value of the warrants received in connection with our investment in Biozone Pharmaceuticals, Inc. (“BZNE”), partially offset by other expense recognized for the decrease in fair value of warrants and options received in connections with our investment in Neovasc and the interest expense incurred on our Chilean and Farmadiet lines of credit.

Loss from investments 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 eight 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 investees' technologies are commercialized, if ever, we anticipate they will continue to report a net loss. Loss from investments in investees was $11.5 million and $2.1 million for the years ended December 31, 2013 and 2012, respectively. The increase in loss from investments in investees is primarily due to the result of increased research and development activities at our investees as well as the impact of including the activities of our recent investments in RXi, Pharmsynthez and Zebra.

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Income taxes. Our income tax provision reflects the projected income tax payable in Israel, Chile, Spain and Canada. We have recorded a full valuation allowance against our deferred tax assets in the U.S. In May 2013, our Israeli API business elected a new tax regime which set its effective tax rate at 12.5% compared to a previous tax rate that was based on a ratio of revenue and turnover basis in the old tax regime, ranging from 10% to 25%.

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

Revenues. Revenues for the year ended December 31, 2012, were $47.0 million, compared with $28.0 million for the year ended December 31, 2011. The increase in revenues for the year ended December 31, 2012, principally resulted from $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 Distribuidora Limitada (“ALS”) in April 2012 and $0.6 million of revenue generated by SciVac, a consolidated variable interest entity in which we have a forty-five percent stake.

Costs of revenues. Costs of revenues for the year ended December 31, 2012, were $27.9 million compared with $17.2 million for the year ended December 31, 2011. Costs of revenue for the year ended December 31, 2012 increased principally due to costs of revenue recorded by FineTech, Farmadiet and SciVac of $1.7 million, $2.7 million and $0.5 million, respectively, which businesses were acquired in December 2011, August 2012 and October 2012, respectively. Cost of revenue from our Chilean operations increased $6.2 million primarily related to increased pricing from our product suppliers.

Selling, general and administrative expenses. Selling, general and administrative expenses for the year ended December 31, 2012 were $27.8 million, compared with $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 OPKO Diagnostics and FineTech, which were acquired in October and December 2011, respectively, and $5.0 million of expenses related to ALS, Farmadiet, SciVac and OPKO Lab, 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 with $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 Common 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 time-line of the development milestones being achieved, were $0.8 million for the year ended December 31, 2012. Contingent consideration liabilities relate 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 $0.1 million 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 connection with our investment in 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 deferred payments related to the Farmadiet acquisition, partially offset by interest earned on our cash and cash equivalents and the currency exchange benefits realized by our Chilean and Mexico operations as a result of their functional currencies strengthening against the U.S. dollar

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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 investees' 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.

Discontinued operations. Income from discontinued operations was $0.1 million for 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 OPKO Lab compared to the OPKO Diagnostics acquisition in 2011. We recorded a full valuation allowance against our net deferred tax assets in the U.S. for the years ended December 31, 2012 and 2011.

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Liquidity and Capital Resources

At December 31, 2013, we had cash and cash equivalents of approximately $185.8 million. Cash used in operations during 2013 principally reflects expenses related to selling, general and administrative activities related to our corporate operations, research and development activities and our operations at OPKO Lab, PROLOR, SciVac, Mexico and OPKO Brazil, partially offset by cash provided by FineTech, Chile and Spain. Cash provided by investing activities includes net cash provided by business combinations of $20.5 million, proceeds from sale of equity securities of $30.6 million and $0.6 million from the sale of property, plant and equipment, partially offset by investments in investees of $17.4 million and capital expenditures of $4.0 million. Cash provided by financing activities primarily reflects the issuance of the 2033 Senior Notes and $23.4 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.

During the year ended December 31, 2013, we exited from certain strategic investments and received $30.6 million in proceeds from such sales.

In August 2013, we completed the acquisition of PROLOR Biotech, Inc. (“PROLOR”), a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins utilizing a platform technology developed at Washington University in St. Louis, Missouri. At closing we delivered 63,670,805 shares of our Common Stock valued at $540.6 million based on the closing price per share of our Common Stock as reported by the NYSE on the closing date of the acquisition, or $8.49 per share. In addition, each outstanding option and warrant to purchase shares of PROLOR Common Stock that was outstanding and unexercised immediately prior to the closing date, whether vested or not vested, was converted into 7,889,265 options and warrants to purchase OPKO Common Stock at a fair value of $46.1 million. Our most advanced product in development using the platform technology is a long-acting version of human growth hormone, known as hGH-CTP, for the long-term treatment of children and adults with growth failure due to inadequate secretion of endogenous growth hormone. The hGH-CTP product is currently in a phase 3 trial in adults and a phase 2 trial in children.

In April 2013, we invested $9.6 million in exchange for approximately 13.6 million shares of Pharmsynthez common stock. Concurrent with our investment, Pharmsynthez also agreed to issue, at its option, approximately 12.0 million shares of its common stock or pay us Russian Rubles (“RUR”) 265.0 million ($8.1 million) on or before December 31, 2013. We have a right to purchase additional shares in Pharmsynthez at a fixed price if Pharmsynthez pays us in RUR rather than the 12.0 million shares of Pharmsynthez common stock. Pharmsynthez delivered approximately 12 million shares of its common stock to us in January 2014.

In January 2013, we issued $175.0 million of the 2033 Senior Notes. The 2033 Senior Notes were sold in a private placement in reliance on exemptions from registration under the Securities Act. A $4.5 million discount was granted to the placement agent and an additional $0.4 million in deferred charges were recorded for professional fees related to the issuance. Net cash proceeds from the offering totaled $170.2 million. Interest on the 2033 Senior Notes is payable semiannually on February 1 and August 1, beginning August 1, 2013. Holders of the 2033 Senior Notes may require us to repurchase the 2033 Senior Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2019, February 1, 2023 and February 1, 2028, or following the occurrence of a fundamental change as defined in the indenture governing the Notes. On August 30, 2013, one of the conversion rights in the 2033 Senior Notes was triggered. Holders of the 2033 Senior Notes converted $16.9 million principal amount into 2,396,145 shares of our Common Stock at a rate of 141.4827 shares of Common Stock per $1,000 principal amount of 2033 Senior Notes. We recorded an $8.7 million loss on early conversion of the 2033 Senior Notes in Other income (expense), net in our Consolidated Statement of Operations. The 2033 Senior Notes were convertible through September 6, 2013 and may be convertible thereafter, if one or more of the conversion conditions are satisfied.

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. 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 price per share of our Common Stock as reported on the NYSE for the 10 trading days immediately preceding the applicable payment date. On August 2, 2013, we issued 585,703 shares of our Common Stock, in accordance with the first Deferred Payment. The number of shares issued was based on the average closing price per share of

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our Common Stock as reported on the NYSE for the 10 trading days up to and including August 1, 2013, or $7.61 per share. On February 14, 2014, we delivered approximately €3.4 million in cash in accordance with the second Deferred Payment.

In connection with our acquisitions of CURNA, OPKO Diagnostics, FineTech and Cytochroma 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, of which $2.7 million was paid in March 2013; up to an additional $19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional $190.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of Cytochroma. In connection with the acquisition of Farmadiet, we agreed to pay an additional €3.4 million (US$4.6 million) in August 2013 and €3.4 million (US$4.6 million) in February 2014 in cash or shares of our Common Stock. On August 2, 2013, we issued 585,703 shares of our Common Stock to satisfy the August 2013 obligation. Further, upon the achievement of certain development milestones, we are obligated to issue 125,000 shares of our Common Stock and €0.8 million (US$1.1 million) in shares of our Common Stock or cash, at our option.

As of December 31, 2013, we have outstanding lines of credit in the aggregate amount of $9.1 million with 16 financial institutions in Chile and Spain, of which $5.5 million is unused. The weighted average interest rate on these lines of credit is approximately 7.7%. 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, 2013, was $16.0 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit 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 that the cash, cash equivalents, and marketable securities on hand at December 31, 2013, which include the net proceeds from the 2033 Senior Notes, 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, 2013, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	2014	2015	2016	2017	2018	2019	Thereafter	Total
Open purchase orders	$10,549	$—	$—	$—	$—	$—	$—	$10,549
Operating leases	2,660	1,841	1,565	951	566	—	—	7,583
3.00% convertible senior notes	—	—	—	—	—	—	211,911	211,911
Deferred payments	840	—	—	—	—	—	—	840
Mortgages and other debts payable (1)	1,972	509	376	337	280	—	1,760	5,234
Lines of credit	9,061	—	—	—	—	—	—	9,061
Interest commitments	4,939	4,867	4,849	4,836	4,853	395	82	24,821
Total	$30,021	$7,217	$6,790	$6,124	$5,699	$395	$213,753	$269,999

(1)Excludes $1.5 million of consolidated liabilities related to SciVac, 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 the following:

- Contractual obligations in connection with clinical trials, which span over two years, and that depend on patient enrollment. The total amount of expenditures is dependent on the actual number of patients enrolled and as such, the contracts do not specify the maximum amount we may owe.
- Product license agreements effective during the lesser of 15 years or patent expiration whereby payments and amounts are determined by applying a royalty rate on uncapped future sales.
- Contingent consideration that includes payments upon achievement of certain milestones including meeting development milestones such as the completion of successful clinical trials, new drug application approvals by the U.S. FDA and revenue milestones upon the achievement of certain revenue targets all of which are anticipated to be paid within the next 7 years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to $71.6 million.

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.

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.

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Goodwill and Intangible Assets. Goodwill and other intangible assets acquired in business combinations, licensing and other transactions were $1.1 billion and $0.2 billion, respectively, at December 31, 2013 and 2012, representing approximately 79% and 61% of total assets, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. We determined the fair value of intangible assets, including in-process research and development ("IPR&D"), using the "income method." This method starts with a forecast of net cash flows, risk adjusted for estimated probabilities of technical and regulatory success (for IPR&D) and adjusted to present value using an appropriate discount rate that reflects the risk associated with the cash flow streams. All assets are valued from a market participant view which might be different than our specific views. The valuation process is very complex and requires significant input and judgment using internal and external sources. Although the valuations are required to be finalized within a one-year period, it must consider all and only those facts and evidence available at the acquisition date. The most complex and judgmental matters applicable to the valuation process are summarized below:

- Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.
- Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.
- Probability of Technical and Regulatory Success ("PTRS") Rate – PTRS rates are determined based upon industry averages considering the respective programs development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent periods leading to impairment charges.
- Projections – Future revenues are estimated after considering many factors such as initial market opportunity, pricing, sales trajectories to peak sales levels, competitive environment and product evolution. Future costs and expenses are estimated after considering historical market trends, market participant synergies and the timing and level of additional development costs to obtain the initial or additional regulatory approvals, maintain or further enhance the product. We generally assume initial positive cash flows to commence shortly after the receipt of expected regulatory approvals which typically may not occur for a number of years. Actual cash flows attributed to the project are likely to be different than those assumed since projections are subjected to multiple factors including trial results and regulatory matters which could materially change the ultimate commercial success of the asset as well as significantly alter the costs to develop the respective asset into commercially viable products.
- Tax rates – The expected future income is tax effected using a market participant tax rate. Our recent valuations typically use a U.S. tax rate (and applicable state taxes) after considering the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also considered that any earnings repatriation would likely have U.S. tax consequences.
- Discount rate – Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Goodwill was $226.4 million and $80.5 million, respectively, at December 31, 2013 and 2012. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, on an enterprise level by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our financial performance compared to budgets, long-term financial plans,

macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test performed in the prior year.

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The estimated fair value of the reporting units whose fair value was calculated for purposes of the 2013 impairment testing is derived from the valuation techniques described above, incorporating the related projections and assumptions. An indication of possible impairment occurs when the estimated fair value of the reporting unit is below the carrying value of its equity. The estimated fair value for these reporting units exceeded their related carrying value as of October 1, 2013. As a result, no goodwill impairment was recorded.

The estimated fair value of the reporting unit is highly sensitive to changes in these projections and assumptions; therefore, in some instances changes in these assumptions could impact whether the fair value of a reporting unit is greater than its carrying value. For example, an increase in the discount rate and decline in the projected cumulative cash flow of a reporting unit could cause the fair value of certain reporting units to be below its carrying value. We perform sensitivity analyses around these assumptions in order to assess the reasonableness of the assumptions and the resulting estimated fair values. Ultimately, future potential changes in these assumptions may impact the estimated fair value of a reporting unit and cause the fair value of the reporting unit to be below its carrying value. The excess of fair value over carrying value for our reporting units as of October 1, 2013, was 70%. We believe that our estimates are consistent with assumptions that marketplace participants would use in their estimates of fair value. However, if actual results are not consistent with our estimates and assumptions, we may be exposed to an impairment charge that could be material.

Intangible assets were $867.9 million and $95.8 million, including IPR&D of $793.3 million and $11.5 million, respectively, at December 31, 2013 and 2012. Intangible assets are tested for impairment whenever events or changes in circumstances warrant a review, although IPRD is required to be tested at least annually. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products or IPR&D. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation. Considering the high risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods. IPR&D is closely monitored and assessed each period for impairment.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as contingent consideration income. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

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 or decrease 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.

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 management's estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our Consolidated Balance Sheets at December 31, 2013 and 2012 was $1.9 million and $0.5 million, respectively.

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Recent accounting pronouncements. In February 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, ("ASU 2013-02"). ASU 2013-02 requires the presentation of reclassifications out of accumulated other comprehensive income in either (1) the notes or (2) the face of the financial statements. We adopted ASU 2013-02 for our first quarter ended March 31, 2013. The adoption of ASU 2013-02 did not have a material impact in our Consolidated Financial Statements, but did require certain additional disclosures.

In July 2013, the FASB issued ASU 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU 2013-11is intended to eliminate inconsistent practices regarding the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is available to reduce the taxable income or tax payable that would result from the dis-allowance of a tax position. This ASU will be effective for our fiscal year beginning January 1, 2014 and subsequent interim periods. The adoption of ASU 2013-11 is not expected to have a material effect on 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 $1.6 million in foreign exchange forward contracts outstanding at December 31, 2013, 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.

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, 2013, we had cash and cash equivalents and marketable securities of $185.8 million. The weighted average interest rate related to our cash and cash equivalents for the years ended December 31, 2013 was 0%. As of December 31, 2013, the principal value of our credit lines was $9.1 million at a weighted average interest rate of approximately 7.7%.

Our $158 million aggregate principal amount of our 3.00% convertible senior notes (the "2033 Senior Notes") has a fixed interest rate, and therefore is not subject to fluctuations in market interest rates.

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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Equity Price Risk – We are subject to equity price risk related to the (i) rights to convert into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. These terms are considered to be embedded derivatives. On a quarterly basis, we are required to record these embedded derivatives at fair value with the changes being recorded in our Consolidated Statement of Operations. Accordingly, our results of operations are subject to exposure associated with increases or decreases in the estimated fair value of our embedded derivatives.

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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, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 3, 2014, expressed an adverse opinion thereon.
/s/ Ernst & Young LLP
Certified Public Accountants
Miami, Florida
March 3, 2014

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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, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (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 PROLOR Biotech, Inc., which is included in the December 31, 2013 consolidated financial statements of OPKO Health, Inc. and subsidiaries and constituted, in the aggregate, $734.4 million of total assets and $573.5 million of net assets as of December 31, 2013 and $0.0 million of revenues and $13.2 million of net loss 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 PROLOR Biotech, Inc.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness in controls related to the company's financial statement close process at its Chilean subsidiary due to the lack of sufficient controls to assure

that inventory and accounts receivable balances are recoded correctly in accordance 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), the consolidated balance sheets of OPKO Health, Inc. and subsidiaries as of December 31, 2013 and 2012, 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, 2013. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2013 financial statements, and this report does not affect our report dated March 3, 2014, which expressed an unqualified opinion on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, OPKO Health, Inc. and subsidiaries has not maintained effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

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/s/ Ernst & Young LLP
Certified Public Accountants
Miami, Florida
March 3, 2014

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OPKO Health, Inc. and Subsidiaries
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	For the years ended December 31,	
	2013[1]	2012[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$185,798	$27,361
Accounts receivable, net	19,767	21,162
Inventory, net	18,079	22,261
Prepaid expenses and other current assets	19,084	7,873
Total current assets	242,728	78,657
Property, plant, equipment, and investment properties, net	17,027	16,526
Intangible assets, net	74,533	84,238
In-process research and development	793,341	11,546
Goodwill	226,373	80,450
Investments, net	30,653	15,636
Other assets	6,861	2,777
Total assets	$1,391,516	$289,830
LIABILITIES, SERIES D PREFERRED STOCK, AND EQUITY		
Current liabilities:		
Accounts payable	$13,414	$10,200
Accrued expenses	65,874	24,656
Current portion of lines of credit and notes payable	12,562	17,526
Total current liabilities	91,850	52,382
3.00% convertible senior notes, net of discount and estimated fair value of embedded derivatives	211,912	—
Other long-term liabilities, principally contingent consideration and deferred tax liabilities	214,775	34,168
Total long-term liabilities	426,687	34,168
Total liabilities	518,537	86,550
Commitments and contingencies:		
Series D Preferred Stock - $0.01 par value, 2,000,000 shares authorized; no shares issued or outstanding at December 31, 2013 and 1,129,032 shares issued and outstanding (liquidation value of $30,595) at December 31, 2012	—	24,386
Equity:		
Series A Preferred Stock - $0.01 par value, 4,000,000 shares authorized; no shares issued or outstanding at December 31, 2013 or 2012	—	—
Series C Preferred Stock - $0.01 par value, 500,000 shares authorized; no shares issued or outstanding at December 31, 2013 or 2012	—	—
Common Stock - $0.01 par value, 750,000,000 shares authorized; 414,818,195 and 305,560,763 shares issued at December 31, 2013 and 2012, respectively	4,148	3,056
Treasury Stock - 2,264,063 shares and 2,293,056 shares at December 31, 2013 and 2012,	(7,362)	(7,457)

respectively		
Additional paid-in capital	1,379,383	565,201
Accumulated other comprehensive income	3,418	7,356
Accumulated deficit	(503,177)	(388,770)
Total shareholders' equity	876,410	179,386
Noncontrolling interests	(3,431)	(492)
Total equity	872,979	178,894
Total liabilities, Series D Preferred Stock, and equity	$1,391,516	$289,830

(1) As of December 31, 2013 and 2012, total assets include $6.7 million and $5.6 million, respectively, and total liabilities include $10.4 million and $5.5 million, respectively related to SciVac Ltd ("SciVac"), previously known as SciGen (I.L.) Ltd, a consolidated variable interest entity. SciVac's consolidated assets are owned by SciVac and the holders of SciVac's consolidated liabilities have no recourse against us. Refer to Note 3.

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OPKO Health, Inc. and Subsidiaries
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	For the years ended December 31,		
	2013	2012	2011
Revenues:			
Products	$68,161	$45,295	$27,844
Revenue from services	11,658	1,749	135
Revenue from transfer of intellectual property	16,711	—	—
Total revenues	96,530	47,044	27,979
Costs and expenses:			
Costs of revenues	48,860	27,878	17,243
Selling, general and administrative	55,320	27,795	19,169
Research and development	53,902	19,520	11,352
Contingent consideration	6,947	785	—
Amortization of intangible assets	11,133	8,335	3,404
Total costs and expenses	176,162	84,313	51,168
Operating loss from continuing operations	(79,632)	(37,269)	(23,189)
Other income and (expense), net:			
Interest income	376	188	288
Interest expense	(13,802)	(1,405)	(1,005)
Fair value changes of derivative instruments, net	(36,489)	1,340	(39)
Other income (expense), net	25,329	(67)	(288)
Other income and (expense), net	(24,586)	56	(1,044)
Loss from continuing operations before income taxes and investment losses	(104,218)	(37,213)	(24,233)
Income tax benefit (provision)	(1,672)	9,626	19,358
Loss from continuing operations before investment losses	(105,890)	(27,587)	(4,875)
Loss from investments in investees	(11,456)	(2,062)	(1,589)
Loss from continuing operations	(117,346)	(29,649)	(6,464)
Income from discontinued operations, net of tax	—	109	5,181
Net loss	(117,346)	(29,540)	(1,283)
Less: Net loss attributable to noncontrolling interests	(2,939)	(492)	—
Net loss attributable to common shareholders before preferred stock dividend	(114,407)	(29,048)	(1,283)
Preferred stock dividend	(420)	(2,240)	(2,379)
Net loss attributable to common shareholders	$(114,827)	$(31,288)	$(3,662)
Loss per share, basic and diluted:			
Loss from continuing operations	$(0.32)	$(0.11)	$(0.03)
Income from discontinued operations	—	—	$0.02
Net loss per share	$(0.32)	$(0.11)	$(0.01)
Weighted average number of common shares outstanding, basic and diluted	355,095,701	295,750,077	280,673,122

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,		
	2013	2012	2011
Net loss attributable to common shareholders	$(114,827)	$(31,288)	$(3,662)
Other comprehensive income (loss), net of tax:			
Change in foreign currency translation	(1,825)	2,289	(2,398)
Available for sale investments:			
Change in other unrealized gains, net	2,467	4,160	384
Less: reclassification adjustments for gains included in net loss, net of tax	(4,580)	—	—
Comprehensive loss	$(118,765)	$(24,839)	$(5,676)

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 EQUITY
(In thousands, except share and per share data)
For the years ended December 31, 2013, 2012, 2011

	Series A Preferred Stock		Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total
	Shares	Dollars	Shares	Dollars	Shares	Dollars					
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	—	—	4,494,380	45	(44,583)	(199)	22,606	—	—	—	22,452

in connection with OPKO Diagnostics acquisition at $5.04 per share	—	—	—	—	—	—	—	—	—	—	—
Issuance of Common Stock in connection with FineTech acquisition at $4.90 per share	—	—	3,615,703	36	—	—	17,681	—	—	—	17,717
Exakta-OPKO purchase price adjustment	—	—	—	—	—	—	92	—	—	—	92
Net loss attributable to common shareholders before preferred stock dividend	—	—	—	—	—	—	—	—	(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

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 EQUITY
(In thousands, except share and per share data)
For the years ended December 31, 2013, 2012, 2011 (continued)

	Series A Preferred Stock		Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total
	Shares	Dollars	Shares	Dollars	Shares	Dollars					
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	—	—	—	—	—	—	—	—	(29,048)	—	(29,048)
Net loss attributable to	—	—	—	—	—	—	—	—	—	(492)	(492)

noncontrolling interests									
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 EQUITY
(In thousands, except share and per share data)
For the years ended December 31, 2013, 2012, 2011 (continued)

	Series A Preferred Stock		Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total
	Shares	Dollars	Shares	Dollars	Shares	Dollars					
Balance at December 31, 2012	—	$—	305,560,763	$3,056	(2,293,056)	$(7,457)	$565,201	$7,356	$(388,770)	$(492)	$178,894
Equity-based compensation expense	—	—	—	—	—	—	10,983	—	—	—	10,983
Exercise of Common Stock options	—	—	9,244,971	92	—	—	22,704	—	—	—	22,796
Exercise of Common Stock warrants	—	—	1,487,774	15	—	—	613	—	—	—	628
Series D Preferred Stock dividend	—	—	—	—	—	—	(3,015)	—	—	—	(3,015)
Conversion of Series D Preferred Stock	—	—	11,290,320	113	—	—	24,273	—	—	—	24,386
Conversion of 3.00% convertible senior notes	—	—	2,396,145	24	—	—	20,815	—	—	—	20,839
Issuance of Common Stock in connection with OPKO Brazil acquisition at $6.73 per share	—	—	64,684	1	—	—	434	—	—	—	435
Issuance of Common Stock in connection with Cytochroma acquisition at $7.16 per share	—	—	20,517,030	205	—	—	146,697	—	—	—	146,902

Issuance of Common Stock in connection with PROLOR acquisition at $8.49 per share and fair value of stock options and warrants exchanged	—	63,670,805	637	—	—	586,006	—	—	—	586,643
Issuance of Common Stock in connection with Farmadiet's first Deferred Payment at $7.52 per share	—	585,703	5	—	—	4,430	—	—	—	4,435
Issuance of Treasury Stock in connection with Farmadiet's Contingent Consideration at $11.60 per share				28,993	95	242				337
Net loss attributable to common shareholders before preferred stock dividend	—	—	—	—	—	—	—	(114,407)	—	(114,407)
Net loss attributable to noncontrolling interests	—	—	—	—	—	—	—	—	(2,939)	(2,939)
Other comprehensive loss	—	—	—		—	—	(3,938)	—	—	(3,938)
Balance at December 31, 2013	—	14,818,195	$4,148	(2,264,063)	$(7,362)	$1,379,383	$3,418	$(503,177)	$(3,431)	$872,979

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,		
	2013	2012	2011
Cash flows from operating activities:			
Net loss	$(117,346)	$(29,540)	$(1,283)
Income from discontinued operations, net of tax	—	(109)	(5,181)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	15,216	10,160	3,830
Non-cash interest on convertible senior notes	5,980	—	2
Amortization of deferred financing costs	1,170	—	—
Losses from investments in investees	11,456	2,062	1,589
Equity-based compensation – employees and non-employees	10,983	5,131	6,953
Provision for (recovery of) bad debts	979	(95)	257
Provision for inventory obsolescence	2,015	2,688	607
Revenue from receipt of equity	(12,740)	(159)	(85)
Realized gain on sale of equity securities	(29,881)	—	—
Loss on conversion of 3.00% convertible senior notes	8,688	—	—
Loss on sale of property, plant and equipment	60	—	—
Change in fair value of derivatives instruments	36,489	(1,340)	39
Change in fair value of contingent consideration	6,947	785	—
Deferred income tax (benefit)/provision	599	(9,958)	(19,749)
Changes in assets and liabilities of continuing operations, net of the effects of acquisitions:			
Accounts receivable	754	763	(1,719)
Inventory	1,892	(5,807)	2,170
Prepaid expenses and other current assets	(1,131)	(2,877)	57
Other assets	(544)	(361)	16
Accounts payable	1,829	1,247	(1,784)
Foreign currency measurement	(2,386)	86	363
Accrued expenses	779	1,902	(21)
Cash used in operating activities of continuing operations	(58,192)	(25,422)	(13,939)
Cash provided by operating activities of discontinued operations	—	7	(4,561)
Net cash used in operating activities	(58,192)	(25,415)	(18,500)
Cash flows from investing activities:			
Investments in investees	(17,441)	(3,396)	(2,013)
Proceeds from sale of equity securities	30,556	—	—
Acquisition of businesses, net of cash acquired	20,528	(19,092)	(28,186)
Purchase of marketable securities	(50,027)	(25,806)	(100,161)
Maturities of short-term marketable securities	50,027	24,997	100,161
Proceeds from the sale of property, plant and equipment	636	—	—
Capital expenditures	(3,962)	(1,472)	(1,953)
Cash provided (or used) by investing activities from continuing operations	30,317	(24,769)	(32,152)
Cash provided by investing activities from discontinued operations	—	—	17,316
Net cash provided (or used) in investing activities	30,317	(24,769)	(14,836)
Cash flows from financing activities:			

Issuance of 3.00% convertible senior notes, net, including related parties	170,184	—	—
Issuance of Common Stock, net (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 related parties	(3,015)	—	(4,704)
Proceeds from the exercise of Common Stock options and warrants	23,425	2,279	1,244
Borrowings on lines of credit	34,577	36,506	15,300
Repayments of lines of credit	(38,997)	(32,754)	(20,127)
Net cash provided by financing activities	186,174	6,031	86,917
Effect of exchange rate on cash and cash equivalents	138	(2)	(81)
Net increase (decrease) in cash and cash equivalents	158,437	(44,155)	53,500
Cash and cash equivalents at beginning of period	27,361	71,516	18,016
Cash and cash equivalents at end of period	$185,798	$27,361	$71,516

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 (unaudited)

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 point-of-care tests, molecular diagnostics tests, laboratory developed 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 Chile, Spain, Mexico, and Uruguay, 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 have also established pharmaceutical operations in Brazil. We own 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. In the U.S., we own a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"), with a urologic focus that generates revenue and we expect will serve as a commercial platform for the U.S. launch of our next generation prostate cancer test to improve cancer risk stratification of patient candidates for prostate biopsy.

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, and Nes Ziona, Israel, which is where our molecular diagnostics research and development, oligonucleotide research and development and carboxyl terminal peptide 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 for our pharmaceutical business directed to chronic kidney disease ("CKD"). Our Chilean and Uruguayan operations are located in leased offices and warehouse facilities in Santiago and Montevideo, respectively. Our Mexican operations are based in owned offices, an owned manufacturing facility and a leased warehouse facility in Guadalajara and in leased offices in Mexico City. Our Spanish operations are based in owned offices in Barcelona, in an owned manufacturing facility in Banyoles and a leased warehouse facility in Palol de Revardit. Our Brazilian operations are located in leased offices in Sao Paulo.

Note 2 Summary of Significant Accounting Policies

Basis of Presentation. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. 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.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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.

Correction of an error. The consolidated statements of operations for the year ended December 31, 2013 include a $2.7 million, or $0.01 per share, reduction of research and development expense. This reduction is the result of correcting the cumulative effect of an error in calculating equity based compensation expense for certain performance based stock options granted to a non-employee. The effect of this error was not material to the financial statements of any prior annual or quarterly periods nor is it material to 2013 financial statements presented herein; and as such, the cumulative effect of such error was recorded as a reduction to research and development expense in the year ended December 31, 2013.

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.

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Shipping and Handling Costs. We do not charge customers for shipping and handling costs. Shipping and handling costs are classified as Cost of revenues 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 $4.1 million, $1.8 million, and $0.4 million for the years ended December 31, 2013, 2012, and 2011, 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”), Prost-Data, Inc. (“OPKO Lab”), Cytochroma Inc. (“Cytochroma”), Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda. (“OPKO Brazil”) and PROLOR Biotech, Inc. (“PROLOR”). Goodwill, in-process research and development (“IPR&D”) and other intangible assets acquired in business combinations, licensing and other transactions at December 31, 2013 and December 31, 2012 were $1.1 billion and $0.2 billion, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. We determined the fair value of intangible assets, including IPR&D, using the “income method.”

Goodwill is tested at least annually for impairment, or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, on an enterprise level by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value.

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 $11.1 million, $8.3 million, and $3.4 million for the years ended December 31, 2013, 2012, and 2011, respectively. Amortization expense from continuing operations for our intangible assets is expected to be $11.0 million, $10.5 million, $9.6 million, $9.4 million and $7.1 million, respectively, for the years ended December 31, 2014, 2015, 2016, 2017, and 2018.

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, 2013 and 2012 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.

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Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as contingent consideration income. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

Derivative financial instruments. We record derivative financial instruments on our Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Consolidated Statement of Operations, when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify 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, 2013 and 2012, our forward contracts for inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments in Fair value changes of derivatives instruments, net, in our Consolidated Statement of Operations. Refer to Note 19.

Research and development expenses. Research and development expenses include external and internal expenses, partially offset by third-party grants and fundings arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. Research and development employee-related expenses include salaries, benefits and stock-based compensation expense. Other unallocated internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

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. Potentially dilutive shares issuable pursuant to the 2033 Senior Notes (defined in Note 6) were not included in the computation of net loss per share for the year ended December 31, 2013, because their inclusion would be anti-dilutive.

A total of 32,105,859, 26,695,436 and 26,661,326 potential shares of Common Stock have been excluded from the calculation of net loss per share for the years ended December 31, 2013, 2012 and 2011, respectively, because their inclusion would be anti-dilutive. During the year ended December 31, 2013, 10,881,570 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 10,732,745 shares of Common Stock. Of the 10,881,570 Common Stock options and Common Stock warrants exercised, 148,825 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements. During the year ended

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December 31, 2012, 1,086,361 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,084,982 shares of Common Stock. Of the 1,086,361 Common Stock options and Common Stock warrants exercised, 1,379 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements. During year ended December 31, 2011, 3,702,497 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 3,348,394 shares of Common Stock. Of the 3,702,497 Common Stock options and Common Stock warrants exercised, 354,103 shares of Common Stock 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 or decrease the risk of product returns.

Revenue for laboratory 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. For the years ended December 31, 2013, 2012 and 2011, respectively, revenue from other services included $0.2 million, $1.4 million and $0.1 million respectively, of revenue related to our consulting agreement with Neovasc and to revenue related to molecular diagnostics collaboration agreements. We recognize this revenue on a straight-line basis over the contractual term of the agreements.

Revenue from transfer of intellectual property includes revenue related to the sale, license or transfer of intellectual property such as 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.

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 services. License fees with ongoing involvement or performance obligations are recorded as deferred revenue, included in 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. For the year ended December 31, 2013, we recorded $16.7 million of revenue from the transfer of intellectual property, of which $12.5 million related to the sale of substantially all of our assets in the field of RNA interference to RXi Pharmaceuticals Corporation ("RXi") and $3.8 million related to the rights granted to OAO Pharmsynthez ("Pharmsynthez") of certain technologies. Refer to Note 3. For the years ended December 31, 2012 and 2011, we recorded no revenues from the transfer of intellectual property, respectively.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Revenue from transfer of intellectual property 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 Revenue from transfer of intellectual property over the term of the arrangement as we complete our performance obligations. Total deferred revenue included in Accrued expenses and Other long-term liabilities was $7.6 million and $1.9 million at December 31, 2013 and 2012, respectively.

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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 the allowance for doubtful accounts was $1.9 million and $0.5 million at December 31, 2013 and 2012, 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 Consolidated 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. 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, 2013, 2012 and 2011, we recorded $11.0 million, $5.1 million and $7.0 million, respectively, of equity-based compensation in the loss from continuing operations.

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. We currently manage our operations in two reportable segments, pharmaceuticals and diagnostics. The pharmaceuticals 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, Spain and Brazil. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired through the acquisition of OPKO Lab 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.

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 strategic investments in development stage and emerging companies. We record these investments as equity method investments or investments available for sale based on 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 based on their closing price per share at the end of each reporting period. Refer to Note 3.

Recent accounting pronouncements. In February 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2013-2, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, (“ASU 2013-2”). ASU 2013-2 requires the presentation of reclassifications out of accumulated other comprehensive income in either (1) the notes or (2) the face of the financial statements. We adopted ASU 2013-2 for our first quarter ended March 31, 2013. The adoption of ASU 2013-2 did not have a material impact in our Consolidated Financial Statements, but did require certain additional disclosures. Refer to Note 7.

In July 2013, the FASB issued ASU 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU 2013-11 is intended to eliminate inconsistent practices regarding the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is available to reduce the taxable income or tax payable that would result from the disallowance of a tax position. This ASU will be effective for our fiscal year beginning

January 1, 2014 and subsequent interim periods. The adoption of ASU 2013-11 is not expected to have a material effect on our Consolidated Financial Statements.

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Note 3 Acquisitions, Investments and Licenses

Acquisitions for the year ended December 31, 2013

PROLOR acquisition

In August 2013, we acquired PROLOR pursuant to an Agreement and Plan of Merger dated as of April 23, 2013 (the "PROLOR Merger Agreement") in an all-stock transaction. PROLOR is an Israeli-based biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins.

Under the terms of the PROLOR Merger Agreement, holders of PROLOR common stock received 0.9951 shares of our Common Stock for each share of PROLOR common stock. At closing we delivered 63,670,805 shares of our Common Stock valued at $540.6 million based on the closing price per share of our Common Stock as reported by the NYSE on the closing date of the acquisition, or $8.49 per share. In addition, each outstanding option and warrant to purchase shares of PROLOR Common Stock that was outstanding and unexercised immediately prior to the closing date, whether vested or not vested, was converted into 7,889,265 options and warrants to purchase OPKO Common Stock at a fair value of $46.1 million.

Until completion of the acquisition of PROLOR, Dr. Phillip Frost, our Chairman and Chief Executive Officer, was PROLOR's Chairman of the Board and a greater than 5% stockholder of PROLOR. Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer and Mr. Steven Rubin, our Executive Vice President, Administration, were both directors of PROLOR and less than 5% stockholders of PROLOR.

Cytochroma acquisition

In March 2013, we acquired Cytochroma, a corporation located in Markham, Canada, whose lead products, both in phase 3 development, are Rayaldy™ (CTAP101), a vitamin D prohormone to treat secondary hyperparathyroidism in patients with stage 3 or 4 CKD and vitamin D insufficiency, and Alpharen™ (Fermagate Tablets), a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the "Cytochroma Acquisition").

In connection with the Cytochroma Acquisition, we delivered 20,517,030 of shares of our Common Stock valued at $146.9 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $7.16 per share. The number of shares issued was based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the 10 trading days immediately preceding the date of the purchase agreement for the Cytochroma Acquisition, or $4.87 per share. 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. As a result, we recorded $47.7 million as contingent consideration. We evaluate the contingent consideration on an ongoing basis and the changes in the fair value are recognized in earnings until the milestones are achieved. Refer to Note 18.

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The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed in the acquisitions of Cytochroma and PROLOR at the dates of acquisition, which are subject to change until contingencies that existed on the acquisition date are resolved:

(In thousands)	Cytochroma	PROLOR
Current assets [(1)]	$1,224	$21,500
Intangible assets:		
In-process research and development	191,530	590,200
Patents	210	—
Total intangible assets	191,740	590,200
Goodwill	2,411	139,784
Property, plant and equipment	306	1,057
Other assets	—	371
Accounts payable and accrued expenses	(1,069)	(9,866)
Deferred tax liability	—	(156,403)
Total purchase price	$194,612	$586,643

(1)Current assets include cash of $0.4 million and $20.5 million related to the Cytochroma and PROLOR acquisitions, respectively.

Goodwill from the acquisition of PROLOR principally relates to the deferred tax liability generated as a result of this being a stock transaction and the assembled workforce. Goodwill from the acquisition of Cytochroma principally relates to the assembled workforce. Goodwill is not tax deductible for income tax purposes.

OPKO Brazil asset acquisition

In February 2013, we acquired the assets of OPKO Brazil, a Brazilian pharmaceutical company, pursuant to a purchase agreement entered into in December 2012. Pursuant to the purchase agreement, we paid $0.3 million in cash and delivered 64,684 shares of our Common Stock at closing valued at $0.4 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $6.73 per share. The number of shares issued was based on the average closing price per share of Common Stock as reported on the NYSE for the 10 trading days immediately preceding the execution of the purchase agreement, or $4.64 per share. We accounted for this acquisition as an asset acquisition rather than a business combination. As a result we recorded the assets at fair value, with most of the value being allocated to the most significant asset, its pharmaceutical business licenses.

Acquisitions for the year ended December 31, 2012

OPKO Lab acquisition

In October 2012, we entered into a definitive merger agreement to acquire OPKO Lab, a Nashville-based CLIA laboratory. In December 2012, we paid $9.4 million in cash and delivered 7,072,748 shares of our Common Stock at closing valued of $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 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 Common Stock issued in the transaction are being held in a separate escrow account to secure indemnification obligations of the former owner.

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

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as interest expense through the respective payment dates. The Deferred 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 price per share of our Common Stock as reported on the NYSE for the 10 trading days immediately preceding the applicable payment date. On August 2, 2013, we issued 585,703 shares of our Common Stock, in accordance with the first Deferred Payment. The number of shares issued was based on the average closing price per share of our Common Stock as reported on the NYSE for the 10 trading days up to and including August 1, 2013, or $7.61 per share. On February 14, 2014, we delivered approximately €3.4 million in cash in accordance with the second Deferred Payment. We had the right to hold back up to €2.8 million (approximately $3.9 million as of December 31, 2013) 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 25% ($0.3 million) was paid at closing through delivery of 70,421 shares of our Common Stock, and (b) 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. In November 2013, we issued 28,993 shares of our Common Stock, as certain of the milestones agreed upon were achieved. 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 10 trading days preceding the required payment date.

ALS acquisition

In April 2012, we completed the acquisition of ALS Distribuidora Limitada ("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. During the year ended December 31, 2013, we paid the remaining $0.8 million that we had agreed to pay upon the legal registration in the name of ALS of certain trademarks and product registrations previously held by the former owner of ALS, Arama Laboratorios y Compañía Limitada.

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

(In thousands)	OPKO Lab	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 OPKO Lab, 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.

Acquisitions for the year ended December 31, 2011

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 10 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.

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 10 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 the sellers 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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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.

Pro forma disclosure for acquisitions

The following table presents the pro forma results of the acquisitions of Cytochroma and PROLOR for the years ended December 31, 2013 and 2012 as if those acquisitions had been completed as of the beginning of each period, respectively.

	For the years ended December 31,	
(In thousands, except per share amounts)	2013	2012
Revenues	$96,530	$53,595
Loss from continuing operations	$—	$(63,479)
Net loss	$(147,546)	$(55,663)
Net loss attributable to common shareholders	$(145,027)	$(57,411)
Basic and diluted loss from continuing operations per share	$(0.37)	$(0.15)
Basic and diluted loss from discontinuing operations per share	$—	$—
Basic and diluted loss per share	$(0.37)	$(0.15)

The unaudited pro forma financial information is presented for information 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 period presented.

We incurred a pre-tax loss related to the activities of Cytochroma and PROLOR of $22.6 million and $13.2 million, respectively, from the date of our acquisitions through December 31, 2013.

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Investments

The total assets, liabilities, and net losses of our equity method investees as of and for the year ended December 31, 2013 were $100.0 million, $39.2 million, and $75.1 million, respectively. The following table reflects our maximum exposure, accounting method, ownership interest and underlying equity in net assets of each of our unconsolidated investments as of December 31, 2013:

(Dollars in thousands, except per share prices) Investee name	Year invested	Accounting method	Ownership at December 31, 2013	Investment	Underlying equity in net assets	Closing share price at December 31, 2013 for investments available for sale
Cocrystal	2009	Equity method	16 %	2,500	205	
Neovasc	2011	Equity method	6 %	3,798	325	
Fabrus	2010	VIE, equity method	12 %	750	(160)	
BZNE common stock	2012	VIE, equity method	16 %	2,976	(1,686)	
RXi	2013	Equity method	19 %	15,000	2,444	
Pharmsynthez	2013	Equity method	11 %	5,036	5,156	
Zebra	2013	VIE, equity method	19 %	2,000	1,220	
TESARO	2010	Investment available for sale	1 %	56		$28.24
Neovasc options	2011	Investment available for sale	N/A	925		CA $4.10
ChromaDex	2012	Investment available for sale	1 %	1,320		$1.52
ARNO	2013	Investment available for sale	5 %	2,000		$3.20
Plus unrealized/realized gains on investments, options and warrants, net				12,766		