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

FORM 10-K

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

For the fiscal year ended December 31, 2010

OR

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

Commission file number 001-33528

OPKO HEALTH, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

4400 Biscayne Blvd., Miami, FL 33137
(Address of Principal Executive Offices, Zip Code)

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

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

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

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

None

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

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Website, 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 ☐ 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. ☐

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

Large Accelerated filer ☐	Accelerated filer ☑	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 ☑

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: $253,812,039.

As of March 8, 2011 the registrant had 255,600,194 shares of common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2011 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 STATEMENTS 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 drug research and development activities may not result in commercially viable products.
- The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- Our business is substantially dependant on our ability to develop, launch and generate revenue from our molecular diagnostic program.
- We expect to 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.
- If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

- In the event that we successfully evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.
- If we fail to acquire and develop other products or product candidates, at all or on commercially reasonable terms, we may be unable to diversify or grow our business.
- We have no experience manufacturing our pharmaceutical product candidates other than our Mexican facility and we therefore rely on third parties to manufacture and supply our pharmaceutical product candidates, and would need to meet various standards necessary to satisfy FDA regulations if and when we commence manufacturing.
- We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile and Mexico for sales in those countries. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates.
- 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. 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 will rely heavily on licenses from third parties.
- We license patent rights to certain of our technology from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.
- Adverse results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition.
- Medicare prescription drug coverage legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.
- Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.
- We may not have the funding available to pursue acquisitions.
- Acquisitions may disrupt our business, distract our management and may not proceed as planned; and we may encounter difficulties in integrating acquired businesses.
- Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

- Our business may become subject to legal, economic, political, regulatory and other risks associated with international operations.
- The market price of our common stock may fluctuate significantly.
- Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interests or in the best interests of our stockholders.
- Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.
- If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as they apply to us, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our common stock price may suffer.
- We may be unable to maintain our listing on the NYSE Amex, 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.

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" refers to OPKO Health, Inc., a Delaware corporation, including our wholly-owned subsidiaries.

ITEM 1. BUSINESS

OVERVIEW

We are a multi-national pharmaceutical 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. Our current focus is on conditions with major unmet medical needs including neurological disorders, infectious diseases, oncology and ophthalmologic diseases. We are developing a range of solutions to diagnose, treat and prevent these conditions, including molecular diagnostics tests, proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets. We have already established emerging markets pharmaceutical platforms in Chile and Mexico, which are delivering revenue and which we expect to deliver cash flow and facilitate future market entry for our products currently in development. We also actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses.

Our lead program under development is an innovative molecular diagnostic platform technology for the rapid identification of molecules or immunobiomarkers that may be useful in the creation of accurate, easy-to-use tests for conditions where we believe no objective diagnostic test currently exists or where presently available tests are characterized by invasive procedures and low levels of accuracy. We have demonstrated in initial studies that our platform has the ability to identify diagnostic biomarkers for a wide range of diseases to which the immune system reacts, including cancers, autoimmune diseases, neurodegenerative diseases and infectious diseases. This technology platform may also allow for the development of vaccines and highly targeted therapeutic agents.

Our most advanced application of this technology is a simple blood test for Alzheimer's disease, a debilitating neurodegenerative disease for which there are limited diagnostic options available today. Based on initial clinical work, as described in the journal *Cell* in January 2011, our Alzheimer's test demonstrated an ability to identify and differentiate Alzheimer's patients by detecting elevated levels of antibodies that appear to be unique to Alzheimer's disease. We are currently conducting a broader validation study that we expect to be completed by late 2011 and we expect to begin marketing our test for Alzheimer's disease in 2013. We believe that this test could initially be useful in stratifying patients for ongoing clinical trials of potential Alzheimer's drugs as well as to confirm the diagnosis in a clinical setting and to track the progression of the disease or effectiveness of a therapeutic in a clinical trial. In December 2010 we entered into a non-exclusive collaboration agreement with Bristol-Myers Squibb Company ("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.

In addition to Alzheimer's disease, we are developing a pipeline of diagnostic tests for other conditions such as pancreatic cancer, Parkinson's disease and non-small cell lung cancer. We anticipate entering into additional collaboration agreements regarding our diagnostic pipeline tests and expect to commercially launch up to three diagnostic tests over the next three years.

Our product pipeline also includes several pharmaceutical compounds and technologies in research and development for a broad range of indications and conditions. We are developing a protein-based influenza vaccine designed to offer multi-season and multi-strain protection, that we believe will offer more effective and longer lasting protection against influenza, in addition to more rapid and efficient production than existing influenza vaccine technologies. We recently acquired an up-regulating oligonucleotide therapeutics technology that 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. In addition to these development programs, we have growing pharmaceutical businesses in Chile and Mexico.

We have a highly experienced management team that we believe has demonstrated an ability to successfully build and manage pharmaceutical businesses. Our Chairman and Chief Executive Officer, Dr. Phillip Frost, founded

and served as Chairman and Chief Executive Officer of IVAX Corporation ("IVAX"), a multi-national pharmaceutical company, from 1987 until the acquisition of IVAX by Teva Pharmaceutical Industries, Limited ("Teva"), in January 2006. Dr. Frost currently serves as Chairman of the Board of Teva. Prior to Ivax, Dr. Frost founded and served as Chairman of the Board of Directors of Key Pharmaceuticals, Inc. from 1972 until the acquisition of Key Pharmaceuticals by Schering Plough Corporation in 1986. Our other senior executive officers, including Dr. Jane Hsiao, our Vice Chairman and Chief Technology Officer, Steven Rubin, our Executive Vice President, Administration, and Dr. Rao Uppaluri, our Senior Vice President and Chief Financial Officer, are former executive officers of IVAX. 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 and small molecules, targeting a broad range of unmet medical needs. We intend to continue to leverage our proprietary technology and our strengths in all phases of pharmaceutical research and development to further develop and commercialize our portfolio of proprietary pharmaceutical and diagnostic products. Key elements of our strategy are to:

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

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

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

Corporate Information

We were originally incorporated in Delaware in October 1991 under the name Cytoclonal Pharmaceutics, Inc., which was later changed to eXegenics, Inc. 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 Amex under the ticker "OPK". Our principal executive offices are located in Miami, Florida. We also have leased lab space at The Scripps Research Institute in Jupiter, Florida, and

leased offices in Santiago, Chile. We also have offices and a manufacturing facility in Guadalajara, Mexico, a leased manufacturing facility in Hialeah, Florida, and a research and development office in the United Kingdom at the University of Kent.

We currently manage our operations in two reportable segments, pharmaceutical and instrumentation segments. The pharmaceutical segment consists of two operating segments, (i) our pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, diagnostic tests, and vaccines, and (ii) the pharmaceutical operations we acquired in Chile and Mexico through the acquisition of OPKO Chile and Exakta-OPKO. The instrumentation segment consists of ophthalmic instrumentation devices and the activities related to the research, development, manufacture, and commercialization of those products.

CURRENT PRODUCT CANDIDATES AND RELATED MARKETS

Molecular Diagnostics

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

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

Currently it is estimated that over five million people in the United States, and over 35 million people worldwide, have Alzheimer's disease and the national cost of caring for people with Alzheimer's and other dementias is estimated to be $172 billion in 2010 in the United States alone. By 2050, it is estimated that between 11 and 16 million people in the United States over the age of 65 will have Alzheimer's, and the global prevalence of people living with Alzheimer's and other dementias is expected to be greater than 115 million. Currently there are no specific tests to detect Alzheimer's disease and follow its progression. Current diagnosis tools such as behavioral and cognitive measurements, brain scans and spinal fluid analysis have limited diagnostic accuracy, may not detect early stage disease, and in the case of spinal fluid analysis are highly invasive. Definitive diagnosis can currently be made only from examination of postmortem brain tissue samples. An effective early diagnostic blood test would provide a significant breakthrough in supporting definitive early diagnosis.

As reported in the January 2011 edition of the journal *Cell*, we demonstrated in a preliminary study that we were able to identify unique biomarkers from serum samples of known Alzheimer's disease patients, and then using these biomarkers we were able to distinguish patients with Alzheimer's disease from healthy controls, patients with Parkinson's disease and patients with lupus. In December 2010, we entered into a collaboration agreement with BMS, under which we and BMS will investigate 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. We have conducted a validation study of 140 patients, and we are expanding the study to include 200 patients with Alzheimer's disease, 200 demographically matched controls, and 180 patients with other conditions. We expect to complete this study by late 2011 and we expect to begin marketing our diagnostic test for Alzheimer's disease in 2013.

In addition to Alzheimer's disease, we are also pursuing the development of diagnostic tests for pancreatic cancer, Parkinson's disease, non-small cell lung cancer, and other diseases for which early detection could lead to earlier therapy and dramatically improved outcomes. We have conducted preliminary studies in pancreatic cancer,

Parkinson's disease, and non-small cell lung cancer patient samples that we believe demonstrate the ability of our technology to identify biomarkers with diagnostic utility for these conditions. We plan to conduct additional studies in larger patient populations to further validate diagnostic tests for these and other conditions. We expect to complete a validation study of an initial cancer diagnostic test in 2012 and we expect to begin marketing an initial cancer diagnostic test in 2013. We anticipate entering into additional collaboration agreements regarding our diagnostic pipeline tests and expect to commercially launch up to three diagnostic tests over the next three years.

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. Our primary focus is on developing and commercializing our novel influenza vaccine and therapeutics based on our oligonucleotide technology platform.

Vaccine Programs

In July 2009, we acquired worldwide rights from Academia Sinica in Taipei, Taiwan, for a new technology to develop protein-based vaccines against influenza and other viral infections. We are developing a proprietary, innovative influenza vaccine designed to provide multi-season and multi-strain protection against many human influenza virus strains, including both seasonal influenza strains as well as global influenza pandemic strains, such as swine flu ("H1N1"), and avian flu ("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 United States alone, with estimated economic costs in excess of $87 billion per year.

There are several major limitations of current influenza vaccines, including:

- *Inability to respond to mutations*. The influenza virus undergoes frequent and unpredictable antigenic changes, or mutations, in its surface proteins, creating new strains of the virus which the immune system often fails to recognize. Currently available vaccines do not provide adequate protection against new influenza strains, leading to the need for the ongoing development and administration of vaccines on an annual basis.
- *Slow development timelines*. Currently available influenza vaccines are based on annual World Health Organization predictions of the influenza strains that will be prevalent in the upcoming season. Because of the long development timeline required to create current influenza vaccines, the actual virus strains prevalent in a given season may differ from the strains used to create the vaccine, resulting in commercially available vaccines that offer limited protection and clinical efficacy.
- *Production cycle limitations*. The annual strain prediction and selection process necessitates annual vaccine manufacturing with time-consuming and expensive annual production cycles. The prediction of optimal production quantities is also difficult and often results in either a shortage or excess of doses.

Instead of the typical method of making a cocktail of inactivated viruses for annual flu shots, our approach to anti-viral vaccines is designed to increase protective antibodies against multiple strains of viral influenza. We believe that our technology will, among other things, permit the development of a molecular protein-based flu vaccine that will provide protection against multiple H1, H3 or H5 flu variances. We believe that our novel vaccine technology addresses the current limitations by providing a wider scope of virus strain coverage with longer-term protection, in a recombinant protein format that requires shorter development timelines and enables efficient year-round and demand-based production.

In addition, in March 2010, we acquired worldwide rights from Academia Sinica to certain alpha-galactosyl ceramide analogs which are believed to be useful as vaccines or vaccine adjuvants for a wide variety of disorders including cancer, infectious disease, and autoimmune disease. We are working in conjunction with Academia Sinica to advance and develop products under these technologies.

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.

Asthma and COPD

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

NK-1 Program

In November 2009, we acquired rolapitant and other neurokinin-1 ("NK-1"), assets from Schering Plough Corporation. Rolapitant, a potent and selective competitive antagonist of the NK-1 receptor, has successfully completed Phase II clinical testing for prevention of chemotherapy induced nausea and vomiting ("CINV"), and post-operative induced nausea and vomiting ("PONV"). Based on studies conducted to-date, we believe that rolapitant may be differentiated from other agents in this class through both its duration of action and lack of drug-drug interactions. Rolapitant has an extended plasma half-life that has the potential to improve the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy treatment. Phase II clinical testing of rolapitant for the prevention of nausea and vomiting in cancer patients treated with highly emetogenic chemotherapy demonstrated promising five-day activity following the administration of a single dose, with no significant drug-drug interactions.

The global emesis market was nearly $2.4 billion in 2009. There are more than two million chemotherapy patients each year in the United States, Europe, and Japan alone, and there are more than 23 million surgery patients in the United States and Europe. NK-1 receptor antagonists and 5HT3 receptor antagonists are major classes of drugs used for prevention of nausea and vomiting. In general, NK-1 inhibitors are complementary to 5HT3 inhibitors with the potential for additive effects in PONV and demonstrated additive effects in CINV. While there are several approved 5HT3 receptor antagonists, including palonosetron (Aloxi), ondansetron (Zofran), and other generics, there is only one NK-1 receptor antagonist approved for commercial use, aprepitant (Emend).

In December 2010, we exclusively out-licensed the development, manufacture and commercialization of rolapitant to TESARO, Inc., an oncology-focused biopharmaceutical company co-founded by former executives of MGI PHARMA, an oncology and acute-care focused biopharmaceutical company acquired by Eisai Co., Ltd. in 2008. We believe that the TESARO team brings significant development and commercialization experience and a demonstrated track record of success in launching and differentiating products for the 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, of which an up-front payment of $6.0 million has been received, 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. In addition, we acquired an approximately 10% equity position in TESARO on an as-converted basis.

Separately, we are also developing a second generation NK-1 receptor antagonist, SCH 900978, for chronic cough. The product has completed a Phase II proof of concept study with no safety issues identified and low drug-drug interaction potential.

Ophthalmics

We have therapeutic programs under development for a range of ophthalmic diseases and conditions such as wet and dry Age Related Macular Degeneration ("AMD"), which represent markets with significant unmet needs. In July 2007, we initiated the first of two required pivotal Phase III trials for our lead ophthalmic product, bevasiranib, a drug candidate in development for the treatment of Wet AMD. On March 6, 2009, following the recommendation of an independent data monitoring committee ("IDMC"), we determined to terminate the Phase III clinical trial of bevasiranib. Review of the data by the IDMC had indicated that the trial as structured was unlikely to meet its primary end point. We are continuing to investigate improved drug delivery methods in an effort to determine appropriate next steps regarding the development of bevasiranib. We may seek to continue development of these programs in the future, or to outlicense or sell these programs.

Emerging Markets Operations

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

In February 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. Exakta-OPKO has also signed a letter of intent to collaborate with the Centro de Investigación y Asistencia Tecnológica y Diseño del Estado de Jalisco ("CIATEJ"), a preeminent technology and research center in the State of Jalisco, Mexico to develop and manufacture vaccines for flu, dengue fever, and West Nile virus. The first project under development with CIATEJ is a new H1N1 vaccine which is expected to launch in Mexico in 2012.

In October 2009, we completed the acquisition of Pharma Genexx, S.A. ("OPKO Chile"). OPKO Chile markets, sells and distributes more than 100 products in the generics market to private, hospital and institutional clients in Chile for a wide range of indications, including, cardiovascular products, vaccines, antibiotics, gastro-intestinal products, and hormones, among others. OPKO Chile has no manufacturing facility.

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 December 2010, we acquired a minority equity interest in TESARO, Inc., 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, 2010, we owned an approximately 10% equity position in TESARO on an as-converted basis.
- In November 2010, we acquired a minority equity interest in Fabrus, LLC, 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, 2010, we owned approximately 13% of the outstanding membership interests of Fabrus.

- In September 2009, we acquired a minority equity interest in Cocrystal Discovery, Inc., 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, 2010, we owned approximately 16% of the outstanding capital stock of Cocrystal Discovery.
- In June 2009 we acquired a minority equity interest in Sorrento Therapeutics, Inc., a publicly held development-stage biopharmaceutical company focused on applying its proprietary technology platform for the discovery and development of human therapeutic antibodies for the treatment of a variety of disease conditions, including cancer, inflammation, metabolic disease and infectious disease. As of December 31, 2010 we owned approximately 21% of the outstanding capital stock of Sorrento Therapeutics.

INSTRUMENTATION BUSINESS

Our instrumentation business consists of the development, commercialization and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Currently, the instrumentation business is primarily based on technology that offers innovative systems with advanced diagnostic imaging capabilities and tools to meet the needs of eye care professionals. We may seek to continue development of this business in the future or to outlicense or sell this business.

RESEARCH AND DEVELOPMENT EXPENSES

During the years ended December 31, 2010, 2009, and 2008, we incurred $7.9 million, $12.9 million, and $21.6 million, respectively, of research and development expenses related to our various product candidates. During the year ended December 31, 2010, our research and development expense consisted of activities related to the development of our molecular diagnostics program, rolapitant prior to its divesture, and our next generation OCT/SLO. Research and development expense for the years ended December 31, 2009 and 2008 primarily relate to bevasiranib. In addition, during 2009 and 2008, we expensed $2.0 million and $1.4 million for acquired in process research and development related to our acquisitions of the NK-1 compounds and Vidus Ocular, Inc.

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 the disease and the molecular basis of potential pharmaceutical intervention.

We actively seek, when appropriate and available, protection for our products and proprietary information by means of United States and foreign patents, trademarks, trade secrets, copyrights, and contractual arrangements. Patent protection in the pharmaceutical field, 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 and biotechnology 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 2010, we completed a strategic licensing transaction pursuant to which we exclusively out-licensed development, manufacture and commercialization of rolapitant to TESARO, an oncology-focused biopharmaceutical company founded by executives with a demonstrated track record in launching successful products for the CINV market. Previously, we also completed strategic licensing transactions with the University of Texas Southwestern Medical Center at Dallas. Academia Sinica, the Trustees of the University of Pennsylvania, and the University of Florida Research Foundation, among others.

COMPETITION

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

We intend to leverage our technological innovation and proprietary position to effectively compete in the pharmaceutical and biopharmaceutical markets. In addition, we are committed to researching, developing and pursuing the commercialization of diagnostic tests for Alzheimer's disease, various cancers and autoimmune disease, 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, For example, Merck currently markets Emend, an NK-1 compound for post-operative nausea and vomiting and chemotherapy induced nausea and vomiting. There are several companies working to develop universal flu vaccines, and several companies have products or development programs for diseases and conditions our ophthalmic product candidates are designed to address. Competitors to our molecular diagnostics business are many and include major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and research institutions.

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

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

- Our ability to meet all necessary regulatory requirements to advance our product candidates through clinical trials and the FDA approval process;
- 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 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 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 OF OUR DRUG AND DEVICE DEVELOPMENT ACTIVITIES

The U.S. government regulates healthcare through various agencies, including but not limited to the following: (i) the U.S. Food and Drug Administration ("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 Law, 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 ("HIPAA"). 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 products and medical devices are subject to extensive regulation by federal, state, and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any drug or device product that we develop must receive all relevant regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country.

Drug Development

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

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

Clinical trials are normally done in three sequential phases and generally take two to five years or longer to complete. Phase I consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase II usually involves studies in a limited patient population to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated, determine dosage tolerance and optimal dosage, and identify possible common

adverse effects and safety risks. Phase III consists of additional controlled testing at multiple clinical sites to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling. Phase IV clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication.

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

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

Device Development

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

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

The second, more comprehensive, approval process applies to a new device that is not substantially equivalent to a pre-1976 product or that is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices. For example, most implantable devices are subject to the approval process. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to approval, as opposed to clearance. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device. These regulations permit a company to undertake a clinical study of a

"non-significant risk" device without formal FDA approval. Prior express FDA approval is required if the device is a significant risk device. Second, the FDA must review the company's PMA application, which contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds there is reasonable assurance that the device is safe and effective for its intended use. The PMA process takes substantially longer than the 510(k) process and it is conceivable that the FDA would not agree with our assessment that a device that we propose to distribute should be a Class I or Class II device. If that were to occur we would be required to undertake the more complex and costly PMA process. However, for either the 510(k) or the PMA process, the FDA could require us to run clinical trials, which would pose all of the same risks and uncertainties associated with the clinical trials of drugs, described above.

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

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

A manufacturer of a device approved through the PMA is not permitted to make changes to the device which affect 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.

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

Regulation by governmental authorities in the United States and other countries may be a significant factor in how we develop, test, produce and market our molecular diagnostic test products. 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 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. Recently, however, the FDA indicated that it was reviewing the regulatory requirements that will apply to LDTs, and held a two-day public meeting on July 19 and July 20, 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. Although the FDA did not indicate when or how those changes would be implemented, it left little doubt that the changes are forthcoming.

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 United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, in the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability and adequacy of reimbursement from third party payers, such as the government or private insurance plans. Third party payers are increasingly challenging established prices, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit. We cannot assure you that any of our products will be considered cost effective, or that reimbursement will be available or sufficient to allow us to sell them competitively and profitably.

Our instrumentation products are subject to regulation by the FDA and similar international health authorities. We also 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.

Anti-Kickback Laws

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. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug or the use of a service or device. Federal and state false claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on us, including 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 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 their broad reach and the

increasing attention given by law enforcement authorities, we cannot assure you that some of our activities will not be challenged or deemed to violate some of these laws.

Foreign Corrupt Practices Act

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

MANUFACTURING AND QUALITY

Other than our facility in Guadalajara, Mexico, 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.

We have an instrumentation manufacturing facility in Hialeah, Florida, which predominantly performs high level assembly for our instrumentation products. Certain of our products' components and optical subsystems are produced by sub-contracted vendors that specialize in optical device manufacturing.

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

SALES & MARKETING

We currently do not have pharmaceutical or diagnostics sales or marketing personnel in the United States and have limited personnel in Chile and Mexico. 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.

Our instrumentation division has offices in the United States and the United Kingdom and a distributor network that currently covers more than 50 countries. Our strategy is to increase sales of existing products through expansion of our sales channel in the United States and to provide additional marketing resources to our international distributor network.

SERVICE & SUPPORT

We currently offer service and telephone support for all of our marketed instrumentation products. Warranties are given on all products against defects of labor and material. Extended Service Contracts are available for purchase. Product repairs are performed onsite at our Hialeah facility.

EMPLOYEES

As of December 31, 2010, we had 220 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 limited revenue from our pharmaceutical operations in Chile and Mexico and from our instrumentation business. We have not yet submitted any pharmaceutical products or molecular diagnostic products for marketing approval or clearance by regulatory authorities and we do not currently have rights to any pharmaceutical product candidates that have been approved for marketing, other than those products sold by our Chilean and Mexican 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 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.

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

Most of our product candidates, including our molecular diagnostic products and vaccine technologies, 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. We may be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates either (i) are safe and effective for use in a diverse population of their intended uses or (ii) with respect to Class I or Class II devices only, 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 III clinical trials or registration trials. In addition our device candidates, as well as our molecular diagnostic 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 a device or diagnostic test approval or clearance. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval or clearance of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA and other non-U.S. regulatory authorities' approval. Any of these regulatory authorities may also approve or clear a product candidate for fewer or more limited indications or uses than we request or may grant approval or clearance contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of our product candidates.

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

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

We will 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 March 14, 2011, we issued 27,000,000 shares of our common stock in an underwritten public offering at a price of $3.75 per share. The net proceeds received in the offering were approximately $96.4 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 United States 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.

Our business is substantially dependant on our ability to develop, launch and generate revenue from our molecular diagnostic program.

Our business is substantially dependant on our ability to develop and launch simple diagnostic tests based on our molecular diagnostics platform for Alzheimer's disease, cancers and other conditions for which we are developing tests. We are committing significant research and development resources to the development of such diagnostic tests, and there is no guarantee that we will be able to successfully launch these or other diagnostic tests on anticipated timelines or at all. We have limited experience in developing, manufacturing, selling, marketing or distributing tests based on the molecular diagnostic platform. 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 ourselves or through a CLIA certified laboratory, 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.

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, molecular diagnostic, and instrumentation 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, including without limitation, Merck, Genentech, Allergan, Alcon Laboratories, Novartis, Alnylam, Regeneron, and QLT. Competitors to our molecular 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 companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals or clearances for drugs 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, molecular diagnostic, and medical device industries are characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete or less competitive.

Our product development activities could be delayed or stopped.

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

- a limited number of, and competition for, suitable patients with the particular types of disease required for enrollment in our clinical trials or that otherwise meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;
- a limited number of, and competition for, suitable 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 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 or medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, which regulations differ from country to country. In general, we are not permitted to market our product candidates in the United States until we receive approval of a new drug application ("NDA"), a clearance letter under the premarket

notification process, or 510(k) process, or an approval of a pre-market approval ("PMA") from the FDA. We have not submitted a NDA or PMA application or premarket notification, nor have we received marketing approval or clearance for any of our proprietary pharmaceutical or diagnostic product candidates. Obtaining approval of a NDA or PMA can be a lengthy, expensive, and uncertain process. With respect to medical devices, while the FDA reviews and clears a premarket notification in as little as three months, there is no guarantee that our products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance that even if a device is reviewed under the 510(k) process that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. If the FDA fails to make this finding, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product. Furthermore, we are not permitted to make changes to a device approved through the PMA or 510(k) which affects the safety or efficacy of the device without first submitting a supplement application to the PMA and obtaining FDA approval or cleared premarket notification for that supplement. In some cases, the FDA may require clinical trials to support a supplement application. In addition, failure to comply with FDA, non-U.S. regulatory authorities, or other applicable United States and non-U.S. regulatory requirements may, either before or after product approval or clearance, if any, subject our company to administrative or judicially imposed sanctions, including, but not limited to the following:

- 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.

Regulation by governmental authorities in the United States and other countries may be a significant factor in how we develop, test, produce and market our molecular diagnostic test products. 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 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 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 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. Recently, however, the FDA indicated that it was reviewing the regulatory requirements that will apply to LDTs, and held a two-day public meeting on July 19 and July 20, 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. Although the FDA did not indicate when or how those changes would be implemented, it left little doubt that the changes are forthcoming.

Our product candidates may have undesirable side effects and cause our approved drugs 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 drug 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 drugs;
- 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.

Our inability to address quality control issues in a timely manner could delay the production and sale of our instrumentation 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 products in Mexico through our Mexican subsidiary. Any quality control issues at our Mexican facility may weaken our competitive position and have a material adverse effect on our business results of operations and financial condition.

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

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

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

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

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

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

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

- timing of market introduction of competitive products;
- safety and efficacy of our product compared to other products;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our products, both in absolute terms and relative to alternative treatments;
- availability of coverage and reimbursement from government and other third-party payors;
- potential product liability claims;
- limitations or warnings contained in a product's regulatory authority-approved labeling; and
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following applicable regulatory authority approval.

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

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, diagnostic tests or medical devices is uncertain, and failure of our pharmaceutical and diagnostic products and procedures using our medical devices 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, diagnostic products, or medical devices. Many medical devices are not directly covered by insurance; instead, the procedure using the device is subject to a coverage determination by the insurer. 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, diagnostic tests, or devices and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective, or less cost-effective than existing or later-introduced products. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our product candidates for insurance coverage and adequate reimbursement. The failure to obtain coverage and adequate or any reimbursement for our product candidates, or health care cost containment initiatives that limit or restrict reimbursement for our product candidates, may reduce any future product revenue. Even though a drug (not administered by a physician) may be approved by the FDA, this does not mean that a Prescription Drug Plan ("PDP"), a private insurer operating under Medicare part D, will list that drug on its formulary or will set a reimbursement level. PDPs are not required to make every FDA-approved drug available on their formularies. If

our drug products are not listed on sufficient number of PDP formularies or if the PDPs' levels of reimbursement are inadequate, the Company's business, results of operations, and financial condition could be materially adversely affected.

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

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

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

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

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

We intend to continue to rely on acquisitions and in-licensing as the source of our products and product candidates for development and commercialization. The success of this strategy depends upon our ability to identify, select, and acquire pharmaceutical and diagnostic products, drug delivery technologies, and medical device product candidates. Proposing, negotiating, and implementing an economically viable product acquisition or license

is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biotechnology and medical device companies, and academic research institutions. Our competitors may have stronger relationships with third parties with whom we are interested in collaborating and/or may have more established histories of developing and commercializing products. Most of our competitors also have substantially greater financial and other resources than us. As a result, our competitors may have a competitive advantage in entering into partnering arrangements with such third parties, as such partnering arrangements are often decided in an auction process in which the highest bidder wins. In addition, even if we find promising product candidates, and generate interest in a partnering or strategic arrangement to acquire such product candidates, we may not be able to acquire rights to additional product candidates or approved products on terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and other non-U.S. regulatory authorities. All product candidates are subject to the risks of failure inherent in pharmaceutical, diagnostic test or medical device product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Even if the product candidates are approved or cleared for marketing, we cannot be sure that they would be capable of economically feasible production or commercial success. If we fail to acquire or develop other product candidates that are capable of economically feasible production and commercial success, our business, results of operations and financial condition and cash flows may be materially adversely affected.

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

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

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

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

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

We currently have no pharmaceutical or diagnostic test marketing, sales or distribution capabilities other than through our Mexican and Chilean subsidiaries for sales in those countries. If our pharmaceutical product candidates are approved, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming. Any failure or delay in the development of any of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our products. With respect to our existing and future pharmaceutical

product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue 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.

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

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

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

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

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

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical, biotechnology, 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, or medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties, including the University of Pennsylvania, the University of Texas Southwestern Medical Center and Academia Sinica.

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 consulting arrangements with TSRI and 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 these arrangements. 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 do not have any rights to any technology or intellectual property that may be developed by TSRI and its employees, including Dr. Kodadek, outside of these arrangements. If TSRI or its employees, including Dr. Kodadek, develops technology or intellectual property that is material to our business and we are unable to license such technology or intellectual property on favorable terms, if at all, or such technology or intellectual property is licensed to or acquired by other parties, our business and competitive position may be harmed.

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

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

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

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

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

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

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, the University of Pennsylvania, UT Southwestern, and Academia Sinica, 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 who we license patents are required to issue compulsory licenses, it could materially adversely affect our business, results of operation and financial condition.

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

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

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.

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.

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

In the United States, there have been a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products 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 payer 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 pay programs could negatively affect our business.

In addition, there are efforts underway to attempt the passage of significant healthcare reform legislation. Any such health care reform may have an adverse effect on our business through decreasing funds available to our customers and to us. Limitations or restrictions on Medicare and Medicaid payments to our customers could adversely impact the liquidity of our customers, resulting in their inability to pay us, or to timely pay us, for our products and services. This inability could have a material adverse effect on our financial position, results of operations and liquidity.

We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

RISKS RELATED TO INTERNATIONAL OPERATIONS

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

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

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

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

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 United States, are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government tenders that are held annually in many cases, nationalization, increasingly complex labor environments, expropriation and other governmental actions, changes in taxation, including legislative changes in U.S. and international taxation of income

earned outside of the United States, importation limitations, export control restrictions, violations of U.S. or local laws, including the U.S. Foreign Corrupt Practices Act, 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

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;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;
- exposure to unforeseen liabilities of acquired companies;
- potential costly and time-consuming litigation, including stockholder lawsuits;
- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our common stock, or which may have a dilutive effect on our stockholders;
- the need to incur additional debt or use cash; and
- the requirement to record potentially significant additional future operating costs for the amortization of intangible assets.

As a result of these or other problems and risks, businesses we acquire 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 will be successfully identified and completed or that, if acquisitions are completed, the acquired businesses, 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 is large relative to our size. Failure to manage effectively our growth through acquisitions could adversely affect our growth prospects, business, results of operations, financial condition and cash flows.

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

We have made and anticipate that we may continue to make acquisitions, investments and strategic alliances with complementary businesses, technologies, products and services to expand our business. Our growth plans rely, in part, on the successful completion of future acquisitions. At any particular time, we may need to raise substantial additional capital or to issue additional equity to finance such acquisitions, investments, and strategic alliances.

There is no assurance that we will be able to secure additional funding on acceptable terms, or at all, or obtain the stockholder approvals necessary to issue additional equity to finance such acquisitions, investments, and strategic alliances. If we are unsuccessful in obtaining the financing, our business would be adversely impacted.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

The market price of our common stock may fluctuate significantly.

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

- the announcement of new products or product enhancements by us or our competitors;
- results of our clinical trials and other development efforts;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the biotechnology, pharmaceutical, and medical device industry;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities, including debt;
- sales of stock by our officers, directors or affiliates;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments, or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for biotechnology, pharmaceutical, diagnostic, and medical device companies in particular, has recently experienced extreme price and volume fluctuations. 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 is limited and restrictions imposed by securities regulation and certain lockup agreements may further reduce our trading, making it difficult for our stockholders to sell shares.

Our common stock began trading on the American Stock Exchange, now known as the NYSE Amex, in June 2007. To date, the liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and changes in security analyst and media coverage, if at all.

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

Future sales of our common stock could reduce our stock price.

Some or all of the "restricted" shares of our common stock issued to former stockholders of Froptix and Acuity in connection with the acquisition or held by other of our stockholders may be offered from time to time in the open market pursuant to an effective registration statement, or beginning April 2, 2008, pursuant to Rule 144. In addition, as described herein, a substantial number of our shares of common stock were subject to lockup agreements which expired on March 27, 2009. We have also issued or agreed to issue a substantial number of securities in private placement transactions with two year lockup restrictions expiring 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 expires in September 2012. Sales of a substantial number of shares of our common stock in the public market pursuant to Rule 144 or after the lockup agreements lapse, or the perception that such sales could occur, could adversely affect the price of our common stock.

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

As of March 8, 2010, 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 49% of the Company's common stock as of March 8, 2010. As a result, Dr. Frost acting alone or 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.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm on the effectiveness of internal control over financial reporting as of December 31, 2010. We are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal control that, or that are reasonably likely to, materially affect internal control over financial reporting. A "material weakness" is a significant deficiency or combination of significant deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. In connection with our November 2010 restatement of our previously issued consolidated financial statements as of and for the three and nine months ended September 30, 2009, and as of and for the year ended December 31, 2009, we determined that a deficiency in controls relating to the accounting for a beneficial conversion feature on, and the classification of, convertible preferred stock existed as of the previous assessment date and further concluded that such a deficiency represented a material weakness as of December 31, 2009. As a result, we concluded that our internal control over financial reporting was not effective as of December 31, 2009. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. 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. We can provide no assurance that we will at all times in the future be able to report that our internal control is effective.

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, new regulations promulgated by the Securities and Exchange Commission and rules promulgated by the NYSE Amex, the other national securities exchanges and the NASDAQ. These new or changed laws, regulations, and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance

matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations, and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, Chief Executive Officer, Chief Financial Officer, and Principal Accounting Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed, which could materially adversely affect our business, results of operations and financial condition.

The conversion of shares of our preferred stock or exercise of warrants we have issued may result in dilution to the holders of our common stock and cause the price of our common stock to decline.

As of December 31, 2010, we had 897,438 outstanding shares of Series A Preferred Stock and 1,209,677 outstanding shares of Series D Preferred Stock, which were convertible as of such date into 897,438 and 12,096,770 shares of our common stock, respectively. In addition, as of December 31, 2010, we had outstanding warrants to purchase 29,194,162 shares of our common stock. The conversion of outstanding shares of our Series A Preferred Stock and Series D Preferred Stock and the exercise of warrants 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 conversion of our preferred stock or the exercise of warrants could cause our stock price to decline as well. In addition, our preferred stockholders have dividend priority and liquidation preferences over shares of our common stock. Thus, the rights of the holders of common stock are and will be subject to, and may be adversely affected by, the rights of the holders of our preferred stock. As of December 31, 2010, our Series A Preferred Stock and Series D Preferred Stock had liquidation preferences of $2.5 million and $33.0 million, respectively.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal corporate office is located at 4400 Biscayne Blvd, Miami, Florida. We lease this space from Frost Real Estate Holdings, LLC, an entity which is controlled by Dr. Phillip Frost, our Chairman of the Board and Chief Executive Officer. Pursuant to the lease agreement with Frost Real Estate Holdings, we lease approximately 8,300 square feet, which encompasses space for our corporate offices, administrative services, project management and pharmacology. The lease is for a five-year term and currently requires annual rent of approximately $0.3 million which amount increases by approximately 4.5% per year.

We lease approximately 10,000 square feet of space in Hialeah, Florida from an entity controlled by Dr. Phillip Frost, our Chairman and Chief Executive Officer, and Dr. Jane Hsiao, our Vice Chairman and Chief Technical Officer, to house manufacturing and service operations for our ophthalmic instrumentation business. We also lease facilities at Scripps Research Institute Jupiter, which is where our molecular diagnostics research and development is based. We maintain a research and development branch office in the United Kingdom at the University of Kent. OPKO Chile, our Chilean subsidiary, leases office space in Santiago, Chile, and through our Mexican subsidiaries, we own a manufacturing facility, laboratory and office space consisting of approximately 38,000 square feet.

ITEM 3. LEGAL PROCEEDINGS.

None.

ITEM 4. (REMOVED AND RESERVED).

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 NYSE Amex (formerly the American Stock Exchange) under the symbol "OPK". 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 Amex:

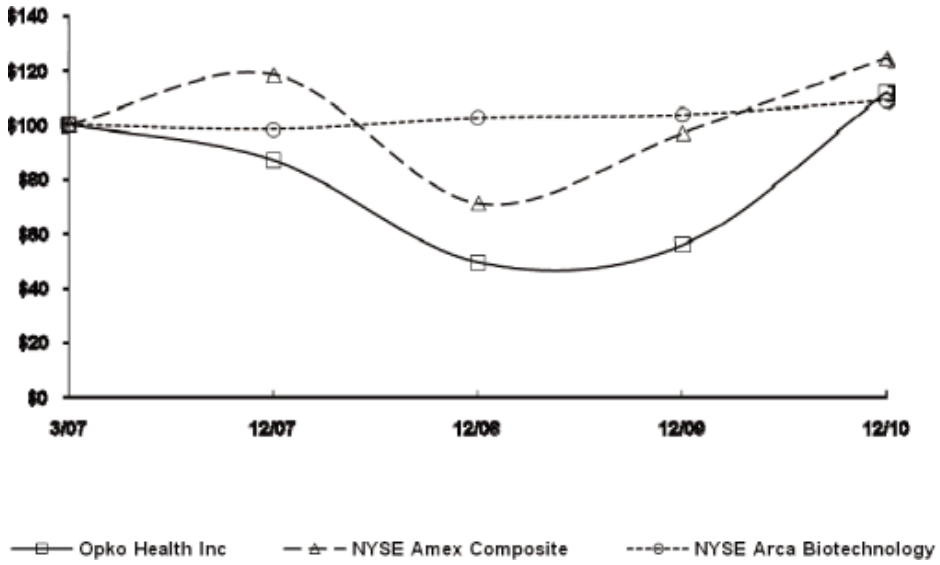
	High	Low
2010		
First Quarter	$2.07	$1.63
Second Quarter	2.55	1.87
Third Quarter	2.60	2.07
Fourth Quarter	3.88	2.23
2009		
First Quarter	$1.70	$0.60
Second Quarter	1.87	0.98
Third Quarter	2.76	1.55
Fourth Quarter	2.43	1.55

As of March 8, 2011, there were approximately 332 holders of record of our common stock.

The Company has not declared or paid any cash dividends on its common stock. No cash dividends have been previously paid on our common stock and none are anticipated in fiscal 2011. The Company also has shares of Series A and Series D Preferred Stock Outstanding that have preferential dividend rights over any dividend payments to holders of common stock.

Stock Performance Graph

COMPARISON OF 45 MONTH CUMULATIVE TOTAL RETURN*
Among Opko Health Inc, the NYSE Amex Composite Index
and the NYSE Arca Biotechnology Index



*$100 invested on 3/27/07 in stock or 2/28/07 index, including reinvestment of dividends.

Fiscal year ending December 31.

ITEM 6. SELECTED FINANCIAL DATA.

The following selected historical consolidated statement of operations data for the years ended December 31, 2010, 2009, 2008, and 2007 and for the period from inception (June 23, 2006) through December 31, 2006 and the consolidated balance sheet data as of December 31, 2010, 2009, 2008, 2007, and 2006, 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.

(in thousands, except share and per shares information)	For the years ended December 31, 2010	2009	2008	2007	For the period from inception June 23, 2006 through December 31, 2006
Statement of operations data					
Revenue	$ 36,880	$ 13,147	$ 9,440	$ 847	$ —
Cost of goods sold	20,501	9,567	8,559	808	—
Gross margin	16,379	3,580	881	39	—
Operating expenses:					
Selling, general and administrative	22,121	13,518	14,790	12,466	375
Research and development	7,908	12,881	21,562	10,850	508
Write-off of acquired in-process research and development	—	2,000	1,398	243,761	—
Other operating expenses; primarily amortization of intangible assets	3,579	3,201	1,694	150	—
Total operating expenses	33,608	31,600	39,444	267,227	883
Operating loss	(17,229)	(28,020)	(38,563)	(267,188)	(883)
Other (expense) income, net	(842)	(2,034)	(1,354)	(671)	6
Loss before income taxes and investment losses	(18,071)	(30,054)	(39,917)	(267,859)	(877)
Income tax (expense) benefit	(141)	294	83	83	—
Net loss before investment losses	(18,212)	(29,760)	(39,834)	(267,776)	(877)
Loss from investments in investees	(714)	(353)	—	(629)	—
Net loss	(18,926)	(30,113)	(39,834)	(268,405)	(877)
Preferred stock dividend	(2,624)	(4,718)	(217)	(217)	—
Net loss attributable to common shareholders	$ (21,550)	$ (34,831)	$ (40,051)	$ (268,622)	$ (877)
Loss per share, basic and diluted	$ (0.08)	$ (0.15)	$ (0.21)	$ (2.09)	$ (0.01)
Weighted average number of common shares outstanding — basic and diluted	255,095,586	233,191,617	187,713,041	128,772,080	58,733,556
Balance sheet data					
Total assets	$ 77,846	$ 87,430	$ 21,764	$ 39,568	$ 116
Working capital	$ 26,473	$ 50,795	$ 5,754	$ 19,489	$ 21
Long-term line of credit with related party, notes payable, and capital lease obligations, net	$ —	$ 11,932	$ 11,867	$ 14,235	$ —
Series D Preferred Stock	$ 26,128	$ 26,128	$ —	$ —	$ —
Stockholders' equity	$ 23,052	$ 31,599	$ 359	$ 16,784	$ 21

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 pharmaceutical 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. Our current focus is on conditions with major unmet medical needs including neurological disorders, infectious diseases, oncology and ophthalmologic diseases. We are developing a range of solutions to diagnose, treat and prevent these conditions, including molecular diagnostics tests, proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets. We have already established emerging markets pharmaceutical platforms in Chile and Mexico, which are delivering revenue and which we expect to deliver cash flow and facilitate future market entry for our products currently in development. We also actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses.

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

RECENT DEVELOPMENTS

On March 14, 2011, we issued 27,000,000 shares of our Common Stock in an underwritten public offering at a price of $3.75 per share. The net proceeds received in connection with the offering were approximately $96.4 million after deducting the underwriters' discounts and commissions and other estimated offering expenses. The offering closed on March 14, 2011. We also granted the underwriters a 30-day option to purchase up to an additional 4,050,000 shares of our Common Stock to cover overallotments, if any. On March 15, 2011, representatives for the underwriters provided us notice that the underwriters exercised a portion of their 4,050,000 share over-allotment option for 2,397,029 additional shares of our Common Stock.

On January 31, 2011, we acquired all of the outstanding stock of CURNA, Inc. ("CURNA"), a privately held therapeutics company, in exchange for $10 million in cash. CURNA is 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.

RESULTS OF OPERATIONS

For The Years Ended December 31, 2010 and December 31, 2009

The results of operations for the year ended December 31, 2010 and 2009 include the post acquisition operations for OPKO Chile (formerly known as Pharma Genexx, S.A.), a privately owned Chilean company engaged in the marketing, sale, and distribution of pharmaceutical products, devices, and over-the-counter products for government, private, and institutional markets in Chile, which we acquired on October 7, 2009. As a result, our operating results for periods prior to October 7, 2009 do not include any results related to OPKO Chile. Further, on February 16, 2010 we acquired Exakta-OPKO (formerly known as Pharmacos Exakta, S.A. de C.V.), a privately owned Mexican company engaged in the manufacture, marketing sale and distribution of pharmaceutical and over-the-counter products for, private and institutional markets in Mexico. As such, our operating results for periods prior to February 16, 2010 do not include any results related to Exakta-OPKO.

Revenue. Revenue for the year ended December 31, 2010 was $36.9 million compared to $13.1 million for the year ended December 31, 2009. Revenue from our pharmaceutical business for 2010 increased as compared to 2009 as a result of the revenue generated by our pharmaceutical business through OPKO Chile and Exakta-OPKO and license revenue generated by the outlicense of our NK-1 development program. In December 2010, we outlicensed our NK-1 development program to TESARO, Inc. ("TESARO") for an upfront cash payment of $6.0 million, future milestone payments of up to $115.0 million, 1.5 million shares of TESARO Series O Preferred Stock ("TESARO Preferred Stock"), as well as royalty payments on future sales. We recorded the TESARO Preferred Stock at fair value and recognized $6.7 million as license revenue, including $6.0 million in cash and $0.7 million of TESARO Preferred Stock.

Gross margin. Gross margin for the year ended December 31, 2010 was $16.4 million compared to $3.6 million for the year ended December 31, 2009. Gross margin improved during 2010 from gross margin in 2009 as a result of our license revenue of $6.7 million related to TESARO, with no associated cost of revenue, and increased gross margin generated by our pharmaceutical business through OPKO Chile and Exakta-OPKO, partially offset by decreased margins from our instrumentation business.

Selling, general and administrative expense. Selling, general and administrative expense in the year ended December 31, 2010 was $22.1 million as compared to $13.5 million during the year ended December 31, 2009. Selling, general and administrative expense increased primarily as a result of expenses related to our pharmaceutical businesses in Chile and Mexico, as well as increased personnel costs, including equity-based compensation, and professional fees. Included in selling, general and administrative expenses were $5.1 million and $3.2 million of equity based compensation expense for the years ended December 31, 2010 and 2009, respectively.

Research and development expense. Research and development expense for the year ended December 31, 2010 was $7.9 million as compared to $12.9 million during the year ended December 31, 2009. Research and development expense decreased during 2010 primarily as a result of the 2009 period including activities related to our Phase III clinical trial for bevasiranib, which was terminated in March 2009. Partially offsetting this decrease were increased activities related to our rolapitant development program prior to its licensure to TESARO in December 2010 and increased activities related to our molecular diagnostics program. In addition, during 2010 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 during 2009 and 2010. Further, we received $0.3 million in research and development credits for certain development programs in Mexico. Included in research and development expense were $1.7 million and $1.3 million of equity based compensation expense for the years ended December 31, 2010 and 2009, respectively.

Write-off of acquired in-process research and development. On October 12, 2009, we entered into an agreement to acquire certain assets from Schering Plough Corporation's neurokinin-1 ("NK-1") development program in an all cash transaction for $2.0 million at closing. We recorded this acquisition as an asset acquisition and recorded the assets at fair value and allocated the entire purchase price to acquired in-process research and development expense and recorded a charge of $2.0 million.

We record expense for in-process research and development projects accounted for as asset acquisitions which have not reached technological feasibility and which have no alternative future use. The NK-1 drug candidates have not reached a stage of technological feasibility and have no alternative future use. We did not have any in-process research and development activities during 2010.

Other operating expenses, principally amortization of intangible assets. Other operating expenses were $3.6 million for the year ended December 31, 2010, compared to $3.2 million for the year ended December 31, 2009. The increase in other operating expenses is a result of increased intangible asset amortization related to our acquisitions of OPKO Chile and Exakta-OPKO. Partially offsetting this increase, the 2009 period includes $1.1 million impairment of goodwill related to our instrumentation business and there was no such impairment in 2010.

Other income and expenses. Other expense was $0.8 million for the year ended December 31, 2010, compared to $2.0 million for the year ended December 31, 2009. Other expenses primarily consist of interest expense incurred on our $12.0 million line of credit with The Frost Group, LLC (the "Frost Group"), a related party, partially offset by interest earned on our cash and cash equivalents. The Frost Group members include the Frost Gamma Investment Trust (the "Gamma Trust") of which Phillip Frost, M.D., our Chairman and CEO, is the sole trustee, Jane Hsiao, the Company's Vice Chairman and Chief Technical Officer, Steven D. Rubin, the Company's Executive Vice President — Administration and a director, and Rao Uppaluri, the Company's Chief Financial Officer.

On June 2, 2010, we repaid all amounts outstanding on the line of credit including $12.0 million in principal and $4.1 million in interest.

For The Years Ended December 31, 2009 and December 31, 2008

The results of operations for the year ended December 31, 2009 include the post acquisition operations for OPKO Chile, which we acquired on October 7, 2009. As a result, our operating results for periods prior to October 7, 2009 do not include OPKO Chile activity.

Revenue. Revenue for the year ended December 31, 2009 was $13.1 million compared to $9.4 million for the year ended December 31, 2008. Revenue for 2009 increased as a result of the revenue generated by OPKO Chile after our acquisition on October 7, 2009. Partially offsetting the revenue from OPKO Chile was decreased revenue from our instrumentation business in international markets. Revenue for 2008 primarily consisted of revenue from our instrumentation business in international markets.

Gross margin. Gross margin for the year ended December 31, 2009 was $3.6 million compared to $0.9 million for the year ended December 31, 2008. Gross margin improved during 2009 primarily as a result of improved gross margin from our instrumentation business and post acquisition gross margin generated by our pharmaceutical business in Chile. Gross margin during 2008 was negatively impacted while we made a number of changes to our instrumentation manufacturing process in an effort to lower the cost of goods sold and increase gross margins. Those improvements included changing suppliers of components for our OCT SLO products and assembling a number of components in-house rather than outsourcing those activities. We realized the benefits of those changes to our manufacturing processes as increased gross margin during the year ended December 31, 2009.

Selling, general and administrative expense. Selling, general and administrative expense in the year ended December 31, 2009 was $13.5 million as compared to $14.8 million during the year ended December 31, 2008. Selling, general and administrative expense decreased primarily as a result of decreased personnel costs, including equity-based compensation, and sales commissions to certain international distributors in our instrumentation business, partially offset by increased professional fees. Included in selling, general and administrative expenses were $3.2 million and $4.2 million of equity based compensation expense for the years ended December 31, 2009 and 2008, respectively

Research and development expense. Research and development expense for the year ended December 31, 2009 was $12.9 million as compared to $21.6 million during the year ended December 31, 2008. The decrease in research and development expense was primarily related to the termination of the Phase III clinical trial of bevasiranib and related reduced personnel costs. Research and development expense for the year ended December 31, 2009 consisted primarily of expenses related to the Phase III clinical trial of bevasiranib through March 6, 2009 and the related costs of analyzing the data generated by the trial. Research and development expense for the year ended December 31, 2008 primarily consisted of expenses related to the Phase III clinical trial of bevasiranib. Included in research and development expense were $1.3 million and $2.5 million of equity based compensation expense for the years ended December 31, 2009 and 2008, respectively.

Write-off of acquired in-process research and development. On October 12, 2009, we entered into an agreement to acquire certain assets from Schering Plough Corporation's neurokinin-1 ("NK-1") development program, of which, rolapitant was our lead pharmaceutical product candidate, in an all cash transaction for $2.0 million at closing. We recorded this acquisition as an asset acquisition and recorded the assets at fair value and allocated the entire purchase price to acquired in-process research and development expense and recorded a charge of $2.0 million. On May 6, 2008, we acquired Vidus Ocular, Inc. in a stock for stock transaction. We recorded Vidus' assets and liabilities at fair value, and as a result, we recorded acquired in-process research and development expense and recorded a charge of $1.4 million. We valued our common stock issued to Vidus shareholders at the average closing price of the common stock on the date of the transaction and two days prior to the transaction.

We record expense for in-process research and development projects accounted for as asset acquisitions which have not reached technological feasibility and which have no alternative future use. The NK-1 drug candidates have not reached a stage of technological feasibility and have no alternative future use. At the time of our acquisition of Vidus, the accounting for business combinations and asset acquisitions were the same and Vidus' projects had not reached a stage of technological feasibility and had no alternative future use. Effective January 1, 2009, in-process research and development projects acquired in business combinations are capitalized.

Other operating expenses, principally amortization of intangible assets. Other operating expenses were $3.2 million for the year ended December 31, 2009, compared to $1.7 million for the year ended December 31, 2008. The increase is primarily the result of the $1.1 million impairment of goodwill related to our instrumentation business. In addition, the increase reflects the amortization expense related to the intangible assets acquired as part of our acquisition of Pharma Genexx.

Other income and expenses. Other expense was $2.0 million for the year ended December 31, 2009, compared to $1.4 million, net of $0.3 million of interest income for the year ended December 31, 2008. Other expenses primarily consist of interest expense incurred on our $12.0 million line of credit, partially offset by interest earned on our cash and cash equivalents.

Liquidity And Capital Resources

At December 31, 2010, we had cash and cash equivalents of approximately $18.0 million compared to $42.7 million on December 31, 2009. Cash used in operations during 2010 primarily reflects expenses related to selling, general and administrative activities related to our corporate and instrumentation operations, as well as our operations in Chile and Mexico. Partially offsetting this, we received $6.0 million in cash from our outlicense to TESARO of our NK-1 development program. 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 private placement of stock and credit facilities available to us.

On March 14, 2011, we issued 27,000,000 shares of our Common Stock in an underwritten public offering at a price of $3.75 per share. The net proceeds received in connection with the offering were approximately $96.4 million after deducting the underwriters' discounts and commissions and other estimated offering expenses. We also granted the underwriters a 30-day option to purchase up to an additional 4,050,000 shares of our Common Stock to cover overallotments, if any.

On January 31, 2011, we acquired all of the outstanding stock of CURNA, Inc. ("CURNA"), a privately held therapeutics company, in exchange for $10.0 million in cash. CURNA is 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.

In connection with our acquisition of OPKO Chile, we have outstanding lines of credit in the aggregate amount of $18.9 million with seven financial institutions in Chile, of which, $4.2 million is unused. The average interest rate on these lines of credit is approximately 6%. 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, 2010 was $14.8 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that this or other funding sources will be available to us on acceptable terms, or at all.

We currently have an unutilized $12.0 million line of credit with the Frost Group. On June 2, 2010, we repaid all amounts outstanding on the line of credit including $12.0 million in principal and $4.1 million in interest. The line of credit, which previously expired on January 11, 2011, was renewed on February 22, 2011 on substantially the same terms as in effect at the time of expiration. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at an 11% annual rate, which is due March 31, 2012. The line of credit is collateralized by all of our U.S. based personal property except our intellectual property.

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

We believe the cash and cash equivalents on hand at December 31, 2010, the amounts available to be borrowed under our lines of credit, and proceeds from the issuance of our Common Stock in an underwritten public offering on March 14, 2011, 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.

The following table provides information as of December 31, 2010 with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (in thousands)	2011	2012	2013	2014	2015	After 2015	Total
Open purchase orders	$ 2,792	$ —	$ —	$ —	$ —	$ —	$ 2,792
Operating leases	506	270	—	—	—	—	776
Credit lines	14,690	—	—	—	—	—	14,690
Total	$ 17,988	$ 270	$ —	$ —	$ —	$ —	$18,258

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

Critical Accounting Policies and Estimates

Accounting Estimates. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. Actual results could differ from those estimates.

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

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

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

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. Certain of our products are sold directly to end-users and require that we deliver, install and train the staff at the end-users' facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred. Return policies in certain international markets for our medical device products provide for stringent guidelines in accordance with the terms

of contractual agreements with customers. Our estimates for sales returns are based upon the historical patterns of products returned matched against the sales from which they originated, and management's evaluation of specific factors that may increase the risk of product returns. We analyze accounts 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, 2010 and December 31, 2009 was $1.2 million and $0.4 million, respectively.

Recent accounting pronouncements. In December 2010, the FASB issued an amendment to the disclosure of supplementary pro forma information for business combinations. The amendment specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The amendment also expands the supplemental pro forma disclosures under current accounting guidance to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. Early adoption is permitted. The adoption of this amendment is not expected to have a material impact on our financial statement disclosures.

In December 2010, the FASB issued an amendment to the accounting for goodwill impairment tests. The amendment modifies Step 1 of the impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. The qualitative factors are consistent with the existing guidance. The amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Early adoption is not permitted. The adoption of this amendment is not expected to have a material impact on our results of operations or financial condition.

In December 2010, the FASB issued an amendment to the accounting for annual excise taxes paid to the federal government by pharmaceutical manufacturers under health care reform. The liability for the fee should be estimated and recorded in full upon the first qualifying branded prescription drug sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. The amendment is effective for calendar years beginning after December 31, 2010, when the fee initially becomes effective. As we currently do not manufacture pharmaceutical products, we do not expect the adoption of this amendment to have a material impact on our results of operations or financial condition.

In March 2010, the FASB reached a consensus to issue an amendment to the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature, and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We have not adopted this guidance early and adoption of this amendment is not expected to have a material impact on our results of operation or financial condition.

In January 2010, the FASB issued an amendment to the accounting for fair value measurements and disclosures. This amendment details additional disclosures on fair value measurements, requires a gross presentation of activities within a Level 3 rollforward, and adds a new requirement to disclose transfers in and out of Level 1 and Level 2 measurements. The new disclosures are required of all entities that are required to provide disclosures about recurring and nonrecurring fair value measurements. This amendment is effective in the first interim or reporting period beginning after December 15, 2009, with an exception for the gross presentation of Level 3 rollforward information, which is required for annual reporting periods beginning after December 15, 2010, and for interim reporting periods within those years. The adoption of this amendment did not have a material impact on our financial statement disclosures.

In October 2009, the FASB issued an amendment to the accounting for multiple-deliverable revenue arrangements. This amendment provides guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration paid should be allocated. As a result of this amendment, entities may be able to separate multiple-deliverable arrangements in more circumstances than under existing accounting guidance. This guidance amends the requirement to establish the fair value of undelivered products and services based on objective evidence and instead provides for separate revenue recognition based upon management's best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The existing guidance previously required that the fair value of the undelivered item reflect the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This amendment will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption and retrospective application is also permitted. We are currently evaluating the potential effect of the adoption of this amendment on our results of operations or financial condition.

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 enter into these contracts with counterparties that we believe to be creditworthy

and do not enter into any leveraged derivative transactions. We had $7.7 million in foreign exchange forward contracts outstanding at December 31, 2010 and $6.3 million at December 31, 2009 primarily to hedge Chilean-based operating cash flows against US dollars. If Chilean Pesos were to strengthen in relation to the US 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, 2010, we had cash and cash equivalents of $18.0 million. The weighted average interest rate related to our cash and cash equivalents for the year ended December 31, 2010 was 0%. As of December 31, 2010, the principal value of our credit lines was $14.7 million, and have a weighted average interest rate of 6%.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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, 2010 and 2009, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida
March 16, 2011

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, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). OPKO Health, Inc. and subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, OPKO Health, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of OPKO Health, Inc. and subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 of OPKO Health, Inc. and subsidiaries, and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida
March 16, 2011

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

	December 31, 2010	December 31, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 18,016	$ 42,658
Accounts receivable, net	13,317	8,767
Inventory, net	19,957	10,520
Prepaid expenses and other current assets	2,782	1,873
Total current assets	54,072	63,818
Property and equipment, net	2,729	593
Intangible assets, net	9,964	12,722
Goodwill	5,856	5,408
Investments, net	5,114	4,447
Other assets	111	442
Total assets	$ 77,846	$ 87,430
LIABILITIES, SERIES D PREFERRED STOCK AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 7,170	$ 4,784
Accrued expenses	5,739	3,918
Current portion of lines of credit and notes payable	14,690	4,321
Total current liabilities	27,599	13,023
Long-term liabilities — interest payable to related party	—	3,409
Other long-term liabilities, principally deferred tax liabilities	1,067	1,339
Line of credit with related party, net of unamortized discount of $0 and $68, respectively	—	11,932
Total liabilities	28,666	29,703
Commitments and contingencies		
Series D Preferred Stock — $0.01 par value, 2,000,000 shares authorized; 1,209,677 and 1,209,677 shares issued and outstanding (liquidation value of $33,013 and $30,613) at December 31, 2010 and 2009, respectively	26,128	26,128
Shareholders' equity		
Series A Preferred Stock — $0.01 par value, 4,000,000 shares authorized; 897,439 and 1,025,934 shares issued and outstanding (liquidation value of $2,468 and $2,564) at December 31, 2010 and 2009, respectively	9	10
Series C Preferred Stock — $0.01 par value, 500,000 shares authorized; No shares issued or outstanding	—	—
Common Stock — $0.01 par value, 500,000,000 shares authorized; 255,412,706 and 253,762,552 shares issued and outstanding at December 31, 2010 and 2009, respectively	2,554	2,538
Treasury stock (45,154 shares at December 31, 2010 and 2009)	(61)	(61)
Additional paid-in capital	376,008	367,028
Accumulated other comprehensive income	2,921	1,313
Accumulated deficit	(358,379)	(339,229)
Total shareholders' equity	23,052	31,599
Total liabilities, Series D Preferred Stock and shareholders' equity	$ 77,846	$ 87,430

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

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

	For the years ended December 31,		
	2010	2009	2008
Revenue			
Products	$ 30,149	$ 13,147	$ 9,440
License	6,731	—	—
Total revenue	36,880	13,147	9,440
Cost of goods sold, excluding amortization of intangible assets	20,501	9,567	8,559
Gross margin, excluding amortization of intangible assets	16,379	3,580	881
Operating expenses			
Selling, general and administrative	22,121	13,518	14,790
Research and development	7,908	12,881	21,562
Write-off of acquired in-process research and development	—	2,000	1,398
Other operating expenses, principally amortization of intangible assets	3,579	3,201	1,694
Total operating expenses	33,608	31,600	39,444
Operating loss	(17,229)	(28,020)	(38,563)
Other expense, net	(842)	(2,034)	(1,354)
Loss before income taxes and investment losses	(18,071)	(30,054)	(39,917)
Income tax (expense) benefit	(141)	294	83
Loss before investment losses	(18,212)	(29,760)	(39,834)
Loss from investments in investees	(714)	(353)	—
Net loss	(18,926)	(30,113)	(39,834)
Preferred stock dividend	(2,624)	(4,718)	(217)
Net loss attributable to common shareholders	$ (21,550)	$ (34,831)	$ (40,051)
Loss per share, basic and diluted	$ (0.08)	$ (0.15)	$ (0.21)
Weighted average number of common shares outstanding, basic and diluted	255,095,586	233,191,617	187,713,041

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

OPKO Health, Inc. and Subsidiaries
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands, except share data)
For the years ended December 31, 2008, 2009 and 2010

	Series A Preferred Stock		Series C Preferred Stock		Common Stock		Treasury		Additional Paid-In Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2007	954,799	$ 10	—	$ —	178,344,608	$1,783	—	—	$284,273	$ —	$(269,282)	$ 16,784
Equity-based compensation expense	—	—	—	—	—	—	—	—	6,730	—	—	6,730
Issuance of equity securities to acquire Vidus Ocular, Inc. at $1.65 per share	—	—	—	—	658,080	7	—	—	1,312	—	—	1,319
Correction of equity securities to Acuity	—	—	—	—	57,408	1	—	—	(1)	—	—	—
Exercise of common stock options	—	—	—	—	5,187,149	52	—	—	154	—	—	206
Exercise of common warrants	—	—	—	—	1,171,899	12	—	—	165	—	—	177
Issuance of common stock in private placement to related party at 1.11	—	—	—	—	13,513,514	135	—	—	14,865	—	—	15,000
Series A preferred stock dividend	86,678	1	—	—	—	—	—	—	—	—	—	1
Conversion of Series A preferred stock	(87,721)	(1)	—	—	87,721	1	—	—	—	—	—	—
Other disposition of assets for stock	—	—	—	—	—	—	(18,000)	(24)	—	—	—	(24)
Net loss for the year ended December 31, 2008	—	—	—	—	—	—	—	—	—	—	(39,834)	(39,834)
Balance at December 31, 2008	953,756	10	—	—	199,020,379	1,991	(18,000)	(24)	307,498	—	(309,116)	359
Equity-based compensation expense	—	—	—	—	—	—	—	—	4,498	—	—	4,498
Exercise of common stock options	—	—	—	—	2,984,945	30	—	—	664	—	—	694
Exercise of common warrants	—	—	—	—	706,164	7	—	—	17	—	—	24
Issuance of common stock in private placement with related parties at $1.00 per share	—	—	—	—	20,000,000	200	—	—	19,800	—	—	20,000
Issuance of common stock in private placement, including related parties, at $1.00 per share	—	—	—	—	31,000,000	310	—	—	30,680	—	—	30,990
Relative fair value of warrants issued In connection with issuance of 8% Series D												

Series A preferred stock dividend	—	—	—	—	—	—	—	—	3,872	—	—	3,872
	93,242	1	—	—	—	—	—	—	(1)	—	—	—
Conversion of Series A preferred stock	(21,064)	(1)	—	—	21,064	—	—	—	—	—	—	(1)
Restricted stock grant	—	—	—	—	30,000	—	—	—	—	—	—	—
Purchase of shares at $3.55	—	—	—	—	—	—	(27,154)	(37)	—	—	—	(37)
Net loss for the year ended December 31, 2009	—	—	—	—	—	—	—	—	—	—	(30,113)	(30,113)
Cumulative translation adjustment net	—	—	—	—	—	—	—	—	—	1,313	—	1,313
Other comprehensive loss												(28,800)
Balance at December 31, 2009	1,025,934	10	—	—	253,762,552	2,538	(45,154)	(61)	367,028	1,313	(339,229)	31,599

	Series A Preferred Stock		Series C Preferred Stock		Common Stock		Treasury		Additional Paid-In Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars	Shares	Dollars	Shares	Dollars				
Equity-based compensation expense	—	—	—	—	—	—	—	—	6,922	—	—	6,922
Exercise of common stock options	—	—	—	—	150,231	2	—	—	72	—	—	74
Series A preferred stock dividend	—	—	—	—	—	—	—	—	—	—	(224)	(224)
Conversion of Series A preferred stock	(128,495)	(1)	—	—	128,495	1	—	—	—	—	—	—
Issuance of common stock to acquire Pharmacos Exakta at $1.46 per share	—	—	—	—	1,371,428	13	—	—	1,986	—	—	1,999
Net loss for the year ended December 31, 2010	—	—	—	—	—	—	—	—	—	—	(18,926)	(18,926)
Cumulative translation adjustment net	—	—	—	—	—	—	—	—	—	1,608	—	1,608
Other comprehensive loss												(17,318)
Balance at December 31, 2010	897,439	$ 9	—	$ —	255,412,706	$2,554	(45,154)	$ (61)	$376,008	$ 2,921	$(358,379)	$ 23,052

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

OPKO Health, Inc. and Subsidiaries
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31,		
	2010	2009	2008
Cash flows from operating activities:			
Net loss	$(18,926)	$(30,113)	$(39,834)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,870	2,357	1,823
Impairment of goodwill	—	1,097	—
Write-off of acquired in-process research and development	—	2,000	1,398
Accretion of debt discount related to notes payable	66	123	190
Losses from investments in investees	714	353	—
Equity based compensation — employees and non-employees	6,922	4,498	6,730
Provision for bad debts	446	73	204
Provision for inventory obsolescence	64	279	255
Foreign exchange	(382)	122	—
Loss on disposal of assets	—	—	148
License of product for equity	(731)	—	—
Changes in:			
Accounts receivable	(3,396)	(1,271)	590
Inventory	(7,589)	(928)	(2,104)
Prepaid expenses and other current assets	894	431	25
Other assets	420	(276)	—
Accounts payable	1,756	(1,019)	(1,225)
Accrued expenses	(3,222)	(1,062)	2,506
Net cash used in operating activities	(19,094)	(23,336)	(29,294)
Cash flows from investing activities:			
Investments in investees	(650)	(4,800)	—
Acquisition of businesses, net of cash	(1,323)	(15,632)	48
Acquisition of rolapitant	—	(2,000)	—
Purchase of marketable securities	(14,997)	(9,997)	—
Maturities of marketable securities	14,997	9,997	—
Capital expenditures	(807)	(172)	(378)
Net cash used in investing activities	(2,780)	(22,604)	(330)
Cash flows from financing activities:			
Issuance of common stock for cash to related party	—	30,990	15,000
Issuance of common stock	—	20,000	—
Issuance of Series D preferred stock and warrants, including related parties	—	30,000	—
Repayments of line of credit with related party	(12,000)	—	—
Proceeds from bridge loan with related party	—	3,000	—
Repayment of bridge loan with related party	—	(3,000)	—
Insurance financing and borrowings on lines of credit	15,424	529	371
Proceeds from the exercise of stock options and warrants	74	718	383
Repayments of notes payable and capital lease obligations	(6,266)	(317)	(2,825)
Net cash (used in) provided by financing activities	(2,768)	81,920	12,929
Net change in cash and cash equivalents	(24,642)	35,980	(16,695)
Cash and cash equivalents at beginning of year	42,658	6,678	23,373
Cash and cash equivalents at end of year	$ 18,016	$ 42,658	$ 6,678

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

OPKO Health, Inc. and Subsidiaries
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Business and Organization

We are a multi-national pharmaceutical 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. Our current focus is on conditions with major unmet medical needs including neurological disorders, infectious diseases, oncology and ophthalmologic diseases. We are developing a range of solutions to diagnose, treat and prevent these conditions, including molecular diagnostics tests, proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets. We have already established emerging markets pharmaceutical platforms in Chile and Mexico, which are delivering revenue and which we expect to deliver cash flow and facilitate future market entry for our products currently in development. We also actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses. We are a Delaware corporation, headquartered in Miami, Florida.

Note 2 Acquisitions, Investments, and Licenses

Rolapitant license

In December 2010, we entered into a license agreement (the "TESARO License") with TESARO, Inc. ("TESARO") granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Under the terms of the TESARO License, we are eligible for payments of up to $121.0 million, including an up-front payment of $6.0 million, which has been received, and additional payments based upon achievement of specified regulatory and commercialization milestones. In addition, TESARO will pay us double digit tiered royalties on sales of licensed product. We will share future profits from the commercialization of licensed products in Japan with TESARO and we will have an option to market the products in Latin America. In connection with the TESARO License, we also acquired a 10% equity position in TESARO. We recorded the 10% equity position at $0.7 million, the estimated fair value based on a discounted cash flow model.

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

We acquired rolapitant on October 12, 2009 from Schering-Plough Corporation ("Schering"). We entered into an asset purchase agreement (the "Schering Agreement") with Schering to acquire rolapitant and other assets relating to Schering's neurokinin-1 ("NK-1") receptor antagonist program. Under the terms of the Schering Agreement, we paid Schering $2.0 million in cash upon closing and agreed to pay up to an additional $27.0 million upon certain development milestones. Rolapitant, the lead product in the NK-1 program, successfully completed Phase II clinical testing for prevention of nausea and vomiting related to cancer chemotherapy and surgery, and other indications. Development of rolapitant and the other assets had been stopped at the time of our acquisition and there were no ongoing clinical trials. None of the assets acquired have alternative future uses, nor have they reached a stage of technological feasibility, as such, we recorded $2.0 million as in-process research and development expense during the year ended December 31, 2009.

Latin America acquisitions

In February 2010, we acquired Exakta-OPKO (previously known as Pharmacos Exakta S.A. de C.V.), a privately-owned Mexican company, engaged in the manufacture, marketing and distribution of ophthalmic and other pharmaceutical products for government and private markets since 1957. Pursuant to a purchase agreement we acquired all of the outstanding stock of Exakta-OPKO and real property owned by an affiliate of Exakta-OPKO for a total aggregate purchase price of $3.5 million, of which an aggregate of $1.5 million was paid in cash and $2.0 million was paid in shares of our Common Stock, par value $.01. In September 2010, we reduced the consideration paid by $0.1 million in working capital adjustments per the purchase agreement. The number of shares to be issued was determined by the average closing price of our Common Stock as reported on the NYSE Amex for the ten trading days ending on February 12, 2010. A total of 1,371,428 shares of our Common Stock were issued in the

transaction which were valued at $2.0 million due to trading restrictions. A portion of the proceeds will remain in escrow for a period of time to satisfy indemnification claims.

In October 2009, we entered into a definitive agreement to acquire OPKO Chile (previously known as Pharma Genexx, S.A.), a privately-owned Chilean company engaged in the representation, importation, commercialization and distribution of pharmaceutical products, over-the-counter products and medical devices for government, private and institutional markets in Chile. Pursuant to a stock purchase agreement with OPKO Chile and its shareholders, Farmacias Ahumada S.A., FASA Chile S.A., and Laboratorios Volta S.A., we acquired all of the outstanding stock of OPKO Chile in exchange for $16 million in cash. A portion of the proceeds will remain in escrow for a period of time to satisfy indemnification claims. The transaction closed on October 7, 2009.

The following table summarizes the estimated fair value of the net assets acquired and liabilities assumed in the acquisition of OPKO Chile at the date of acquisition:

(in thousands)	
Current assets (including cash of $368)	$12,208
Intangible assets	7,826
Goodwill	4,983
Other assets	20
Accounts payable and accrued expenses	(9,037)
Total purchase price	$16,000

Investments

In November 2010, we made an investment in Fabrus, LLC, a privately held early stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities. Fabrus is using its proprietary antibody screening and engineering approach to discover promising lead compounds against several important oncology targets. In exchange for the investment, we acquired approximately 13% of Fabrus' outstanding membership interests on a fully diluted basis. Our investment was part of a $2.1 million financing for Fabrus and included other related parties. Refer to Note 11.

Effective September 21, 2009, we entered into an agreement pursuant to which we invested $2.5 million in cash in Cocrystal Discovery, Inc., a privately held biopharmaceutical company ("Cocrystal") in exchange for 1,701,723 shares of Cocrystal's Convertible Series A Preferred Stock or approximately 16%. Cocrystal is focused on the discovery and development of novel antiviral drugs using a combination of protein structure-based approaches. Refer to Note 11.

On June 10, 2009, we entered into a stock purchase agreement with Sorrento Therapeutics, Inc. ("Sorrento"), a publicly held company with a technology for generating fully human monoclonal antibodies, pursuant to which we invested $2.3 million in Sorrento. OPKO owns approximately 53,113,732 shares of Sorrento Common Stock, or approximately 21% of Sorrento's total outstanding common stock at December 31, 2010. The closing stock price for Sorrento's common stock, a thinly traded stock, as quoted on the over-the-counter markets was $0.60 per share on December 31, 2010. Refer to Note 11.

The following table reflects our maximum exposure to each of our investments:

Investee name	(in thousands)	Accounting method
Sorrento	$ 2,300	Equity method
Cocrystal	2,500	VIE, equity method
Fabrus	650	VIE, equity method
TESARO	731	VIE, cost method
Less accumulated losses in investees	(1,067)	
Total	$ 5,114	

Other acquisition

On May 6, 2008, we completed the acquisition of Vidus Ocular, Inc. ("Vidus"), a privately-held company that is developing Aquashunt™, a shunt to be used in the treatment of glaucoma. Pursuant to a Securities Purchase Agreement with Vidus, each of its stockholders, and the holders of convertible promissory notes issued by Vidus, we acquired all of the outstanding stock and convertible debt of Vidus in exchange for (i) the issuance and delivery at closing of 658,080 shares of our common stock (the "Closing Shares"); (ii) the issuance of 488,420 shares of our common stock to be held in escrow pending the occurrence of certain development milestones (the "Milestone Shares"); and (iii) the issuance of options to acquire 200,000 shares of our common stock. Additionally, in the event that the stock price for our common stock at the time of receipt of approval or clearance by the U.S. Food & Drug Administration of a pre-market notification 510(k) relating to the Aquashunt is not at or above a specified price, we will be obligated to issue an additional 413,850 shares of our common stock. A portion of the Closing Shares and the Milestone Shares remained in escrow for a period of one year to satisfy indemnification claims.

We accounted for the Vidus acquisition as an asset acquisition. We valued the common stock issued to Vidus' stockholders at the average closing price on the date of the acquisition and the two days prior to the transaction, or

$1.65 per share. In addition, we valued the options to acquire our common stock that were issued to the founders of Vidus using the Black-Scholes-Merton pricing model and recorded the value of those options as part of the purchase price of Vidus, or $1.17 per common stock option. All other contingent consideration will be valued and added to the purchase price if the milestones occur.

The table below reflects the estimated fair value of the net assets acquired at the date of acquisition:

(in thousands)	
Current assets (cash of $48)	$ 48
In-process research and development	1,398
Accounts payable and accrued expenses	(127)
Total purchase price	$ 1,319

The portion of the purchase price allocated to in-process research and development of $1.4 million was immediately expensed.

Variable interest entities

We have determined that we hold variable interests in three entities ("VIE"), TESARO, Fabrus and CoCrystal. We made this determination as a result of our assessment that they do not have sufficient resources to carry out their principal activities without additional subordinated financial support.

In order to determine the primary beneficiary of Cocrystal and Fabrus, we evaluated our investment as well as our investment combined with a related party group to identify who had the most power to control each entity and who received the largest benefits (absorbed the most losses) from each entity. The related party group when considering our investment in Cocrystal includes OPKO and the Frost Group. As of December 31, 2010 we own approximately 16% of Cocrystal and members of the Frost Group own approximately 42% of Cocrystal's voting stock on an as converted basis, including 39% held by the Gamma Trust. Dr. Frost, Mr. Rubin, and Dr. Hsiao currently serve on the Board of Directors of Cocrystal and represent 50% of its board. The Gamma Trust influenced the design of Cocrystal and can significantly influence the success of Cocrystal through its board representation and voting power. As such, we have determined that the Gamma Trust is the primary beneficiary within the related party group. The related party group when considering our investment in Fabrus includes OPKO and the Gamma Trust, Hsu Gamma Investment, L.P., of which Jane Hsiao is the general partner, and the Richard Lerner Family Trust. Dr.'s Frost, Hsiao and Lerner are all members of our Board of Directors. As of December 31, 2010 we own approximately 13% of Fabrus and Dr.'s Frost, Hsiao and Lerner own 24% of Fabrus' voting stock on an as converted basis, including 16% held by the Gamma Trust. Dr.'s Frost and Hsiao currently serve on the Board of Managers of Fabrus and represent 40% of its board. The Gamma Trust can significantly influence the success of Fabrus through its board representation and voting power. As such, we have determined that the Gamma Trust is the primary beneficiary within the related party group. Because we have the ability to exercise significant influence over Cocrystal's and Fabrus' operations through our related party affiliates, we account for our investments in Cocrystal and Fabrus, under the equity method.

In order to determine the primary beneficiary of TESARO, we evaluated the power and benefits held by its equity holders. On an as converted basis, we hold an equity interest of approximately 9% of TESARO as of December 31, 2010. In addition, we do not hold any seats on the Board of Directors and we do not have any management positions. The largest equity holder owns approximately 49% of TESARO, on an as converted basis and is represented by two members of TESARO's board of directors. As a result of that equity holder having the power to influence TESARO and being entitled to the largest share of the benefits of TESARO, we determined such holder is the primary beneficiary of TESARO. Because we do not have the ability to exercise significant influence over TESARO's operations, we have accounted for TESARO under the cost method of accounting.

We have not provided financial or other support to the variable interest entities other than those associated with our original investments in Cocrystal and Fabrus or those associated with our TESARO License and we are not obligated to provide ongoing financial support to them.

Pro forma disclosures for acquisitions

The following table includes the pro forma results for the years ended December 31, 2009 and 2008 of the combined companies as though the acquisition of OPKO Chile had been completed as of the beginning of each period, respectively.

	For the year ended December 31,	
(in thousands, except per share amounts)	2009	2008
Revenue	$ 25,615	$ 20,365
Net loss	$ (28,443)	$ (39,713)
Basic and diluted loss per share	$ (0.12)	$ (0.21)

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

Note 3 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 United States and with the instructions to Form 10-K and of Regulation S-X. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents. We consider all non-restrictive, highly liquid short-term investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents.

Inventories. Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method.

Property and Equipment. Property and equipment 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 and leasehold improvements — the lesser of their useful life or the lease term. Expenditures for repairs and maintenance are charged to expense as incurred, while betterments reduce accumulated depreciation. Depreciation expense was $0.3 million, $0.2 million, and $0.1 million for the years ended December 31, 2010, 2009, and 2008, 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 OPKO Chile, Exakta-OPKO, and OTI. Refer to Note 2. We do not amortize goodwill, however, we perform an annual impairment test of goodwill during the fourth quarter. During the fourth quarter of

2009, we performed an impairment test and determined the $1.1 million goodwill related to our instrumentation business was impaired and written down to $0. As a result of competition in the U.S. market, the broad global economic conditions, and pricing pressures globally, we determined that goodwill was impaired for the instrumentation reporting unit. The impairment loss was determined by calculating the fair value of the instrumentation reporting unit based on a discounted net present-value calculation. We did not record any impairments during 2010. We evaluate our goodwill for impairment annually and whenever events and changes in circumstances suggest that the carrying amount may not be recoverable.

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 sooner 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 was $3.6 million, $2.1 million, and $1.7 million for the years ended December 31, 2010, 2009, and 2008, respectively. In addition, the 2010 and 2009 years include amortization related to the acquisition of OPKO Chile and the 2010 year end includes amortization related to our acquisition of Exakta-OPKO. Amortization expense for our intangible assets as of December 31, 2010 for the years ending December 31, 2011, 2012, 2013, 2014, and 2015 is expected to be $2.2 million, $1.8 million, $0.8 million, $0.8 million, and $0.8 million, respectively.

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 by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Fair Value Measurements. The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair value due to the short-term maturities of these instruments. Investments are considered available-for-sale as of December 31, 2010 and 2009, and are carried at fair value.

Short-term investments 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 17.

Derivative financial instruments. We record derivative financial instruments (primarily forward purchase contracts) on our balance sheet at their fair value and the changes in the fair value are recognized in income when they occur, the only exception being derivatives that qualify as hedges. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At December 31, 2010, our forward contracts did not meet the documentation requirements to be designated effective hedges. Accordingly, we recognize all changes in fair values of our forward contracts in income.

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

Income Taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the

enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

Loss Per Common Share. Basic and diluted earnings or loss per common share is based on the net loss increased by dividends on preferred stock divided by the weighted average number of common shares outstanding during the period. In the periods in which their effect would be anti-dilutive, no effect has been given to outstanding options, warrants or convertible preferred stock in the diluted computation. The diluted loss per share does not include the weighted average impact of the outstanding options, warrants, and other contingent consideration of 21,213,035, 17,743,032, and 24,022,713 shares for the years ended December 31, 2010, 2009, and 2008 respectively, because their inclusion would have been anti-dilutive. As of December 31, 2010, the holders of our Series A Preferred Stock and Series D Preferred Stock could convert their shares into approximately 987,182 and 13,311,823 shares of our Common Stock, respectively, including accrued dividends.

Revenue Recognition. Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Certain of our products are sold directly to end-users and require that we deliver, install and train the staff at the end-users' facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred.

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 management's estimate of the collectability of accounts receivable. Estimated allowances for sales returns are based upon our history of product returns. The amount of allowance for doubtful accounts at December 31, 2010 and 2009 was $1.2 million and $0.4 million, respectively.

Product Warranties. Product warranties are accrued at the time we record revenue for a product. The costs of warranties are recorded as a component of cost of sales. We estimate warranty costs based on our estimated historical experience and adjust for any known product reliability issues.

Equity-Based Compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the statement of operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow rather than as a reduction of taxes paid in cash flow from operations. Refer to Note 8. 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.

Comprehensive income or loss. Our comprehensive loss for the year ended December 31, 2010 includes net loss for the year and the cumulative translation adjustment, net, for the translation of our OPKO Chile and Exakta-OPKO results. Comprehensive loss for the year ended December 31, 2009 is our net loss for the year and the cumulative translation adjustment, net, for the translation of our OPKO Chile.

Segment reporting. Our chief operating decision-maker ("CODM") is comprised of our executive management with the oversight of our board of directors. Our CODM review our operating results and operating plans and make resource allocation decisions on a company-wide or aggregate basis. Accordingly, we have aggregated our three operating segments, instrumentation, pharmaceutical operating business and our pharmaceutical and device research and development activities into two reporting segments, instrumentation and pharmaceutical.

Recent accounting pronouncements: In December 2010, the FASB issued an amendment to the disclosure of supplementary pro forma information for business combinations. The amendment specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The amendment also expands the supplemental pro forma disclosures under current accounting guidance to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. Early adoption is permitted. The adoption of this amendment is not expected to have a material impact on our financial statement disclosures.

In December 2010, the FASB issued an amendment to the accounting for goodwill impairment tests. The amendment modifies Step 1 of the impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. The qualitative factors are consistent with the existing guidance. The amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Early adoption is not permitted. The adoption of this amendment is not expected to have a material impact on our results of operations or financial condition.

In December 2010, the FASB issued an amendment to the accounting for annual excise taxes paid to the federal government by pharmaceutical manufacturers under health care reform. The liability for the fee should be estimated and recorded in full upon the first qualifying branded prescription drug sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. The amendment is effective for calendar years beginning after December 31, 2010, when the fee initially becomes effective. As we currently do not manufacture pharmaceutical products, we do not expect the adoption of this amendment to have material impact on our results of operations or financial condition.

In March 2010, the FASB reached a consensus to issue an amendment to the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature, and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We have not adopted this guidance early and adoption of this amendment is not expected to have a material impact on our results of operation or financial condition.

In January 2010, the FASB issued an amendment to the accounting for fair value measurements and disclosures. This amendment details additional disclosures on fair value measurements, requires a gross presentation of activities within a Level 3 rollforward, and adds a new requirement to disclose transfers in and out of Level 1 and Level 2 measurements. The new disclosures are required of all entities that are required to provide disclosures about recurring and nonrecurring fair value measurements. This amendment is effective in the first interim or reporting period beginning after December 15, 2009, with an exception for the gross presentation of Level 3 rollforward information, which is required for annual reporting periods beginning after December 15, 2010, and for interim reporting periods within those years. The adoption of this amendment is not expected to have a material impact on our financial statement disclosures.

In October 2009, the FASB issued an amendment to the accounting for multiple-deliverable revenue arrangements. This amendment provides guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration paid should be allocated. As a result of this amendment, entities may be able to separate multiple-deliverable arrangements in more circumstances than under existing accounting guidance. This guidance amends the requirement to establish the fair value of undelivered products and services based on objective evidence and instead provides for separate revenue recognition based upon management’s best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The existing guidance previously required that the fair value of the undelivered item reflect the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This amendment will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption and retrospective application is also permitted. We are currently evaluating the potential effect of the adoption of this amendment on our results of operations or financial condition.

Note 4 Composition of Certain Financial Statement Captions

(in thousands)	December 31, 2010	2009
Accounts receivable, net		
Accounts receivable	$ 14,482	$ 9,118
Less allowance for doubtful accounts	(1,165)	(351)
	$ 13,317	$ 8,767
Inventories, net		
Raw materials (components)	$ 4,868	$ 3,764
Work in-process	889	1,365
Finished products	14,632	5,632
Less inventory reserve	(432)	(241)
	$ 19,957	$10,520
Prepaid expenses and other current assets		
Prepaid supplies and clinical	$ 96	$ 559
Other receivables	675	441
Prepaid insurance	119	162
Taxes recoverable	1,441	414
Other	451	297
	$ 2,782	$ 1,873
Property and equipment, net		
Machinery and equipment	$ 2,406	$ 388
Building	288	—
Land	495	—
Furniture and fixtures	179	207
Software	609	207
Leasehold improvements	109	237
Less accumulated depreciation	(1,357)	(446)
	$ 2,729	$ 593
Intangible assets, net		
Customer relationships	$ 7,719	$ 7,259
Product registrations	4,227	3,829
Technology	4,597	4,597
Tradename	666	578
Covenants not to compete	349	317
Other	7	7
Less accumulated amortization	(7,601)	(3,865)
	$ 9,964	$12,722
Accrued expenses		
Income taxes payable	$ 422	$ 492
Accrued royalties	316	315
Accrued distributor commissions	398	372
Product warranties — medical device products	512	257
Clinical trials	801	163
Customer deposits	321	307
Professional fees	288	223
Employee benefits	304	340
Suppliers	1,240	—
Other	1,137	1,449
	$ 5,739	$ 3,918

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

(in thousands)	Fair value assigned	Weighted average amortization period
Customer relationships	$ 7,797	3 years
Technology	4,597	10 years
Product registrations	3,829	10 years
Covenants not to compete	366	3 years
Tradename	666	3 years
Other	7	Indefinite
Total amortizing intangible assets	17,262	
Goodwill	5,408	Indefinite
Total intangible assets acquired	$ 22,670	

All of the intangible assets and goodwill acquired relate to our acquisitions of OPKO Chile, Exakta-OPKO, and OTI. The weighted average period prior to the next renewal or extension for our product registrations is 2.7 years. We do not anticipate capitalizing the cost of product registration renewals, rather we expect to expense these costs, as incurred. Our goodwill is not tax deductible for income tax purposes in Chile.

The changes to goodwill for the year ended December 31, 2010 is primarily due to a $0.4 million increase resulting from foreign exchange translation of the assets and liabilities of OPKO Chile. The purchase price allocation of the assets acquired in the Exakta-OPKO acquisition are subject to change while contingencies that existed on the acquisition date are resolved.

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

(in thousands)	Beginning balance	Charged to expense	Written-off	Charged to other	Ending balance
2010					
Allowance for doubtful accounts	$ (351)	(446)	—	(368)	$ (1,165)
Inventory reserve	$ (241)	(64)	170	(297)	$ (432)
Tax valuation allowance	$(51,697)	(2,555)	—	—	$(54,252)
2009					
Allowance for doubtful accounts	$ (407)	(73)	129	—	$ (351)
Inventory reserve	$ (255)	(279)	293	—	$ (241)
Tax valuation allowance	$(35,197)	(16,699)	—	199	$(51,697)

Note 5 Debt

We have a $12.0 million line of credit with the Frost Group, a related party. On June 2, 2010 we repaid all amounts outstanding on the line of credit including $12 million in principal and $4.1 million in interest. The line of credit was renewed on February 22, 2011 with a new maturity date of March 31, 2012. We have the ability to draw funds under the line of credit until its expiration in March 2012. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at an 11% annual rate. The line of credit is collateralized by all of our U.S. personal property except our intellectual property.

We have entered into lines of credit agreements with seven financial institutions in Chile in addition to our line of credit with the Frost Group. Those lines of credit are used primarily as a source of working capital for inventory purchases. The following table summarizes the lines of credit:

(in thousands) Lender	Interest rate on borrowings	Maximum borrowings	Amount outstanding at December 31, 2010	2009
The Frost Group LLC	11%	$ 12,000	$ —	$ 12,000
Itau Bank	Libor +2.8%	3,000	1,849	270
Bank of Chile	Libor +2.8%	3,000	3,100	988
BICE Bank	Libor +2.8%	3,300	2,813	1,459
Santander Bank	Libor +2.8%	2,500	1,826	324
Corp Banca	Libor +2.8%	1,050	426	62
BBVA Bank	Libor +2.8%	3,500	3,123	1,218
Scotiabank	Libor +2.8%	2,500	1,553	—
Total		$ 30,850	$ 14,690	$ 16,321

On March 4, 2009, the Gamma Trust, a related party, advanced $3.0 million to us pursuant to a Promissory Note we issued to the Gamma Trust (the "Note"). The entire amount of this advance and all accrued interest thereon was due and payable on the earlier of May 4, 2009, or such earlier date following the closing of the stock purchase transaction with the Gamma Trust discussed in Note 6. The Note bore interest at a rate equal to 11% per annum and could be prepaid in whole or in part without penalty or premium. We repaid the Note and $48 thousand of interest on April 27, 2009.

Note 6 Equity Offerings

Effective September 18, 2009, we entered into a securities purchase agreement (the "Preferred Purchase Agreement") with the private investors (the "Preferred Investors"), pursuant to which the Preferred Investors agreed to purchase an aggregate of 1,209,677 shares (the "Preferred Shares") of our newly-designated 8.0% Series D Cumulative Convertible Preferred Stock, par value $0.01 per share ("Series D Preferred Stock") (Refer to Note 7) at a purchase price of $24.80 per share, together with warrants (the "Warrants") to purchase up to an aggregate of 3,024,196 shares of our common stock, par value $.01 at an exercise price of $2.48 per share (the "Preferred Investment"). Initially, the Series D Preferred Stock was convertible into ten shares of our Common Stock, and the Preferred Shares purchase price was based on the average closing price of our Common Stock as reported on the NYSE Amex for the five days preceding the execution of the Preferred Purchase Agreement. In connection with the Preferred Investment, we issued the Preferred Shares and Warrants and received an aggregate of $30.0 million in cash on September 28, 2009.

We allocated the $30.0 million of proceeds from the Preferred Investment between the Series D Preferred Stock and the Warrants based on their relative fair values as follows:

(in thousands)	
Series D Preferred Stock	$26,128
Warrants Settlements in kind or expired	3,872
Total	$30,000

We allocated the $30 million in proceeds received from the issuance of the Preferred Stock and warrants to those instruments based on their relative fair values, which resulted in a $3.9 million beneficial conversion feature. We recorded the $3.9 million beneficial conversion feature as a further discount to the Series D Preferred Stock and an increase to additional paid-in capital.

The Series D Preferred Stock was immediately convertible into shares of our common stock. As a result, the discount was immediately recognized as a deemed dividend and included in preferred stock dividends in the accompanying consolidated statement of operations. The Series D Preferred Stock contains redemption features that are not solely within our control. As a result, the Series D Preferred Stock is classified outside of permanent equity. The Series D Preferred Stock is recorded at this time at initial fair value and not at its Liquidation Amount as it is not probable that it will be redeemed.

We agreed to issue the Preferred Shares and the Warrants in reliance upon the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Act"). The Preferred Shares issued in the Preferred Investment, including the shares of the Company's Common Stock into which the Preferred Shares and Warrants may be converted, are "restricted securities" as that term is defined by Rule 144 under the Act, subject to a three year contractual lockup, and no registration rights have been granted.

On May 26, 2009, May 29, 2009, and June 1, 2009, we entered into stock purchase agreements with a total of seven accredited investors ("Investors") pursuant to which the Investors agreed to make a $31.0 million investment in the Company in exchange for 31,000,000 shares of our Common Stock at $1.00 per share, representing a range of discounts of approximately 16-21% to the average closing price of our Common Stock on the NYSE Amex for the five trading days immediately preceding the closing date of the agreements. The shares issued were restricted securities and were exempt from registration requirements under Section 4(2) of the Act because the transaction did not involve a public offering.

On February 23, 2009, we entered into a Stock Purchase Agreement with the Gamma Trust, pursuant to which the Gamma Trust agreed to make a $20.0 million cash investment in the Company in exchange for 20,000,000 shares (the "Shares") of our Common Stock, at $1.00 per share, representing an approximately 20% discount to the average closing price of our Common Stock on the NYSE Amex for the five trading days immediately preceding the effective date of Audit Committee and stockholder approval of the transaction. We issued the Shares and received the proceeds on April 27, 2009. The Shares issued were restricted securities, subject to a two-year lockup and no registration rights were granted.

On September 10, 2008, we issued 13,513,514 shares of our Common Stock to a group of investors, including members of the Frost Group, in exchange for $15.0 million. The shares were issued at $1.11 per share, representing an approximately 40% discount to the five-day average closing price of our Common Stock on the NYSE Amex. The shares issued were restricted securities, subject to a two year lockup, and no registration rights have been granted. The issuance of the shares was exempt from the registration requirements under Section 4(2) of the Act because the transaction did not involve a public offering.

Note 7 Shareholders' Equity

Our authorized capital stock consists of 500,000,000 shares of common stock, par value $.01 per share, and 10,000,000 shares of preferred stock, par value $.01 per share.

Common Stock

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

In addition to our equity-based compensation plans, we have issued warrants to purchase our common stock. Refer to Note 8 for additional information on our share-based compensation plans. The table below provides additional information for warrants outstanding as of December 31, 2010.

Warrants	Number of warrants	Weighted average exercise price	Expiration date
Outstanding at December 31, 2009	29,194,162		
Issued	—		
Exercised	—		
Expired	—		
Outstanding and Exercisable at December 31, 2010	29,194,162	$ 0.89	Various from September 2014 through March, 2017

Preferred Stock

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

Series A Preferred Stock

Of the authorized preferred stock, 4,000,000 shares have been designated Series A preferred stock. Dividends are payable on the Series A preferred stock in the amount of $0.25 per share, payable annually in arrears. At the option of our board of directors, dividends will be paid either (i) wholly or partially in cash or (ii) in newly issued shares of Series A preferred stock valued at $2.50 per share to the extent cash dividend is not paid.

Holders of Series A preferred stock have the right to convert their shares, at their option exercisable at any time, into shares of our common stock on a one-for-one basis subject to anti-dilution adjustments. These anti-dilution adjustments are triggered in the event of any subdivision or combination of our outstanding common stock, any payment by us of a stock dividend to holders of our common stock or other occurrences specified in the certificate of designations relating to the Series A preferred stock. We may elect to convert the Series A preferred stock into common stock or a substantially equivalent preferred stock in the case of a merger or consolidation in which we do not survive, a sale of all or substantially all of our assets or a substantial reorganization of us.

Each share of Series A preferred stock is entitled to one vote on all matters on which the common stock has the right to vote. Holders of Series A preferred stock are also entitled to vote as a separate class on any proposed adverse change in the rights, preferences or privileges of the Series A preferred stock and any increase in the number of authorized shares of Series A preferred stock. In the event of any liquidation or winding up of the Company, the holders of the Series A preferred stock will be entitled to receive $2.50 per share plus any accrued and unpaid dividends before any distribution to the holders of the common stock and any other class of series of preferred stock ranking junior to it.

We may redeem the outstanding shares of Series A preferred stock for $2.50 per share (plus accrued and unpaid dividends), at any time.

Series C Preferred Stock

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

8% Series D Cumulative Convertible Preferred Stock

Of the authorized preferred stock, 2,000,000 shares were designated 8% Series D Cumulative Convertible Preferred Stock (“Series D Preferred Stock”). Holders of the Series D Preferred Stock are entitled to receive, when, as and if declared by the Company’s Board of Directors, dividends on each share of Series D Preferred Stock at a rate per annum equal to 8.0% of the sum of (a) $24.80, plus (b) any and all declared and unpaid and accrued dividends thereon, subject to adjustment for any stock split, combination, recapitalization or other similar corporate action (the “Liquidation Amount”). All dividends shall be cumulative, whether or not earned or declared, accruing on an annual basis from the issue date of the Series D Preferred Stock. As of December 31, 2010 we had approximately $2.49 per Series D Preferred Share, or $3.0 million of Series D Preferred Stock dividends in arrears.

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

Common Stock and all other classes and series of our capital stock entitled to vote on such matter, taken together as a single class.

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

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

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

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

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

Note 8 Equity-Based Compensation

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

We classify the cash flows resulting from the tax benefit that arises when the tax deductions exceed the compensation cost recognized for those equity awards (excess tax benefits) as financing cash flows. There were no excess tax benefits for the years ended December 31, 2010, 2009, and 2008.

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

Valuation and Expense Information

We recorded equity based compensation expense of $6.9 million, $4.5 million, and $6.7 million for the years ended December 31, 2010, 2009 and 2008, respectively, all of which were reflected as operating expenses. Of the $6.9 million of equity based compensation expense recorded in the year ended December 31, 2010, $5.2 million was recorded as selling, general and administrative expense and $1.7 million was recorded as research and development

expenses. Of the $4.5 million of equity based compensation expense recorded in the year ended December 31, 2009, $3.2 million was recorded as selling, general and administrative expense and $1.3 million was recorded as research and development expenses. For the year ended December 31, 2008, of the $6.7 million of equity based compensation expense recorded, $4.2 million was recorded as selling, general and administration expense and $2.5 million was recorded as research and development expense.

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

As of December 31, 2010, there was $8.2 million of unrecognized compensation cost related to the stock options granted under our stock plans. That cost is expected to be recognized over a weighted-average period of approximately 2 years.

Stock Options

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

	Year Ended December 31, 2010	Year Ended December 31, 2009	Year Ended December 31, 2008
Expected term (in years)	0.6 - 7.0	0.6 - 7.9	1.6 - 8.9
Risk-free interest rate	1.3% - 2.7%	1.4% - 3.0%	1.5% - 3.7%
Expected volatility	69% - 74%	70% - 77%	70% - 75%
Expected dividend yield	0%	0%	0%

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

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

Expected Volatility: The expected volatility was based on a peer group of publicly-traded stocks' historical trading which we believe will be representative of the volatility over the expected term of the options. We believe the peer group's historical volatility is appropriate as our equity shares have been publicly traded for a limited period of time.

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

We maintain incentive stock plans that provide for the grants of stock options to our directors, officers, employees and non-employee consultants. As of December 31, 2010, there were 11,106,725 shares of common stock reserved for issuance under our 2007 Incentive Plan. We intend to issue new shares upon the exercise of options. Stock options granted under these plans have been granted at an option price equal to the closing market value of the stock on the date of the grant. Options granted under these plans to employees typically become exercisable over four years in equal annual installments after the date of grant, and options granted to non-employee directors become exercisable in full one-year after the grant date, subject to, in each case, continuous service with the Company during the applicable vesting period. The Company assumed options to grant common stock as part of the mergers with Acuity Pharmaceuticals, Inc. and Froptix, Inc., which reflected various vesting schedules, including monthly vesting to employees and non-employee consultants.

A summary of option activity under our stock plans as of December 31, 2010, and the changes during the year is presented below:

Options	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2009	12,623,556	$ 2.36	5.5	$ 4,544
Granted	2,736,000	$ 2.25		
Exercised	(150,231)	$ 0.49		
Forfeited	(396,554)	$ 3.76		
Expired	(104,625)	$ 3.42		
Outstanding at December 31, 2010	14,708,146	$ 2.31	4.8	$ 23,464
Vested and expected to vest at December 31, 2010	13,852,934	$ 2.32	4.8	$ 22,134
Exercisable at December 31, 2010	6,775,064	$ 2.53	4.0	$ 10,467

The total intrinsic value of stock options exercised for the years ended December 31, 2010, 2009, and 2008 was $0.3 million, $3.8 million, and $9.5 million, respectively.

The weighted average grant date fair value of stock options granted for the years ended December 31, 2010, 2009 and 2008 was $1.39, $0.99, and $1.13, respectively. The total fair value of stock options vested during the years ended December 31, 2010, 2009 and 2008 was $3.4 million, $5.1 million, and $4.1 million, respectively. The following table provides the grant date fair value for each of the following groups of stock option activity during 2010:

Options	Number of options	Weighted average grant date fair value
Nonvested at December 31, 2009	7,516,418	$ 1.47
Granted	2,736,000	$ 1.39
Forfeited	396,554	$ 2.32
Nonvested at December 31, 2010	7,933,082	$ 1.32

Restricted Stock

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

Note 9 Income Taxes

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

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

(in thousands)	For the year ended December 31, 2010	2009	2008
Current			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	(489)	140	83
	(489)	140	83
Deferred			
Federal	—	—	—
State	—	—	—
Foreign	348	154	—
	348	154	—
Total, net	$ (141)	$ 294	$ 83

Deferred income tax assets and liabilities as of December 31, 2010 and 2009 are comprised of the following:

(in thousands)	December 31, 2010	December 31, 2009
Deferred income tax assets:		
Federal net operating loss	$ 33,489	$ 26,690
State net operating loss	3,694	4,816
Foreign net operating loss	1,481	1,198
Capitalized research and development expense	3,677	4,378
Research and development tax credit	2,342	6,492
Canadian research and development pool	1,212	1,464
Canadian tax credits	828	1,089
Amortization and depreciation	298	258
Accruals	19	555
Other	8,898	6,663
Deferred income tax assets	55,938	53,603
Deferred income tax liabilities:		
Intangible assets	(2,318)	(3,114)
Other	(308)	—
Deferred income tax liabilities	(2,626)	(3,114)
Net deferred income tax assets	53,312	50,489
Valuation allowance	(54,252)	(51,697)
Net deferred income tax liabilities	$ (940)	$ (1,208)

The change in deferred income tax assets, liabilities and valuation allowances at December 31, 2010 reflect the acquisition of various legal entities, including the tax attributes. The acquisitions were accounted for under U.S. GAAP as asset acquisitions and business combinations. As of December 31, 2010, we have federal, state, and foreign net operating loss carryforwards of approximately $162.7 million, $138.7 million, and $6.0 million, respectively, that expire at various dates through 2030. We have research and development tax credit carryforwards of approximately $2.7 million that expire in varying amounts through 2030. We have determined a full valuation allowance is required against all of our tax assets that we do not expect to be utilized by the turning of deferred income tax liabilities.

Under Section 382 of the Internal Revenue Code of 1986, as amended, certain significant changes in ownership may restrict the future utilization of our income tax loss carryforwards and income tax credit carryforwards in the United States. The annual limitation is equal to the value of our stock immediately before the ownership change,

multiplied by the long-term tax-exempt rate (i.e., the highest of the adjusted Federal long-term rates in effect for any month in the three-calendar-month period ending with the calendar month in which the change date occurs). This limitation may be increased under the IRC§ 338 Approach (IRS approved methodology for determining recognized Built-In Gain). As a result, federal net operating losses and tax credits may expire before we are able to fully utilize them.

During 2008, we conducted a study to determine the impact of the various ownership changes that occurred during 2007 and 2008. As a result, we have concluded that the annual utilization of our net operating loss carryforwards ("NOLs") and tax credits is subject to a limitation pursuant to Internal Revenue Code section 382. Under the tax law, such NOLs and tax credits are subject to expiration from 15 to 20 years after they were generated. As a result of the annual limitation that may be imposed on such tax attributes and the statutory expiration period, some of these tax attributes may expire prior to our being able to use them. As we have established a valuation allowance against all of our net deferred tax assets, including such NOLs and tax credits, there is no current impact on these financial statements as a result of the annual limitation. This study did not conclude as to whether eXegenics' pre-merger NOLs were limited under Section 382. As such, of the $162.7 million of federal net operating loss carryforwards, at least approximately $52.0 million may not be able to be utilized.

Uncertain Income Tax Positions

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

U.S. Federal: Under the tax statute of limitations applicable to the Internal Revenue Code, we are no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for years before 2006. However, because we are carrying forward income tax attributes, such as net operating losses and tax credits from 2006 and earlier tax years, these attributes can still be audited when utilized on returns filed in the future.

State: Under the statutes of limitation applicable to most state income tax laws, we are no longer subject to state income tax examinations by tax authorities for years before 2006 in states in which we have filed income tax returns. Certain states may take the position that we are subject to income tax in such states even though we have not filed income tax returns in such states and, depending on the varying state income tax statutes and administrative practices, the statute of limitations in such states may extend to years before 2006.

Foreign: Under the statutes of limitations applicable to our foreign operations, we are no longer subject to tax examination for years before 2006 in jurisdictions we have filed income tax returns.

As a result of our January 1, 2007 implementation of ASC 740, the total amount of gross tax benefits, excluding the offsetting full valuation allowance, that became unrecognized, was approximately $0.4 million. There were no accrued interest and penalties resulting from such unrecognized tax benefits. As of December 31, 2010 and December 31, 2009, the total amount of gross unrecognized tax benefits was approximately $5.4 million and $6.8 million, respectively, and accrued interest and penalties on such unrecognized tax benefits was $0 in each period.

The following table rolls forward the 2010 activity in our gross unrecognized income tax benefits.

(in thousands)	
Unrecognized tax benefits January 1, 2010	$ 6,818
Gross increases — tax positions in prior period	—
Gross decreases — tax positions in prior period	(1,405)
Unrecognized tax benefits at December 31, 2010	$ 5,413

There are no net unrecognized tax benefits that, if recognized, would impact the effective tax rate as of December 31, 2010 as a result of the full valuation allowance.

Other Income Tax Disclosures

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

	For the year ended December 31,		
	2010	2009	2008
Federal statutory rate	35.0%	35.0%	35.0%
State income taxes, net of federal benefit	3.5	3.7	3.6
Foreign income tax	(1.0)	0.1	—
Acquired in-process research and development	—	(2.6)	(1.4)
Research and development tax credits	5.8	6.7	10.7
OID	3.7	5.0	—
Impairment of goodwill	—	(1.4)	—
Other items including valuation allowance and permanent items	(47.0)	(45.5)	(48.0)
Other	(0.8)	0.0	0.3
Total	(0.8)%	1.0%	0.2%

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

	For the year ended December 31,		
(in thousands)	2010	2009	2008
Pre-tax loss			
U.S.	$(16,256)	$(29,214)	$(37,153)
Foreign	(1,815)	(840)	(2,764)
Total	$(18,071)	$(30,054)	$(39,917)

Note 10 Supplemental Cash Flow Information

Supplemental cash flow information is summarized as follows:

	For the year ended December 31,		
(in thousands)	2010	2009	2008
Interest paid	$ 4,386	$ 95	$ 101
Income taxes paid, net	$ 235	$ —	$ —
Non-cash financing			
Issuance of capital stock to acquire Exakta-OPKO and Vidus	$ 1,999	$ —	$ 1,319

Note 11 Related Party Transactions

We have a $12.0 million line of credit with the Frost Group, a related party. On June 2, 2010 we repaid all amounts outstanding on the line of credit including $12 million in principal and $4.1 million in interest. The line of credit, which previously expired on January 11, 2011, was renewed on February 22, 2011 until March 31, 2012 on substantially the same terms as in effect at the time of expiration. We have the ability to draw funds under the line of credit until its expiration in March 2012. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at an 11% annual rate. The line of credit is collateralized by all of our U.S. personal property except our intellectual property.

In November 2010, we made an investment in Fabrus, LLC, a privately held early stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities. In exchange for the investment, we acquired approximately 13% of Fabrus' outstanding membership interests on a fully diluted basis. Our investment was part of a $2.1 million financing for Fabrus. Other investors participating in the financing include Frost Gamma Investments Trust, of which Phillip Frost is the sole trustee, and Hsu Gamma Investment, L.P., of which Jane Hsiao, the Company's Vice Chairman and Chief Technical Officer, serves as the general partner. In connection with the financing, Drs. Frost and Hsiao joined the Fabrus Board of Managers. Dr.

Richard Lerner, a director of the Company, owns approximately 5% of Fabrus. Vaughn Smider, Founder and CEO of Fabrus, is an Assistant Professor at The Scripps Research Institute ("TSRI"). Dr. Frost serves as a Trustee for TSRI, and Richard Lerner serves as its President.

On July 20, 2010, we entered into a use agreement for approximately 1,100 square feet of space in Jupiter, Florida to house our molecular diagnostics operations with TSRI. Dr. Frost is a member of the Board of Trustees of TSRI and Dr. Richard Lerner, a member of our Board of Directors, is also the President of TSRI. Pursuant to the terms of the use agreement, which is effective as of November 1, 2009, gross rent is approximately $40 thousand per year for a two-year term which may be extended, upon mutual agreement, for one additional year.

On June 1, 2010, the Company entered into a cooperative research and development agreement with Academia Sinica in Taipei, Taiwan, for pre-clinical work for a compound against various forms of cancer. Dr. Alice Yu, a member of our board of directors, is a Distinguished Research Fellow and Associate Director at the Genomics Research Center, Academia Sinica. In connection with the agreement, we are required to pay Academia Sinica approximately $0.2 million over the term of the agreement.

Effective March 5, 2010, the Frost Group assigned two license agreements with Academia Sinica to the Company. The license agreements pertain to alpha-galactosyl ceramide analogs and their use as immunotherapies and peptide ligands in the diagnosis and treatment of cancer. In connection with the assignment of the two licenses, the Company agreed to reimburse the Frost Group for the licensing fees previously paid by the Frost Group to Academia Sinica in the amounts of $50 thousand and $75 thousand, respectively, as well as reimbursement of certain expenses of $50 thousand.

Effective September 21, 2009, we entered into an agreement pursuant to which we invested $2.5 million in Cocrystal in exchange for 1,701,723 shares of Cocrystal's Convertible Series A Preferred Stock. A group of Investors, led by the Frost Group (the "CoCrystal Investors"), previously invested $5 million in Cocrystal, and agreed to invest an additional $5 million payable in two equal installments in September 2009 and March 2010. As a result of an amendment to the CoCrystal Investors agreements dated June 9, 2009, OPKO, rather than the CoCrystal Investors, made the first installment investment ($2.5 million) on September 21, 2009. Refer to Note 2.

On September 18, 2009, we entered into the Preferred Purchase Agreement with various investors. Refer to Note 6. Included among the investors is the Gamma Trust, Hsu Gamma Investment, L.P, a limited partnership controlled by Jane H. Hsiao and Oracle Partners LP, a limited partnership in which Dr. Frost is a limited partner.

On July 20, 2009, we entered into a worldwide exclusive license agreement with Academia Sinica in Taipei, Taiwan, for a new technology to develop protein vaccines against influenza and other viral infections. Dr. Alice Yu, a member of our board of directors, is a Distinguished Research Fellow and Associate Director at the Genomics Research Center, Academia Sinica.

On June 16, 2009, we entered into an agreement to lease approximately 10,000 square feet of space in Hialeah, Florida to house manufacturing and service operations for our ophthalmic instrumentation business (the "Hialeah Facility") from an entity controlled by Dr. Frost and Dr. Jane Hsiao. Pursuant to the terms of a lease agreement, which is effective as of February 1, 2009, gross rent is $0.1 million per year for a one-year lease and was extended through February 1, 2011. From April 2008 through January 2009, we leased 20,000 square feet at the Hialeah Facility from a third party landlord pursuant to a lease agreement which contained an option to purchase the facility. We initially elected to exercise the option to purchase the Hialeah Facility in September 2008. Prior to closing, however, we assigned the right to purchase the Hialeah Facility to an entity controlled by Drs. Frost and Hsiao and leased a smaller portion of the facility as a result of several factors, including our inability to obtain outside financing for the purchase, current business needs, the reduced operating costs for the smaller space, and the minimization of risk and expense of unutilized space.

On June 10, 2009, we entered into a stock purchase agreement with Sorrento, pursuant to which we invested $2.3 million in Sorrento. Refer to Note 2. In exchange for the investment, we acquired approximately one-third of the outstanding common shares of Sorrento and received a fully-paid, exclusive license to the Sorrento antibody library for the discovery and development of therapeutic antibodies in the field of ophthalmology. On September 21, 2009, Sorrento entered into a merger transaction with Quikbyte Software, Inc. Prior to the merger transaction, certain investors, including Dr. Frost and other members of OPKO management, made an investment in Quikbyte. Dr. Richard Lerner, a member of our Board of Directors, serves as a consultant and scientific advisory board member to Sorrento and owns less than one percent of its shares.

On May 26, 2009, May 29, 2009, and June 1, 2009, we entered into stock purchase agreements with a total of seven accredited investors pursuant to which we agreed to sell an aggregate of 31 million shares of the Company's Common Stock in exchange for $31 million. Under the terms of each investment, OPKO issued shares to the investors at a price of $1.00 per share. Refer to Note 6. Oracle Partners, LP and Vector Group Ltd. were among the investors in the transaction and purchased 4 million and 5 million shares of our Common Stock, respectively. At the time of the investment, Dr. Frost may also be deemed to beneficially own 11.5% of Vector Group Ltd.'s outstanding stock.

On March 4, 2009, the Gamma Trust advanced $3.0 million to us under a Promissory Note we issued to the Gamma Trust, which was repaid in full on April 27, 2009, including interest of $48 thousand. Refer to Note 5.

In March 2009, we paid the $45 thousand filing fee to the Federal Trade Commission in connection with filings made by us and Dr. Frost, under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR"). The filings permitted Dr. Frost and his affiliates to acquire additional shares of our Common Stock upon expiration of the HSR waiting period on March 23, 2009.

On February 23, 2009, we entered into a Stock Purchase Agreement with the Gamma Trust, of which Dr Frost is the sole trustee. Refer to Note 6.

On September 10, 2008, in exchange for a $15.0 million cash investment in the Company, we issued 13,513,514 shares of our Common Stock to a group of investors which included members of the Frost Group. The shares were issued at a price of $1.11 per share, representing an approximately 40% discount to the 5 day average trading price of our stock on the NYSE Amex. Refer to Note 6.

In November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC, an entity affiliated with Dr. Frost. The lease is for approximately 8,300 square feet of space in an office building in Miami, Florida, where the Company's principal executive offices are located. We had previously been leasing this space from Frost Real Estate Holdings on a month-to-month basis while the parties were negotiating the lease. The lease provides for payments of approximately $18 thousand per month in the first year increasing annually to $24 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking. The rent for the first year was reduced to reflect a $30 thousand credit for the costs of tenant improvements. From January 1, 2008 through October 1, 2008, we leased an additional 1,100 square feet of general office and laboratory space on a ground floor annex of our corporate office building pursuant to an addendum to the Lease, which required us to pay annual rent of $19 thousand per year for the annex space.

On September 19, 2007, we entered into an exclusive technology license agreement with Winston Laboratories, Inc. ("Winston"). On February 23, 2010, we provided Winston notice of termination of the license agreement, and the agreement terminated on May 24, 2010. Previously, members of the Frost Group beneficially owned approximately 30% of Winston Pharmaceuticals, Inc., and Dr. Uppaluri, our Chief Financial Officer, served as a member of Winston's board. Effective May 19, 2010, the members of the Frost Group sold 100% of Winston's capital stock beneficially owned by them (consisting of an aggregate of 18,399,271 outstanding shares of common stock and warrants to purchase an aggregate of 8,958,975 shares of common stock) to an entity whose members include Dr. Joel E. Bernstein, the President and Chief Executive Officer of Winston. As consideration for the sale, the Frost Group members received an aggregate of $789,500 in cash and non-recourse promissory notes in the aggregate principal amount of $10,263,500 (the "Promissory Notes"). Dr. Uppaluri resigned from the Winston board effective May 19, 2010. In connection with the license agreement, we reimbursed Winston $29 thousand, and $3 thousand in the years ended December 31, 2009 and 2008, respectively, for services provided by Winston personnel to assist us with the clinical program for the product we licensed.

As part of the merger with Acuity Pharmaceuticals, Inc. ("Acuity") in 2007, we assumed a line of credit with the Frost Group from Acuity and amended and restated that line of credit to increase borrowing availability. In

connection with the increase of the borrowing availability, we issued 4,000,000 warrants to the Frost Group. Refer to Note 5.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost in an amount equal to the cost of a first class airline ticket between the travel cities for each executive, including Dr. Frost, traveling on the airplane for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive; nor do we pay for any other fixed or variable operating costs of the airplane. For the fiscal years ending December 31, 2010, 2009, and 2008, we reimbursed Dr. Frost approximately $46 thousand, $92 thousand, and $108 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

During the year ending December 31, 2008, we reimbursed SafeStitch Medical, Inc. ("SafeStitch") approximately $49 thousand for time SafeStitch's personnel spent assisting us with the implementation of certain quality and control standard operating procedures at our manufacturing facility in Toronto, Ontario. Dr. Hsiao serves as chairman of the board of directors for SafeStitch; Steven Rubin and Richard Pfenniger, each of whom are members of our board of directors, also serve on the board of directors of SafeStitch. We have not reimbursed SafeStitch any amounts in 2010 or 2009.

Note 12 Employee Benefit Plans

Effective January 1, 2007, the OPKO Health Savings and Retirement Plan ("Plan") permits employees to contribute up to 50% of qualified pre-tax annual compensation up to annual statutory limitations. The discretionary company match for employee contributions to the Plan is 100% of up to the first 4% of the participant's earnings contributed to the Plan. Our matching contributions to the plan were approximately $0.2 million for each of the years ended December 31, 2010 and 2009.

Note 13 Commitments and Contingencies

On January 7, 2010, we received a letter from counsel to Nidek Co., Ltd. ("Nidek") alleging that Ophthalmic Technologies, Inc. ("OTI") or OPKO breached its service obligations to Nidek under the Service Agreement between OTI, Nidek and Newport Corporation, dated December 29, 2006, and the Service Agreement by and between Nidek and OTI, dated the same date. We have had discussions with Nidek regarding the matter, but it is too early to assess the likelihood of litigation in this matter or the probability of a favorable or unfavorable outcome. We do not believe this matter will have a material impact on our results of operations or financial condition. We are also assessing possible claims of indemnification against a supplier in connection with the matter.

On May 6, 2008, we completed the acquisition of Vidus. Pursuant to a Securities Purchase Agreement with Vidus, each of its stockholders, and the holders of convertible promissory notes issued by Vidus, we acquired all of the outstanding stock and convertible debt of Vidus in exchange for (i) the issuance and delivery at closing of 658,080 shares of our Common Stock (the "Closing Shares"); (ii) the issuance of 488,420 shares of our Common Stock to be held in escrow pending the occurrence of certain development milestones (the "Milestone Shares"); and (iii) the issuance of options to acquire 200,000 shares of our Common Stock. Additionally, in the event that the stock price for our Common Stock at the time of receipt of approval or clearance by the U.S. Food & Drug Administration of a pre-market notification 510(k) relating to the Aquashunt™ is not at or above a specified price, we will be obligated to issue an additional 413,850 shares of our Common Stock.

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

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

Note 14 Strategic Alliances

We plan to develop a portfolio of product candidates through a combination of internal development and external partnerships. On December 10, 2010, we entered into a definitive agreement granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Refer to Note 2. We have also completed strategic deals with the Trustees of the University of Pennsylvania, the University of Florida Research Foundation, the University of Texas Southwestern, and Academia Sinica, among others. In connection with these license agreements, upon the achievement of certain milestones we are obligated to make certain payments and upon sales of products developed under the license agreements, have royalty obligations. At this time, we are unable to estimate the timing and amounts of payments as the obligations are based on future development of the licensed products.

Note 15 Leases

We conduct certain of our operations under operating lease agreements. Rent expense was approximately $1.0 million for the year ended December 31, 2010, and $0.7 million for the year ended December 31, 2009.

As of December 31, 2010, the aggregate future minimum lease payments under all non-cancelable operating leases with initial or remaining lease terms in excess of one year are as follows:

Year Ending	(in thousands)
2011	$ 506
2012	270
2013	—
2014	—
2015	—
Total minimum lease commitments	$ 776

Note 16 Segments

We currently manage our operations in two reportable segments, pharmaceutical and instrumentation segments. 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, diagnostic tests and vaccines, and (ii) the pharmaceutical operations we acquired in Chile and Mexico through the acquisition of OPKO Chile and Exakta-OPKO. The instrumentation segment consists of ophthalmic instrumentation products and the activities related to the research, development, manufacture and commercialization of those products. There are no inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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

(in thousands)	For the years ended December 31, 2010	2009	2008
Product revenue			
Pharmaceutical	$ 21,763	$ 4,418	$ —
Instrumentation	8,386	8,729	9,440
Corporate	—	—	—
	$ 30,149	$ 13,147	$ 9,440
Operating income (loss)			
Pharmaceutical	$ 373	$(11,920)	$(19,437)
Instrumentation	(5,971)	(6,843)	(9,704)
Corporate	(11,631)	(9,257)	(9,422)
	$(17,229)	$(28,020)	$(38,563)
Depreciation and amortization			
Pharmaceutical	$ 2,082	$ 507	$ 29
Instrumentation	1,673	1,797	1,753
Corporate	115	53	41
	$ 3,870	$ 2,357	$ 1,823
Net loss of investees			
Pharmaceutical	$ (714)	$ (353)	$ —
Instrumentation	—	—	—
Corporate	—	—	—
	$ (714)	$ (353)	$ —
Product revenue			
United States	$ 827	$ 813	$ 112
Chile	17,977	4,418	—
Mexico	4,110	24	1
All others	7,235	7,892	9,327
	$ 30,149	$ 13,147	$ 9,440

	As of December 31, 2010	2009
Assets		
Pharmaceutical	$ 51,599	$28,813
Instrumentation	8,637	12,262
Corporate	17,610	46,355
	$ 77,846	$87,430

During the year ended December 31, 2010, we also recorded $6.7 million of license revenue related to our license agreement with TESARO and is part of our pharmaceutical business.

During the year ended December 31, 2010, one customer represented 13% of our total product revenue. During the year ended December 31, 2009, no customers represented greater than 10% of revenue. During the year ended December 31, 2008, four customers represented 18%, 17%, 13%, and 11%, respectively, of revenue. As of December 31, 2010, two customers represented 32% and 11% of our accounts receivable balance. As of December 31, 2009, two customers represented 32% and 19% of our accounts receivable balance.

Note 17 Fair Value Measurement

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

As of December 31, 2010, we held money market funds that qualify as cash equivalents and forward contracts for inventory purchases (Refer to Note 18) that are required to be measured at fair value on a recurring basis. Our other assets and liabilities carrying value approximate their fair value due to their short-term nature.

Any future fluctuation in fair value related to these instruments that is judged to be temporary, including any recoveries of previous write-downs, would be recorded in accumulated other comprehensive income or loss. If we determine that any future valuation adjustment was other-than-temporary, we would record a charge to the consolidated statement of operations as appropriate.

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

	Fair value measurements as of December 31, 2010			
(in thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3	Total
Assets:				
Money market funds	$ 16,895	$ —	$ —	$16,885
Liabilities:				
Forward contracts	$ —	$ 689	$ —	$ 689

Note 18 Derivative Contracts

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

We record derivative financial instruments on our balance sheet at their fair value as an accrued expense and the changes in the fair value are recognized in income in other expense net when they occur, the only exception being derivatives that qualify as hedges. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At December 31, 2010, the forward contracts did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values in income.

The outstanding contracts at the end of the year 2010 have been valued at fair value, and their maturity details are as follows:

(in thousands) Days until maturity	Contract value	Fair value at December 31, 2010	Effect on loss
0 to 30	$ 359	$ 386	$ (27)
31 to 60	1,129	1,244	(115)
61 to 90	1,924	2,061	(137)
91 to 120	2,787	3,033	(246)
121 to 180	1,192	1,335	(143)
More than 180	379	400	(21)
Total	$ 7,770	$ 8,459	$ (689)

Note 19 Selected Quarterly Financial Data (Unaudited)

	For the 2010 Quarters Ended			
(in thousands)	March 31	June 30	September 30	December 31
Revenue	$ 7,922	$ 7,455	$ 7,599	$ 13,904
Gross margin	2,394	2,605	2,344	9,036
Net loss attributable to common shareholders	(5,346)	(6,876)	(8,010)	(1,318)
Basic and diluted loss per share	$ (0.02)	$ (0.03)	$ (0.03)	$ (0.01)

	For the 2009 Quarters Ended			
(in thousands)	March 31	June 30	September 30	December 31
Revenue	$ 2,301	$ 2,347	$ 1,501	$ 6,998
Gross (deficit) margin	740	583	446	1,811
Net (loss) income attributable to common shareholders	(9,055)	(5,734)	(10,298)	(9,744)
Basic and diluted (loss) income per share	$ (0.05)	$ (0.03)	$ (0.04)	$ (0.04)

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

On December 10, 2010, we licensed our rolapitant development program and as a result, recorded $6.7 million of revenue. Refer to Note 2. In addition, we acquired Exakta-OPKO on February 16, 2010. On October 7, 2009 we acquired OPKO Chile. The results of operations include the results of Exakta-OPKO and OPKO Chile after their acquisitions. Refer to Note 2. In the fourth quarter of 2009, we recorded a $1.1 million impairment charge related to goodwill associated with our instrumentation business. Refer to Note 2. In the quarter ended September 30, 2009, we recorded a $3.9 million preferred stock dividend related to a beneficial conversion feature of our Series D Preferred Stock. Refer to Note 6.

Note 20 Subsequent Events

On March 14, 2011, we issued 27,000,000 shares of our Common Stock in a public offering at a price of $3.75 per share. The net proceeds received were approximately $96.4 million after deducting the underwriters discounts and commissions and other estimated offering expenses. We also granted the underwriters a 30-day option to purchase up to an additional 4,050,000 shares of our Common Stock to cover overallotments, if any. On March 15, 2011, representatives for the underwriters provided us notice that the underwriters exercised a portion of their 4,050,000 share over-allotment option for 2,397,029 additional shares of our Common Stock. As part of the offering, Frost Gamma Investments Trust, of which Phillip Frost is the sole trustee, and Hsu Gamma Investment, L.P., of which Jane Hsiao, the Company's Vice Chairman and Chief Technical Officer, serves as the general partner, purchased an aggregate of 3,733,000 shares of our Common Stock at the public offering price. Jefferies & Company, Inc. and J.P. Morgan Securities LLC acted as joint book-running managers for the offering. UBS Investment Bank and Lazard Capital Markets LLC acted as co-lead managers for the offering and Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., acted as co-manager for the offering. Dr. Frost is the Chairman of the Board of Directors and principal shareholder of Ladenburg Thalmann Financial Services Inc.

On February 22, 2011, we entered into Amendment No. 2 (the "Amendment") to our Credit Agreement, dated March 27, 2007, as amended, with the Frost Group (the "Credit Agreement"). The Amendment renewed the Company's $12.0 million line of credit with the Frost Group. The line of credit, which previously expired on January 11, 2011, was renewed until March 31, 2012 on substantially the same terms as in effect at the time of expiration. We are obligated to pay interest upon maturity, compounded quarterly, on outstanding borrowings under the line of credit at an 11% annual rate.

On January 28, 2011, we entered into a definitive agreement (the "CURNA Merger Agreement") with CURNA, Inc., ("CURNA") and each of CURNA's shareholders and optionholders, pursuant to which we agreed to acquire all of the outstanding stock of CURNA in exchange for $10 million in cash. 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. Closing of the transaction occurred on January 31, 2011.

We have reviewed all subsequent events and transactions that occurred after the date of our December 31, 2010 consolidated balance sheet date, through the time of filing this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Securities and Exchange Commission ("SEC") Rule 13a-15(e) as of December 31, 2010. Based on that evaluation, CEO and CFO have concluded that the Company's disclosure controls and procedures are effective to ensure that information the Company is required to disclose in reports that it files or submits under the Securities Exchange Act is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

Management's Annual Report on Internal Control Over Financial Reporting

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

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010, based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on our evaluation under the framework in Internal Control — Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2010.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2010 has been audited by Ernst & Young LLP, our independent registered public accounting firm, who also audited our consolidated financial statements included in this Annual Report on Form 10-K, as stated in their report which appears with our accompanying consolidated financial statements.

Changes to the Company's Internal Control Over Financial Reporting

As part of the Company's September 30, 2010 close process, the Company identified that it had not properly accounted for a beneficial conversion feature on, and the classification of convertible preferred stock. As a result, the Company has implemented additional controls and procedures over financial reporting including adding additional review procedures on its complex accounting issues. In addition, in connection with our acquisitions of Exakta-OPKO and OPKO Chile, we continue to implement a new accounting system, as well as standards and procedures, upgrading and establishing controls over accounting systems and adding employees who are trained and experienced in the preparation of financial statements in accordance with U.S. GAAP to ensure that we have appropriate internal control over financial reporting at Exakta-OPKO and OPKO Chile. Other than as set forth above with respect to Exakta-OPKO and OPKO Chile and the additional review procedures of complex accounting issues, there have been no changes to the Company's internal control over financial reporting that occurred during the Company's fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

The information required in Items 10 (Directors, Executive Officers and Corporate Governance), Item 11 (Executive Compensation), Item 12 (Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters), Item 13 (Certain Relationships and Related Transactions, and Director Independence), and Item 14 (Principal Accounting Fees and Services) is incorporated by reference to the Company's definitive proxy statement for the 2011 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2010.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

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

(3) Exhibits: See below.

Exhibit Number	Description
2.1(1)	Merger Agreement and Plan of Reorganization, dated as of March 27, 2007, by and among Acuity Pharmaceuticals, Inc., Froptix Corporation, eXegenics, Inc., e-Acquisition Company I-A, LLC, and e-Acquisition Company II-B, LLC.
2.2(5)+	Securities Purchase Agreement dated May 6, 2008, among Vidus Ocular, Inc., OPKO Instrumentation, LLC, OPKO Health, Inc., and the individual sellers and noteholders named therein.
2.3(11)	Purchase Agreement, dated February 17, 2010, among Ignacio Levy García and José de Jesús Levy García, Inmobiliaria Chapalita, S.A. de C.V., Pharmacos Exakta, S.A. de C.V., OPKO Health, Inc., OPKO Health Mexicana S. de R.L. de C.V., and OPKO Manufacturing Facilities S. de R.L. de C.V.
3.1(2)	Amended and Restated Certificate of Incorporation.
3.2(4)	Amended and Restated By-Laws.
3.3(9)	Certificate of Designation of Series D Preferred Stock.
4.1(1)	Form of Common Stock Warrant.
4.2(9)	Form of Common Stock Warrant.
10.1(1)	Form of Lockup Agreement.
10.2(1)	License Agreement, dated as of March 31, 2003, by and between the Trustees of the University of Pennsylvania and Acuity Pharmaceuticals, Inc. (Reich/Tolentino).
10.3(1)	License Agreement, dated as of March 31, 2003, by and between the Trustees of the University of Pennsylvania and Acuity Pharmaceuticals, Inc. (Reich/Gewirtz).
10.4(1)	First Amendment to License Agreement, dated as of August 1, 2003, by and between the Trustees of the University of Pennsylvania and Acuity Pharmaceuticals, Inc. (Reich/Tolentino).
10.5(1)	First Amendment to License Agreement, dated as of August 1, 2003, by and between the Trustees of the University of Pennsylvania and Acuity Pharmaceuticals, Inc. (Gewirtz).
10.6(1)	Credit Agreement, dated as of March 27, 2007, by and among eXegenics, Inc., The Frost Group, LLC, and Acuity Pharmaceuticals, LLC.
10.7(1)	Amended and Restated Subordination Agreement, dated as of March 27, 2007, by and among The Frost Group, LLC, Horizon Technology Funding Company LLC, Acuity Pharmaceuticals, LLC, and eXegenics, Inc.
10.8(4)	Share Purchase Agreement, dated April 11, 2007, by and between Ophthalmic Technologies, Inc. and eXegenics, Inc.

Exhibit Number	Description
10.9(3)	Lease Agreement dated November 13, 2007, by and between Frost Real Estate Holdings, LLC and the Company.
10.10(4)	Share Purchase Agreement, dated as of November 28, 2007, by and among Ophthalmic Technologies, Inc., OTI Holdings Limited, and the Shareholders named therein.
10.11(4)	Exchange and Support Agreement, dated as of November 28, 2007, by and among OPKO Health, Inc. and OTI Holdings Limited and the holders of exchangeable shares named therein.
10.12(4)	Stock Purchase Agreement, dated December 4, 2007, by and between members of The Frost Group, LLC and the Company.
10.13(4)*	OPKO Health, Inc. 2007 Equity Incentive Plan.
10.14(5)	Form of Director Indemnification Agreement.
10.15(5)	Form of Officer Indemnification Agreement.
10.16(6)	Stock Purchase Agreement, dated August 8, 2008 by and among the Company and the Investors named therein.
10.17(7)	Stock Purchase Agreement, dated February 23, 2009 by and between the Company and Frost Gamma Investments Trust.
10.18(7)	Promissory Note to Frost Gamma Investments Trust, dated March 4, 2009.
10.19(8)	Form of Stock Purchase Agreement for transactions between the Company and Nora Real Estate SA., Vector Group Ltd., Oracle Partners LP, Oracle Institutional Partners, LP., Chung Chia Company Limited, Gold Sino Assets Limited and Grandtime Associates Limited.
10.20(8)	Stock Purchase Agreement, dated June 10, 2009, by and among the Company and Sorrento Therapeutics, Inc.
10.21(9)	Form of Securities Purchase Agreement Series D Preferred Stock.
10.22(10)*	Form of Restricted Share Award Agreement (Director).
10.23(10)	Cocrystal Discovery, Inc. Agreements.
10.24(13)	Stock Purchase Agreement, dated October 1, 2009, by and among the OPKO Chile Limitada and Inversones OPKO Limitada, subsidiaries of the Company, and the Sellers named therein.
10.25+(12)	Asset Purchase Agreement, dated October 12, 2009, by and between the Company and Schering Corporation.
10.26(12)	Letter Agreement, dated June 29, 2010, by and between the Company and Schering Corporation.
10.27+	Exclusive License Agreement by and between the Company and TESARO, Inc. dated December 10, 2010.
21	Subsidiaries of the Company.
23.1	Consent of Ernst & Young LLP.
31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Exchange Act Rules 13a-14 and 15d-14.

Exhibit Number	Description
31.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14 and 15d-14.
32.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Denotes management contract or compensatory plan or arrangement.

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

(1) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 2, 2007, and incorporated herein by reference.

(2) Filed with the Company's Current Report on Form 8-A filed with the Securities and Exchange Commission on June 11, 2007, and incorporated herein by reference.

(3) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2007 for the Company's three-month period ended September 30, 2007, and incorporated herein by reference.

(4) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008 and incorporated herein by reference.

(5) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2008 for the Company's three-month period ended June 30, 2008, and incorporated herein by reference.

(6) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2008 for the Company's three-month period ended September 30, 2008, and incorporated herein by reference.

(7) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 8, 2009 for the Company's three-month period ended March 31, 2009, and incorporated herein by reference.

(8) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2009 for the Company's three-month period ended June 30, 2009, and incorporated herein by reference.

(9) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009, and incorporated herein by reference.

(10) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2009 for the Company's three-month period ended September 30, 2009, and incorporated herein by reference.

(11) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2010 for the Company's three-month period ended March 31, 2010, and incorporated herein by reference.

(12) Filed with the Company's Amendment to Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 3, 2011.

(13) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2010.

SIGNATURES

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

OPKO HEALTH, INC.

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

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

Signature	Title	Date
/s/ Dr. Phillip Frost, M.D. Dr. Phillip Frost, M.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 16, 2011
/s/ Dr. Jane H. Hsiao Dr. Jane H. Hsiao	Vice Chairman and Chief Technical Officer	March 16, 2011
/s/ Steven D. Rubin Steven D. Rubin	Director and Executive Vice President — Administration	March 16, 2011
/s/ Rao Uppaluri Rao Uppaluri	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	March 16, 2011
/s/ Adam Logal Adam Logal	Executive Director of Finance, Chief Accounting Officer and Treasurer (Principal Accounting Officer)	March 16, 2011
/s/ Robert Baron Robert Baron	Director	March 16, 2011
/s/ Thomas E. Beier Thomas E. Beier	Director	March 16, 2011
/s/ Pascal J. Goldschmidt, M.D. Pascal J. Goldschmidt, M.D.	Director	March 16, 2011
/s/ Richard A. Lerner, M.D. Richard A. Lerner, M.D.	Director	March 16, 2011
/s/ John A. Paganelli John A. Paganelli	Director	March 16, 2011
/s/ Richard C. Pfenniger, Jr. Richard C. Pfenniger, Jr.	Director	March 16, 2011
/s/ Alice Lin-Tsing Yu, M.D., Ph.D. Alice Lin-Tsing Yu, M.D., Ph.D.	Director	March 16, 2011

EXHIBIT INDEX

Exhibit Number	Description
10.27+	Exclusive License Agreement by and between the Company and TESARO, Inc. dated December 10, 2010.
21	Subsidiaries of the Company.
23.1	Consent of Ernst & Young LLP.
31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Exchange Act Rules 13a-14 and 15d-14.
31.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14 and 15d-14.
32.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

CONFIDENTIAL MATERIAL OMITTED AND FILED
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.
ASTERISKS DENOTE SUCH OMISSIONS.

Exhibit 10.27

EXCLUSIVE LICENSE AGREEMENT

BY AND BETWEEN

TESARO, INC.

AND

OPKO HEALTH, INC.

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EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement, made this 10th day of December, 2010 (the "Effective Date"), is by and between TESARO, Inc., a Delaware company, with principal offices located at 309 Waverley Oaks Rd., Suite 101, Waltham, MA 02452 ("TESARO") and OPKO Health, Inc., a Delaware corporation, with principal offices located at 4400 Biscayne Blvd., Miami, FL 33137 ("OPKO"). Each of TESARO and OPKO may be referred to, individually, as a "Party", and, collectively, as the "Parties".

RECITALS

WHEREAS, OPKO owns or controls certain patent rights and know-how related to the neurokinin-l (NK-l) receptor antagonists, SCH 619734 (Rolapitant) and SCH 900978;

WHEREAS, TESARO is interested in obtaining an exclusive license under such patent rights and to such know-how to develop and commercialize pharmaceutical products incorporating either or both of the foregoing compounds, and OPKO is willing to grant TESARO such a license, in each case on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained in this Agreement, OPKO and TESARO, intending to be legally bound, hereby agree as follows:

ARTICLE I
DEFINITIONS

When used in this Agreement, each of the following capitalized terms, whether used in the singular or plural, shall have the meaning set forth in this Article I.

1.1. "Affiliate" of an entity means any person or entity which, directly or indirectly, controls, is controlled by or is under common control with such entity. For the purposes of this definition, "control" refers to any of the following: (i) direct or indirect ownership of fifty percent (50%) or more of the voting securities entitled to vote for the election of directors in the case of a corporation, or of fifty percent (50%) or more of the equity interest with the power to direct management in the case of any other type of legal entity; (ii) status as a general partner in any partnership; or (iii) any other arrangement where a person or entity possesses, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract or otherwise. Notwithstanding the foregoing, the term "Affiliate" with respect to TESARO shall not include New Enterprise Associates.

1.2. "Agreement" means this Exclusive License Agreement, including any and all exhibits, schedules, appendices and other addenda to it and as it may be amended from time to time in accordance with the provisions of this document.

1.3. "API" means the active pharmaceutical ingredient contained in Licensed Product.

1.4. "API Cost" means the Cost of Goods of API.

1.5. "Asset Purchase Agreement" means that certain Asset Purchase Agreement between OPKO and Schering Corporation (now Merck & Co., Inc.) dated as of October 12, 2009, as amended by letter agreement dated June 29, 2010, under which OPKO purchased certain assets related to the Compounds.

1.6. "Combination Product" means any pharmaceutical product containing both a Licensed Product component and one or more other active pharmaceutical ingredients or other significant components.

1.7. "Commercially Reasonable Efforts" means the level of efforts and resources, including financial resources, at least equal to those normally used by a company to conduct the relevant activity, including, in the case of research, development or commercialization, the level of effort and resources at least equal to those normally used by such a company to research, develop, manufacture or commercialize, as the case may be, a product owned by such company or to which it has rights, which product is at a similar stage in its development or product life and is of a similar market and profitability potential to Licensed Product, taking into account all relevant factors including the patent and other proprietary position of the product, product labeling or anticipated labeling, market potential, financial return, medical and clinical considerations, regulatory environment and competitive market conditions, and other technical, legal, scientific, medical or commercial factors that such a company would deem to be relevant.

1.8. "Compounds" means SCH 619734 (Rolapitant) and SCH 900978.

1.9. "Confidential Information" means any and all information, data and materials of a confidential or proprietary nature, which are provided by or on behalf of one Party or any of its Affiliates to the other Party or any of its Affiliates in connection with this Agreement.

1.10. "Control" or "Controlled", other than for purposes of Section 1.1, means the possession of the right to grant licenses or sublicenses or to disclose proprietary or trade secret information without violating the terms of any agreement or other arrangement with a Third Party and without misappropriating or infringing the proprietary or trade secret information of a Third Party.

1.11. "Cost of Goods" means, with respect to API or Licensed Product, as the case may be, the aggregate of costs of TESARO or any of its Affiliates or Sublicensees to manufacture, package, label and release such API or Licensed Product, calculated as follows: (i) to the extent that the API or Licensed Product is manufactured, packaged, labeled or released by TESARO or any of its Affiliates or Sublicensees, their actual direct material costs and direct labor costs plus manufacturing overhead, directly and exclusively attributable to such API or Licensed Product (including the API incorporated into such Licensed Product), all calculated in accordance with GAAP; or (ii) to the extent that API or Licensed Product is manufactured, packaged, labeled or released by a Third Party, the actual amounts paid by TESARO or any of its Affiliates or Sublicensees to such Third Party for such activities performed on a specified quantity of such API or Licensed Product plus the costs of any materials (including API and raw materials) provided by TESARO or any of its Affiliates or Sublicensees to such Third Party for such activities, and any manufacturing overhead, quality control and distribution costs incurred by TESARO or any of its Affiliates or Sublicensees with respect to such materials provided or such Licensed Product, as calculated in accordance with clause (i) of this Section 1.11.

1.12. "Cover", "Covering" or "Covered" means, with respect to a Patent Right and invention, that, in the absence of ownership of, or a license under, such Patent Right, the practice of such invention would infringe a Valid Claim of such Patent Right (including in the case of a Patent Right that is a patent application, a Valid Claim of such patent application as if such patent application were an issued patent).

1.13. "EMA" means the European Medicines Agency or any successor agency.

1.14. "EU" means the countries of the European Union, as it is constituted as of the Effective Date and as it may be expanded from time to time.

1.15. "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.16. "Field" means with respect to SCH 619734 (Rolapitant) all therapeutic, prophylactic, palliative and diagnostic uses in humans, and means, with respect to SCH 900978, treatment of nausea or

vomiting of any cause; (ii) treatment of disease or treatment of symptoms or side effects of disease in oncology indications; (iii) treatment of side effects of oncology treatments or therapies; and (iv) any other supportive care indications in oncology.

1.17. "First Commercial Sale", as to a particular country, means the first commercial sale of a Licensed Product by TESARO or any of its Affiliates or Sublicensees to a Third Party in such country after approval of the NDA, or if approval of an NDA is not required in such country, then following receipt of Marketing Approval required to market such Licensed Product in such country.

1.18. "GAAP" means United States generally accepted accounting principles applied on a consistent basis, or any other accounting principles generally accepted for public companies in the United States such as International Financial Reporting Standards ("IFRS"). Unless otherwise defined or stated, financial terms shall be calculated under GAAP.

1.19. "IND" means an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application (CTA) or a clinical trial exemption (CTX).

1.20. "Japan Income" **** received from a Sublicensee with respect to development or commercialization of Licensed Product in Japan, less applicable **** of Licensed Product in Japan, provided that, if a royalty payment made by such Sublicensee to TESARO or any of its Affiliates includes the purchase price of a Licensed Product, then only **** of such Licensed Product will be included as Japan Income. For the sake of clarity, Japan Income will not include any of the following amounts received by TESARO or any of its Affiliates from a Sublicensee: (i) ****, which is **** or any of its Affiliates for expenditures actually incurred by **** or such Affiliate and which are directly attributable to development and commercialization of Licensed Product ****; (iii) reimbursement for **** or any of its Affiliates; and (iv) amounts paid by a **** or any of its Affiliates as **** actually incurred by TESARO or such Affiliate and which are directly attributable to ****, including reimbursement of ****, and the costs of maintaining the ****.

1.21. "Japan Income Sharing Term" has the meaning set forth in Section 4.6(b).

1.22. "Know-how" means all biological materials and other tangible materials, inventions, practices, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, procedures, specifications, assays, skills, experience, techniques, data and results of experimentation and testing, including pharmacological, toxicological, safety, stability and pre-clinical and clinical test data and analytical and quality control data, patentable or otherwise.

1.23. "Licensed Product" means any product comprising, incorporating or containing any Compound, or an alternate form of any Compound, including, but not limited to, a pharmaceutically acceptable salt, polymorph, crystal form, prodrug, or solvate of any Compound to the extent such alternate form is claimed in the OPKO Patent Rights.

1.24. "Major EU Markets" means the United Kingdom, France, Italy, Spain and Germany.

1.25. "Marketing Approval" means any approval, including price approval, registration, license or authorization from any Regulatory Authority required to market and sell a Licensed Product in a jurisdiction and shall include an approval, registration, license or authorization granted in connection with an NDA.

1.26. "NDA" means a New Drug Application, Biologics License Application or equivalent submission filed with the FDA in connection with seeking Marketing Approval of a Licensed Product, or an equivalent application filed with any equivalent regulatory agency or governmental authority in any jurisdiction other than the United States.

1.27. "Net Sales" means the gross amount invoiced on sales of Licensed Product in the Territory (not including sales of Licensed Product by a Sublicensee in Japan) by TESARO, its Affiliates or Sublicensees to any Third Party, less the following deductions with respect to the sale of such Licensed Product:

(i) normal trade, cash and quantity discounts and other customary discounts actually given to customers in the ordinary course of business;

(ii) rebates, credits and allowances given by reason of rejections, returns, damaged or defective product or recalls;

(iii) government-mandated rebates and any other compulsory payments, credits, adjustments and rebates actually paid or deducted;

(iv) price adjustments, allowances, credits, chargeback payments, discounts, rebates, fees, reimbursements or similar payments granted to managed care organizations, group purchasing organizations or other buying groups, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other health care institutions (including hospitals), health care administrators or patient assistance or other similar programs, or to federal, state/provincial, local and other governments, including their agencies, or to wholesalers, distributors or other trade customers;

(v) reasonable and customary freight, shipping, insurance and other transportation expenses, if actually borne by such TESARO or its Affiliates or Sublicensees without reimbursement from any Third Party;

(vi) sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, delivery or use of Licensed Product (but not including taxes assessed directly against the income derived from such sale) net of any credits or allowances received by TESARO or its Affiliates or Sublicensees with respect to such taxes or charges;

(vii) amounts previously included in Net Sales of Licensed Product that are written off as uncollectible after reasonable collection efforts, in accordance with standard practices of the applicable party; and

(viii) any item, substantially similar in character or substance to any of the foregoing, calculated in accordance with GAAP consistently applied and customary in the pharmaceutical industry to be deducted in the definition of net sales in a license agreement of this type.

Notwithstanding anything in this Agreement to the contrary, the transfer of a Licensed Product between or among TESARO, its Affiliates and Sublicensees will not be considered a sale.

Net Sales will include the cash consideration received on a sale and the fair market value of all non-cash consideration.

Disposition of Licensed Product for, or use of the Licensed Product in, clinical trials or other scientific testing, as free samples, or under compassionate use, patient assistance, or test marketing programs or other similar programs or studies where a Licensed Product is supplied without charge shall not result in

any Net Sales however if TESARO or any of its Affiliates or Sublicensees charges for such Licensed Product, the amount billed will be included in the calculation of Net Sales.

Net Sales will be determined from books and records maintained in accordance with GAAP, consistently applied throughout the organization and across all products of the entity whose sales of Licensed Product are giving rise to Net Sales.

In the event a Licensed Product is sold in the form of a Combination Product, then the Net Sales for any such Combination Product shall be determined by multiplying the Net Sales of the Combination Product during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the weighted (by sales volume) average sale price of the Licensed Product component when sold separately in finished form in the country in which the Combination Product is sold and B is the weighted (by sales volume) average sale price of the other active pharmaceutical ingredients or significant components included in the Combination Product when sold separately in finished form in the country in which the Combination Product is sold, in each case during the applicable royalty reporting period or, if sales of both the Licensed Product component and the other active pharmaceutical ingredients or significant components did not occur in such period, then in the most recent royalty reporting period during the preceding twelve (12) months in which sales of both occurred, if any. In the event that such average sale price cannot be determined for both the Licensed Product and all other active pharmaceutical ingredients or significant components included in the Combination Product, then the Parties will in good faith discuss and agree on a pro-rata allocation of the Net Sales that reflects the Licensed Product's contribution to the Combination Product on an equitable basis. TESARO covenants that neither it nor any of its Affiliates or Sublicensees will intentionally manipulate the fraction A/(A+B) to avoid or reduce royalty payments or obligations that would otherwise be due for sales of Licensed Product in combination form or otherwise

1.28. "OPKO Patent Rights" means (i) any and all patents and patent applications owned or otherwise Controlled by OPKO or any of its Affiliates on the Effective Date or at any time during the Term anywhere in the Territory that Cover OPKO Know-how or that otherwise Cover the research, formulation, development, manufacture, import, marketing, sale or use of Licensed Product in the Field; and (ii) any and all extensions or restorations of the foregoing patents or patent applications by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and supplementary protection certificates and the like. OPKO Patent Rights includes the patents and patent applications listed in Exhibit C.

1.29. "OPKO Japan Share" has the meaning set forth in Section 4.5, subject to adjustment as set forth in Section 4.7.

1.30. "OPKO Know-how" means any Know-how owned or otherwise Controlled by OPKO or any of its Affiliates as of the Effective Date or any time during the Term that (i) is incorporated into Licensed Product or the manufacturing process for Licensed Product; (ii) was used or generated in the development, manufacture or use of Licensed Product; or (iii) is otherwise reasonably necessary or useful to the research, formulation, development (including filing for and obtaining Marketing Approval), manufacture, import, marketing, sale or use of Licensed Product in the Field.

1.31. "Patent Rights" means patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, supplemental protection certificates and extensions and the like thereof, and all counterparts thereof in any country.

1.32. "Regulatory Authority" means any federal, national, multinational, state, county, city, provincial, or local regulatory agency, department, bureau or other governmental entity with authority over the marketing, commercialization, manufacture or sale of a pharmaceutical product in the Territory, including the FDA in the United States and the EMA in the EU.

1.33. "Royalty Term" has the meaning set forth in Section 4.6 (a).

1.34. "SCH 619734" (Rolapitant) means the compound described in Exhibit A.

1.35. "SCH 900978" means the compound described in Exhibit B.

1.36. "Sublicensee" means a Third Party to whom TESARO or any of its Affiliates or another Sublicensee grants an express sublicense under the OPKO Patent Rights and OPKO Know-how to develop, manufacture, commercialize or use Licensed Product in the Field, provided that the term "Sublicensee" does not include any wholesaler or third party distributor who re-sells a Licensed Product purchased from TESARO or any of its Affiliates or Sublicensees in final finished form (but not necessarily in final packaged, and labeled form), provided that OPKO is paid the royalty specified in Section 4.4 on the purchase price of such Licensed Product paid by such wholesaler or distributor to TESARO or any of its Affiliates or Sublicensees.

1.37. "Technology Transfer Plan" means the plan for transfer to TESARO of OPKO Know-how attached to this Agreement as Exhibit D.

1.38. "Term" means the term of this Agreement determined in accordance with Section 9.1.

1.39. "Territory" means worldwide.

1.40. "TESARO Improvement" means any Know-how owned or otherwise Controlled by TESARO or any of its Affiliates that constitutes an improvement of the OPKO Know-how developed during the Term and is incorporated into the Licensed Product by TESARO or any of its Affiliates.

1.41. "TESARO Improvement Patent Rights" means Patent Rights owned or Controlled by TESARO or any of its Affiliates Covering any TESARO Improvement.

1.42. "Third Party" means any person other than a Party or any of its Affiliates or their respective employees.

1.43. "Third Party Agreements" has the meaning set forth in Section 7.2(k).

1.44. "Third Party Payments" means all **** under licenses to intellectual property or to acquire intellectual property that is necessary for the development, manufacture, import, sale or use of Licensed Product in the Field. For purposes of this definition, the term "necessary" shall mean that, in the reasonable determination ****, if the relevant Patent Right of the Third Party were to be found to be valid, there would be **** that the manufacture, use or sale of Licensed Product would be found to infringe such Patent Right, provided that nothing in the foregoing requires a court or other legal determination of validity or infringement.

1.45. "United States" or "U.S." means the United States of America and its territories and possessions.

1.46. "Valid Claim" means (i) a claim of an issued and unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or been dedicated to the public, and (ii) a claim in a pending patent application that is being prosecuted and that has not been abandoned, disclaimed, allowed to lapse or finally determined to be unallowable by the

applicable governmental authority in a decision from which no appeal can be taken or from which no appeal is taken within the time allowed for appeal.

ARTICLE II
LICENSE GRANT

2.1. License Grant. Subject to the terms and conditions of this Agreement, OPKO and its Affiliates grant to TESARO an exclusive license (or sublicense, as the case may be) under the OPKO Patent Rights and the OPKO Know-how, in each case with the right to grant sublicenses, to the extent provided in Section 2.2, to research, develop, make, have made, use, import, export, market, offer for sale, sell and have sold, Licensed Product in the Territory within the applicable Field.

2.2. Sublicenses.

(a) Sublicensing. The rights granted to TESARO by OPKO under Section 2.1, may be extended to an Affiliate or sublicensed, in whole or in part, to a Third Party (through multiple levels of sublicensing); provided, that any sublicense that includes commercialization rights will require the prior consent of OPKO which such consent OPKO shall not unreasonably withhold, condition or delay. Notwithstanding anything in this Agreement to the contrary, OPKO shall be deemed to have granted its consent to any sublicense under this Section if OPKO has not provided TESARO with written notice of OPKO's reasonable objection to the sublicense within **** business days of receipt of a written request for such consent from TESARO, along with an unredacted copy of the relevant term sheet for an agreement which transfers rights granted hereunder so that OPKO may consider granting consent. In addition, TESARO will, promptly after signature, provide OPKO with an unredacted copy of each agreement with a Sublicensee executed by TESARO or any of its Affiliates. Permitted Sublicensees may also extend the rights granted under Section 2.1 to any of their Affiliates.

(b) Performance by Sublicensees. TESARO will be fully responsible for performance by each Sublicensee of its obligations under this Agreement. Each sublicense granted by TESARO pursuant to this Section 2.2 will contain terms and conditions consistent with those sections of this Agreement applicable to Sublicensees. Each sublicense agreement will contain the following provisions: (i) a requirement that any Sublicensee selling Licensed Product submit applicable sales or other reports to TESARO to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement; (ii) an audit requirement as to those Sublicensees selling Licensed Product consistent with that set forth in Section 4.15; and (iii) a requirement that such Sublicensee comply with the confidentiality provisions and restrictions on use of Confidential Information consistent with Article VI with respect to Confidential Information of OPKO. If TESARO becomes aware of a material breach by a Sublicensee of the rights granted to TESARO under Section 2.1, TESARO will promptly notify OPKO of the particulars of the same, and will use Commercially Reasonable Efforts to enforce the terms of such sublicense.

2.3. Covenant Not to Sue. At the request of TESARO, OPKO will use Commercially Reasonable Efforts to enforce the covenant not to sue obligations of Merck & Co., Ltd. under Section 7.7 of the Asset Purchase Agreement with respect to the activities of TESARO and its Affiliates and Sublicensees under this Agreement; provided, that TESARO will promptly reimburse all out-of-pocket expenses (including reasonable attorneys' fees and expenses) incurred by OPKO in connection with such requested efforts.

2.4. Responsibility; Decision-making. During the Term, **** will, including through **** Affiliates and Sublicensees, have **** responsibility for and **** decision-making authority with respect to, the research, development, manufacture, marketing, sale and use of Licensed Product in the Field, and except as otherwise expressly set forth in this Agreement, will be responsible for **** associated with such activities during the Term.

2.5. Diligence. TESARO will use Commercially Reasonable Efforts during the Term to develop and obtain Marketing Approval for a Licensed Product in the United States and in each Major EU Market, and to commercialize such Licensed Product in the United States and each Major EU Market if the relevant Marketing Approval is obtained. TESARO shall keep OPKO informed as to TESARO's progress in these efforts. In addition, TESARO will use Commercially Reasonable Efforts to secure any data and market exclusivity, including New Chemical Entity exclusivity, for a Licensed Product for which Marketing Approval is obtained to the extent available from the applicable Regulatory Authorities. TESARO agrees to register this Agreement with any foreign governmental agency, which requires such registration and where the failure to so register would have a material adverse impact on commercialization of Licensed Product in a major market, and **** in connection therewith. TESARO shall not be relieved of any of its obligations under this Agreement by any failure to register this Agreement in any country, and, specifically, shall not be relieved of its obligation to make any payment due to OPKO where such payment is blocked due to any failure to register this Agreement.

2.6. Joint Steering Committee.

(a) Formation. Within **** days after the Effective Date, the parties will form a committee (the "Joint Steering Committee") comprising at least **** representatives from each party.

(b) Responsibilities. The Joint Steering Committee will be responsible for (i) reviewing the status and progress of efforts related to the development, manufacture and registration of the Licensed Product; and (ii) discussing other matters related to this Agreement referred to it by agreement of the Parties. Each Party's representatives to the Joint Steering Committee shall communicate with one another as necessary to perform the Parties' respective obligations under this Agreement.

(c) Meetings. The Joint Steering Committee shall hold its first meeting in person within forty-five (45) days after the Effective Date. Thereafter, the Joint Steering Committee will meet as often as necessary either in person or by telephone at mutually acceptable times and locations. Either party may call a Joint Steering Committee meeting upon reasonable written notice, but not more than twice each year, unless both Parties mutually agree.

(d) Development Plan. The parties agree that **** shall prepare a written development plan (the "Development Plan") for the development of the Licensed Product within forty-five (45) days after the Effective Date. The Development Plan shall include schedules and milestones for the development activities of TESARO. **** may amend the Development Plan at any time ****. **** shall present the Development Plan and any material amendments to the Joint Steering Committee for review.

2.7. Latin America. OPKO will have the option to become the exclusive distributor of Licensed Product in Latin America on terms to be mutually agreed upon by the Parties (the "Latin America Option." To exercise its Latin America Option, OPKO must give written notice of such exercise to TESARO within **** after **** for Licensed Product in the **** . In the event OPKO does not give notice of its exercise of the Latin America Option within the foregoing time period or the Parties are unable, despite good faith negotiation, to agree on mutually acceptable terms of a distribution agreement, OPKO will have no further rights under this Section, and TESARO will be free to distribute Licensed Product in Latin America itself or through an Affiliate, Sublicensee or a Third Party distributor. Notwithstanding the foregoing, in the event the Parties are unable, despite good faith negotiation, to agree on mutually acceptable terms of a distribution Agreement, TESARO agrees that it will not enter into a final agreement with any Third Party regarding the rights to distribute Licensed Product in all of or any territory within Latin America (a "Latin American Opportunity") without first giving OPKO a good faith opportunity to agree to such Latin American Opportunity on material terms substantially similar to those offered (or intended to be offered) by TESARO to the Third Party (or offered by the Third Party to

TESARO) ("Right to Match"). OPKO's Right to Match with regard to Latin American Opportunities operates as follows:

(a) When a Latin American Opportunity arises, TESARO shall give OPKO prompt written notice of the material financial, intellectual property, term and termination, indemnification, governing law and other material terms of the Latin American Opportunity. Within **** after receiving TESARO's written notice under this Subsection 2.7(a), OPKO shall respond in writing to TESARO regarding whether it will substantially match or decline to substantially match the material terms of TESARO's proposed agreement.

(b) If, in its response, OPKO indicates its interest in substantially matching the material terms of TESARO's proposed agreement, the Parties shall negotiate in good faith a definitive agreement (with material terms substantially similar to those set forth in TESARO's proposed agreement) for a period of up to **** after TESARO received OPKO's response. If, after such time, a final agreement cannot be reached and the Parties do not mutually extend the negotiation period, TESARO shall be free to execute its proposed agreement with the Third Party on material terms no more favorable to the Third Party than the material terms presented to OPKO under subsection (a) above were to OPKO. However, if such material terms are more favorable to the Third Party, then TESARO must offer, and OPKO has a Right to Match, such terms in accordance with the procedures and restrictions contained in this Section 2.7.

ARTICLE III
TECHNOLOGY TRANSFER AND TRANSITION ACTIVITIES

3.1. Know-how Transfer. OPKO agrees to transfer to TESARO the OPKO Know-how specified in the Technology Transfer Plan in accordance with the time-lines and other requirements set forth in such plan, and to transfer such other OPKO Know-how, as TESARO may from time to time reasonably request during the Term, promptly after such request. In addition, OPKO will, as part of transfer of OPKO Know-how, assign to TESARO those Third Party Agreements as to which TESARO specifically requests assignment and which by their terms may be assigned. To the extent the consent of any Third Party is required to assign a Third Party Agreement to TESARO, OPKO will use Commercially Reasonable Efforts to obtain such consent. In the event a Third Party Agreement is not assigned to TESARO, OPKO will, as set forth in the Technology Transfer Plan, or as otherwise requested by TESARO, use Commercially Reasonable Efforts to obtain any information or other benefits under such agreement related to access to OPKO Know-how as would be available to OPKO.

3.2. Cooperation. OPKO shall make its personnel reasonably available to TESARO to respond to questions related to the OPKO Know-how, and to provide such ongoing support and assistance as TESARO may reasonably request in the transition of development and manufacturing responsibility for Licensed Products to TESARO. In connection with the foregoing, at the request of TESARO, OPKO will seek the assistance of Merck & Co., Ltd. to the extent such support continues to be available under Section 2.5 of the Asset Purchase Agreement.

3.3. Regulatory Transition. Within **** after the Effective Date, or as otherwise mutually agreed, the Parties will file with applicable Regulatory Authorities such documentation as may be required to transfer any IND to TESARO, and the Parties will use Commercially Reasonable Efforts to take such actions as any such Regulatory Authority may request to effect any such transfer. Prior to transfer of the IND, OPKO will continue to perform such obligations as are required under applicable law with respect to an IND holder, but under the direction of TESARO.

3.4. Supply of Material. OPKO will, **** transfer to TESARO in accordance with the Technology Transfer Plan all quantities of API and Licensed Product in OPKO's possession or control. To the extent such API or Licensed Product is identified as GMP-grade materials in the Technology Transfer Plan,

OPKO represents that (i) since OPKO's acquisition of such materials, OPKO has handled and stored such materials in accordance with current Good Manufacturing Practices as defined in the U.S. ("GMP"), and (ii) nothing has come to OPKO's attention which leads it to believe that any such material has not been manufactured and stored in accordance with GMP, that it would not conform in all material respects to the applicable specifications or would not be fit for use in clinical trials pursuant to FDA guidelines and requirements. OPKO will provide copies of batch records and certificates of compliance in its possession with respect to such material. In addition, OPKO will, at the request of TESARO, require Merck & Co., Inc. to deliver the Hold Back API, as defined in the Asset Purchase Agreement, to TESARO or its designee, and to supply addition quantities of API to the extent consistent with Merck & Co., Inc.'s obligation under Section 7.11(b) of the Asset Purchase Agreement on terms to be approved by TESARO.

3.5. Costs. Each Party **** associated with technology transfer activities to be provided under this Section. To the extent any technology transfer activities to be provided under this Section require **** bear the costs of such external resources, provided that such activities and costs are expressly set forth in the Technology Transfer Plan or are otherwise approved in writing in advance by ****.

ARTICLE IV
FINANCIAL PROVISIONS

4.1. License Fee. Within ten (10) days of the Effective Date, TESARO will pay to OPKO a non-creditable, non-refundable license fee of $6,000,000, as compensation for past and future research and development expenses, patent prosecution and maintenance fees, and for exclusive rights to the Licensed Product in the U.S.

4.2. Intentionally Left Blank

4.3. Milestones Payments by TESARO. Subject to the terms and conditions of this Agreement, TESARO will pay OPKO a milestone payment upon the first occurrence of each of the following events, no later than thirty (30) days after the occurrence of the event:

Event Milestone	Event Milestone Payment
(i) Acceptance by the FDA of the first NDA for Marketing Approval of Licensed Product in the United States	$ ****,000,000
(ii) First Commercial Sale of Licensed Product in the U.S.	$ ****,000,000

Event Milestone	Event Milestone Payment
(iii) First Commercial Sale of Licensed Product in the EU	$ ****,000,000

Each of the above milestone payments will be payable only upon the first occurrence of the applicable event, regardless of how many times the event is ultimately achieved.

In addition, TESARO will pay to OPKO the following commercial milestone payments upon the first achievement of the corresponding event:

First achievement of calendar year Net Sales in excess of $**** million	$****,000,000
First achievement of calendar year Net Sales in excess of $**** million	$****,000,000
First achievement of calendar year Net Sales in excess of $**** million	$****,000,000

4.4. Royalty Payments by TESARO. Subject to the adjustment, if any, to be made under Sections 4.7 and 4.8, TESARO will pay to OPKO royalties on Net Sales of Licensed Product in the Field in the Territory (other than sales of Licensed Product by a Sublicensee in Japan) by TESARO and its Affiliates and Sublicensees, calculated using the following royalty rates:

(a) U.S. and EU. For the sale of Licensed Product in the U.S. and the EU, the royalty rate will be the Tier One Royalty Rate or the Tier Two Royalty Rate, as set forth below, depending on the applicable ****. The Tier One royalty rates will apply if the average **** of Licensed Product sold by TESARO and its Affiliates and Sublicensees during the preceding calendar year was equal to or greater than ****. The Tier Two royalty rates will apply if the average **** of Licensed Product sold by TESARO and its Affiliates and Sublicensees during the preceding calendar year was less than ****. Notwithstanding the foregoing, the **** used to determine whether to apply the Tier One Royalty Rate or the Tier Two Royalty Rate in the launch year will be based the average **** for the **** during the **** preceding the date of First Commercial Sale.

Portion of Calendar Year Net Sales in the United States	Tier One Royalty Rates	Tier Two Royalty Rates
On that portion of calendar year Net Sales in the U. S. less than or equal to $**** million	****%	****%
On that portion of calendar year Net Sales in the U. S. greater than $**** million but less than or equal to $**** million	****%	****%
On that portion of calendar year Net	****%	****%

Portion of Calendar Year Net Sales in the United States	Tier One Royalty Rates	Tier Two Royalty Rates
Sales in the U.S. greater than $**** million but less than or equal to $**** million On that portion of calendar year Net Sales in the U.S. greater than $**** million	****%	****%

Portion of Calendar Year Net Sales in the EU	Tier One Royalty Rate	Tier Two Royalty Rate
On that portion of calendar year Net Sales in the EU less than or equal to $**** million	****%	****%
On that portion of calendar year Net Sales in the EU greater than $**** million but less than or equal to $**** million	****%	****%
On that portion of calendar year Net Sales in the EU greater than $**** million but less than or equal to $**** million	****%	****%
On that portion of calendar year Net Sales in the EU greater than $**** million	****%	****%

(b) Rest of World Other than Japan. The royalty rate outside the U.S., EU and Japan will be ****%.

(c) Minimum Annual Royalty. If the aggregate amount of royalties paid or payable by TESARO to OPKO on sales of Licensed Products under this Section during each of the first **** calendar years commencing with the **** calendar year following the **** of Licensed Product in the **** and ending with the calendar year in which the **** anniversary of the **** occurs (the "Measurement Period") is less than **** (the "Minimum Annual Royalty"), then within forty-five (45) days of the end of each such calendar year, TESARO will pay OPKO an amount equal to the difference between the **** and the aggregate amount of royalties paid or payable to OPKO on sales of the Licensed Product during such calendar year (the "Annual Royalty Shortfall"). During the Measurement Period, any Annual Royalty Shortfall paid or payable by TESARO **** the aggregate amount of royalties **** Measurement Period that exceeded **** and any royalties payable during the Measurement Period that exceed **** by the amount of any Annual Royalty Shortfall payments made in any **** and not ****. The Minimum Annual Royalty will not apply, and no Annual Royalty Shortfall will be due, in the event the commercial potential of any Licensed Product in the U.S. has been materially adversely affected by: (i) the ****; (ii) **** identified in the course of **** or commercialization of Licensed Product; (iii) **** of an issued patent within OPKO Patent Rights Covering the Licensed Product in the United States.

4.5. Japan. TESARO will pay OPKO **** of all Japan Income (the "OPKO Japan Share"). In the event OPKO is required to make payments to a Third Party under an agreement in existence as of the Effective Date, based on the OPKO Japan Share of the Japan Income (the "OPKO Third Party Obligation"), TESARO will pay up to **** of such OPKO Third Party Obligation, provided that, in no event will TESARO's share of the OPKO Third Party Obligation exceed **** of the amounts that would otherwise be payable to OPKO **** Obligation. In the event sales of Licensed Product in Japan **** any of its Affiliates and are **** a Sublicensee, TESARO will pay to OPKO royalties on Net Sales of Licensed Product in Japan at the rate of ****, subject to the adjustments set forth in Section 4.7 and 4.8 to the same extent as applicable to royalties on Net Sales payable under Section 4.4.

4.6. Royalty and Income Sharing Term.

(a) Royalties. Royalties under Section 4.4 will be payable on a country by country and Licensed Product-by-Licensed Product basis during the period commencing on the First Commercial Sale of such Licensed Product in the applicable Field in such country and ending upon the later of (i) the date of expiration, unenforceability or invalidation of the last Valid Claim of OPKO Patent Rights

Covering such Licensed Product in such country, and (ii) **** years from the date of First Commercial Sale in such country (the "Royalty Term").

(b) Japan Income Sharing. TESARO's obligation to share Japan Income under Section 4.5 will be payable on a Licensed Product-by-Licensed Product basis during the period commencing on the Effective Date and ending upon the later of (i) the date of expiration, unenforceability or invalidation of the last Valid Claim of OPKO Patent Rights Covering Licensed Product in Japan, and (ii) **** from the date of First Commercial Sale in Japan ("Japan Income Sharing Term).

(c) End of Royalty Term or Japan Income Sharing Term. Upon expiration of the Royalty Term or Japan Income Sharing Term, as the case may be, in the country of sale, the license granted to TESARO and its Affiliates and Sublicenses under Article II will convert to a fully paid-up, non-royalty-bearing, license in the applicable country.

4.7. Reduction for No Valid Claim. The royalties payable under Section 4.4 with respect to Net Sales of a Licensed Product will be reduced, on a country by country and Licensed Product-by-Licensed Product basis, by **** of the amounts otherwise payable under Section 4.4, during any portion of the Royalty Term when there is no Valid Claim of an issued patent within OPKO Patent Rights Covering such Licensed Product in the country of sale or other protective data or marketing exclusivity. Notwithstanding the foregoing, in the event there is no Valid Claim of an issued patent within OPKO Patent Right Covering a Licensed Product being sold in a country and a Third Party has obtained Marketing Approval in such country for a product containing the same active ingredient as contained in Licensed Product, the reduction on royalties under the preceding sentence will be increased to ****.

4.8. Third Party Payments.

(a) OPKO Payments. Except as specifically set forth in Section 4.5, **** will pay all milestones and other payments due under ****, and under any other agreement to which OPKO or any of its Affiliates is a party.

(b) Other Third Party Payments. **** will have the right to deduct from **** payable to **** under Section 4.4 (after application of the deductions set forth in Section 4.7), **** of Third Party Payments, provided that in no event will the royalty payable to OPKO on Net Sales of Licensed Product be reduced as a result of application of this paragraph, to less than **** of the amount otherwise payable under Section 4.4, as reduced by Section 4.7. Amounts available for offset under this Section and not used as a credit against royalties in the period incurred may be carried over to future periods until fully utilized.

4.9. Payments; Reports. TESARO will pay royalties due on Net Sales and amounts due with respect to Japan Income received in a calendar quarter within **** days of the end of such calendar quarter. Within **** days after the end of each calendar quarter for which amounts are payable by TESARO under Section 4.4 or 4.5, TESARO will submit to OPKO a report, on a country-by-country basis, providing in reasonable detail an accounting of all Net Sales by TESARO and its Affiliates and Sublicensees in the Territory (including, in each case, an accounting of all unit sales of the Licensed Product and a calculation of the deductions from gross invoice price to Net Sales in accordance with Section 1.27) made during such calendar quarter and all Japan Income and the calculation of the applicable amounts due under Section 4.4 and 4.5. TESARO will, at the time TESARO submits a report under this Section, pay to OPKO all amounts due to OPKO under Sections 4.4 and 4.5, as indicated in the applicable report.

4.10. Taxes. TESARO will make all payments to OPKO under this Agreement without deduction or withholding except to the extent that any such deduction or withholding is required by applicable law to be made on account of Taxes (as that term is defined below). Any Tax required to be

withheld under applicable law on amounts payable under this Agreement will promptly be paid by TESARO or its Affiliates or Sublicensees on behalf of OPKO to the appropriate governmental authority, and TESARO will furnish OPKO with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by OPKO. TESARO will give notice of its intention to begin withholding any such Tax in advance and cooperate to use reasonable and legal efforts to reduce such Tax on payments made to OPKO hereunder. The Parties will cooperate with respect to all documentation required by any relevant government taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes. Solely for purposes of this Section 4.10, "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by a government authority, but not including TESARO income taxes.

4.11. United States Dollars. All dollar ($) amounts specified in this Agreement are United States dollar amounts.

4.12. Currency Conversion. All payments to be made by TESARO to OPKO will be made in U.S. Dollars, to a bank account designated by OPKO. In the case of sales outside the United States, payments received by TESARO will be expressed in the U.S. Dollar equivalent calculated on a quarterly basis in the currency of the country of sale and converted to their U.S. Dollar equivalent using the average rate of exchange over the applicable calendar quarter to which the sales relate, in accordance with GAAP and the then current standard methods of TESARO or the applicable Sublicensee, to the extent reasonable and consistently applied. TESARO will inform OPKO as to the specific exchange rate translation methodology used for a particular country or countries.

4.13. Blocked Payments. If, by reason of applicable laws or regulations in any country, it becomes impossible or illegal for TESARO or any of its Affiliates or Sublicensees to move revenues related to Licensed Product out of such country, TESARO will promptly notify OPKO of the conditions preventing such transfer, and royalties on the affected Net Sales or amounts payable on Japan Income shall, in lieu of payment under Section 4.9, be deposited in local currency in the relevant country to the credit of OPKO in a recognized banking institution in such county designated by OPKO or, if none is designated by OPKO within a period of thirty (30) days, in a recognized banking institution in such county selected by TESARO or its Affiliates or Sublicensees, as the case may be, and identified in a notice given to the Party on whose account the funds are deposited.

4.14. Late Payments. TESARO will pay interest to OPKO on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of one and **** per month or the highest rate permitted by applicable law, calculated based on the number of days such payments are paid after the date such payments are due.

4.15. Records and Audits. TESARO will keep complete and accurate records relating to the calculations of Net Sales and Japan Income generated in the then current calendar year, and during the preceding ****. OPKO will have the right, **** at its ****, to have a nationally recognized, independent, certified public accounting firm, selected by it and reasonably acceptable to TESARO, review any such records of TESARO and its Affiliates and Sublicensees (the "Audited Party") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 4.4 and 4.5 within the **** period preceding the date of the request for review. No **** will be subject to audit under this Section more than once. TESARO will receive a copy of each such report concurrently with receipt by OPKO. Should such inspection lead to the discovery of a discrepancy to OPKO's detriment, TESARO will, within thirty (30) days after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy, plus interest on the underpayment at a rate per annum equal to the lesser of **** per month or the highest rate permitted by applicable law,

calculated from the date the underpayment was made until the date of payment to OPKO of the underpayment. **** will pay the full cost of the review unless the underpayment of amounts due to **** is greater than **** of the amount due for the entire period being examined, in which case **** will pay the reasonable cost charged by such accounting firm for such review. Any undisputed overpayment of royalties by TESARO revealed by an examination will be paid by OPKO within **** of OPKO's receipt of the applicable report. Any disagreement regarding the results of any audit conducted under this Section will be subject to the dispute resolution provisions set forth in Article X.

ARTICLE V
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

5.1. Prosecution and Maintenance of Patent Rights. Within **** after the Effective Date, OPKO will transfer to TESARO responsibility for filing, prosecuting and maintaining all OPKO Patent Rights (other than the OPKO Patent Rights, if any, that were licensed but not assigned to OPKO under the Asset Purchase Agreement) in such a way that there is not any loss of rights during such **** day period or in connection with the transition, including consulting with TESARO and cooperating with TESARO related to such activities prior to completion of the transition, and contacting the foreign agents of OPKO to assist in the transfer of power of attorney as required by the relevant patent offices for TESARO to assume prosecution of such files. Commencing after notification to the USPTO and OPKO foreign agent of the change in prosecution status, TESARO will have responsibility, at TESARO's cost, for filing, conducting prosecution, and maintaining (including the defense of any interference or opposition proceedings) all such OPKO Patent Rights as to which OPKO has assumed and maintains responsibility under this Section, and shall use Commercially Reasonable Efforts in the conduct of such activities. TESARO will provide to OPKO copies of all prosecution filings and material submissions and correspondence related to OPKO Patent Rights for which TESARO has assumed and maintains responsibility under this Section sent to or received from patent offices, and other service providers including maintenance fee providers, and, with respect to patent applications, and material submissions, will use reasonable efforts to provide OPKO with a draft of each such filing or material submission reasonably in advance of submission, and will consider in good faith any comments that OPKO may timely provide. In addition, TESARO will provide to OPKO such other information related to prosecution of the OPKO Patent Rights for which TESARO has assumed and maintains responsibility under this Section as OPKO may from time to time reasonably request to allow OPKO to track prosecution and maintenance of such OPKO Patent Rights including docket reports of all pending and issued patents and patent applications within OPKO Patent Rights. In the event TESARO decides to abandon prosecution in any country with respect to an OPKO Patent Right for which TESARO is responsible under this Section in a particular country or decides to not otherwise maintain or extend any OPKO Patent Right for which TESARO is responsible under this Agreement in a particular country, in either case where a substitute is not filed for such OPKO Patent Right (such OPKO Patent Right in the applicable country being referred to in this Agreement as an "Abandoned Patent Right"), TESARO will give OPKO written notice, and will transfer the relevant files and authority to OPKO, sufficiently in advance of any loss of rights to allow OPKO to file, prosecute, maintain or extend, as the case may be, claims with respect to such Abandoned Patent Rights in the relevant country, and such Abandoned Patent Right in the relevant country will no longer be included as an OPKO Patent Right licensed to TESARO under Agreement.

5.2. Patent Term Extensions. TESARO will use Commercially Reasonable Efforts to obtain patent term extensions (including those extensions available under U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country) wherever applicable to licensed OPKO Patent Rights as to which TESARO controls prosecution that Cover Licensed Product in the Field in the Territory, and OPKO will cooperate, at TESARO's request and expense in connection with such activities. All filings for such extensions shall be made by the Party responsible for filing, prosecuting and maintaining the relevant Patent Rights in accordance with this Section.

5.3. Third Party Infringement.

(a) Notices. Each Party will promptly report in writing to the other Party any (i) known or suspected infringement of any OPKO Patent Rights, or (ii) unauthorized use or misappropriation of any OPKO Know-how by a Third Party, of which such Party becomes aware, in each case only to the extent relevant to Licensed Product or the development, manufacture, commercialization or use of Licensed Product in the Field in the Territory, and will provide the other Party with all available information evidencing such infringement, or unauthorized use or misappropriation.

(b) TESARO First Right to Enforce Certain OPKO Patent Rights. TESARO or its designated Affiliate or Sublicensee will have the first right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to prevent or abate actual or threatened infringement or misappropriation of, or otherwise protect or enforce, the OPKO Patent Rights as to which TESARO controls prosecution against a Third Party who is researching, developing, making, using or selling a product in the Field in a country within the Territory. OPKO and its Affiliates will join such suit if the relevant court would lack jurisdiction if OPKO or such Affiliate were absent from such suit and OPKO and such Affiliates will execute such legal papers and cooperate in the prosecution of such suit as may be reasonably requested by TESARO; provided, that **** incurred by **** and such Affiliates in connection with such requested cooperation.

(c) OPKO Rights if TESARO Elects Not to Proceed. If TESARO does not initiate a suit or take other appropriate action pursuant to Section 5.3(b) within **** days after knowledge of such infringement or misappropriation or, in the case of receipt of a notice letter sent by a Third Party pursuant to the requirements of 21 U.S.C. § 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) or under any analogous provisions, within **** before any statutory or regulatory deadline for filing such suit, then OPKO will have the immediate right to initiate a suit or take other appropriate action that it believes is reasonably required to prevent or abate actual or threatened infringement or misappropriation of, or otherwise to protect or enforce the relevant OPKO Patent Rights. TESARO and its Affiliates will join such suit if the relevant court would lack jurisdiction if TESARO or such Affiliates were absent from such suit and TESARO and such Affiliates will execute such legal papers and cooperate in the prosecution of such suit as may be reasonably requested by OPKO; provided, that **** (including ****) incurred by **** and such Affiliates in connection with such requested cooperation.

(d) Enforcement Against Other Infringement of OPKO Patent Rights. Except as provided in Section 5.3(b), OPKO will have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to prevent or abate actual or threatened infringement or misappropriation of, or otherwise to protect or enforce, OPKO Patent Rights during the Term.

(e) Right to Enforce Know-how. Responsibility for preventing or abating actual or threatened infringement or misappropriation of, or otherwise protecting or enforcing OPKO Know-how will be determined in the same manner as the right to enforce OPKO Patent Rights under paragraph (b) and (c). The enforcing Party shall keep the other Party informed of the status of all enforcement activities, and shall consider in good faith all comments of the other Party regarding any aspect of such enforcement.

(f) Conduct of Certain Actions; Costs. The Party initiating suit under this Section 5.3 will have the sole and exclusive right to select counsel for any suit initiated by it pursuant to this Section. The initiating Party will assume and **** incurred in connection with any litigation or proceedings initiated by it pursuant to this Section, including the **** selected by it.

(g) Recoveries.

(i) If TESARO initiates suit as permitted in accordance with Section 5.3(b) or, with respect to OPKO Know-how, in the same manner as set forth in Section 5.3(b), any damages, settlements, accounts of profits, or other financial compensation actually paid to TESARO by a Third Party based upon such suit, after deducting TESARO's actual out of pocket expenses (including reasonable attorneys' fees and expenses) incurred in pursuing such suit (such net amount, the "Recovery"), will be treated as Net Sales, and will be subject to the royalty payment obligations under Section 4.4 (provided that, for purposes of calculating the applicable royalty rate, such Recovery will not be combined with any calendar year Net Sales), with TESARO retaining the balance after such payment.

(ii) If OPKO initiates suit pursuant to Section 5.3(b) or with respect to OPKO Know-how, in the same manner as set forth in Section 5.3(b), OPKO may retain any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party based upon such suit.

5.4. Patent Invalidity Claim. Each of the Parties will promptly notify the other Party in the event of any legal or administrative action by any Third Party against an OPKO Patent Right, or any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) or 355G)(2)(A)(vii)(IV) or any notice under any analogous provisions, with respect to such Patent Rights, of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Responsibility for defending against any such action shall be determined in the same manner as enforcement of the relevant Patent Rights pursuant to Section 5.3.

5.5. Patent Marking. TESARO agrees to comply with the patent marking statutes in each country in which the Licensed Product is sold by TESARO or its Affiliates or Sublicensees.

ARTICLE VI
CONFIDENTIALITY

6.1. Confidential Information. During the Term and for a period of **** after any termination or expiration of this Agreement, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement (which, in the case of TESARO and its Affiliates and Sublicensees, includes activities contemplated by the licenses granted in Sections 2.1) or as otherwise specifically permitted under this Agreement, any Confidential Information of the other Party. The terms of this Agreement will be considered Confidential Information of both Parties, subject to permitted disclosures as set forth in this Article VI. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section 6.1 will not apply to any Confidential Information that:

(i) was known by the receiving Party prior to disclosure by the disclosing Party hereunder (as evidenced by the receiving Party's written records or other competent evidence);

(ii) is or becomes part of the public domain through no fault of the receiving Party;

(iii) is disclosed to the receiving Party by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party and provided such Third Party is not disclosing such information on behalf of the disclosing Party; or

(iv) is independently developed by personnel of the receiving Party who did not have access to the Confidential Information (as evidenced by the receiving Party's written records or other competent evidence).

In addition, if either Party is required to disclose Confidential Information of the other Party by regulation, law or legal process, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or Nasdaq, such Party shall provide prior written notice and a copy of such intended disclosure to such other Party if possible under the circumstances, will consider in good faith the other Party's comments, will disclose only such Confidential Information of such other Party as is required to be disclosed and will cooperate in the disclosing Party's efforts to obtain a protective order or to limit the scope of the required disclosures. Notwithstanding anything in this Agreement to the contrary, either Party may disclose to bona fide potential or existing investors or lenders, potential acquirors/acquirees, and, in the case of TESARO, to potential and existing sublicensees and collaborators, and to such Party's consultants and advisors, the existence and terms of this Agreement to the extent necessary in connection with a proposed equity or debt financing of such Party, or a proposed acquisition or business combination or transaction, so long as such recipients are bound in writing to maintain the confidentiality of such information.

6.2. Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, consultants, advisors and bona fide potential acquirors, and, in the case of TESARO as the receiving Party, to service providers, investigators, Third Party contractors, potential and existing Sublicensees and distributors, in each case who, in such Party's reasonable judgment, have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement (which, in the case of TESARO and its Affiliates and Sublicensees, includes activities contemplated by the license granted in Sections 2.1) or in connection with a potential business relationship or investment that would encompass Licensed Product, and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party under Section 6.1. OPKO and TESARO shall each remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants, advisors and permitted contractors, sublicensees and distributors, to treat such Confidential Information as required under Section 6.1 (as if such Affiliates, employees, consultants, advisors, contractors, sublicensees and distributors were Parties directly bound to the requirements of Section 6.1). TESARO may also disclose Confidential Information of OPKO to Regulatory Authorities and other governmental authorities, but solely in connection with the activities contemplated by this Agreement.

6.3. Limitation on OPKO Disclosure of OPKO Know-how. During the Term of this Agreement, OPKO will not disclose OPKO Know-how that is specific to Licensed Product or the development, manufacture, commercialization or use of Licensed Product to any Third Party without the express written consent of TESARO.

6.4. Publicity. Neither Party will issue a press release or public announcement relating to the terms of this Agreement without the prior written approval of the other Party, which approval shall not be unreasonably withheld or delayed, except that (i) either or both of the Parties may issue a press release in the form attached as Exhibit E; (ii) a Party may issue such press release or public announcement if the contents of such press release or public announcement are consistent with a previously approved press release or have otherwise previously been made public other than through a breach of this Agreement, and (ii) a Party may issue such a press release or public announcement if required by applicable law, including by the rules or regulations of the United States Securities and Exchange Commission (SEC) or similar regulatory agency in a country other than the United States or of any stock exchange or Nasdaq; provided that such Party complies with the notice and review provisions set forth in this Section. In no

event will OPKO make any public disclosure related to TESARO's activities under this Agreement or related to the results generated by TESARO or any of its Affiliates or Sublicensees with respect to Licensed Product without the prior written consent of TESARO except to the extent required by applicable law. In the event OPKO is required by applicable law to publicly disclose any of the results generated by TESARO or any of its Affiliates or Sublicensees or any information provided by TESARO related to Licensed Product or either Party is required by applicable law to disclose the terms of this Agreement, such Party will give the other Party at least two (2) business days' prior written notice, will provide to such other Party a copy of the required disclosure, will, if requested by such other Party, to the extent permitted by applicable law, request confidential treatment of any financial and other materials terms of this Agreement not previously disclosed under this Section, and will consider in good faith any other comments of such other Party on such public disclosure.

6.5. Publications. TESARO and its Affiliates and Sublicensees shall have the sole right to publish the results of development, manufacture, commercialization and use of Licensed Product during the Term.

6.6. Return of Confidential Information. Upon termination of this Agreement prior to the end of the Term, the receiving Party shall, at the request of, and as directed by, the disclosing Party, return or destroy Confidential Information of the disclosing Party in the receiving Party's possession, and shall destroy any reports or notes in receiving Party's possession t6 the extent containing the disclosing Party's Confidential Information, and any electronic copies of any of the foregoing, provided that (i) the receiving Party may retain one copy of Confidential Information of the disclosing Party for archival purposes, and (ii) neither Party shall be required to return or destroy copies of the other Party's Confidential Information stored on automatically created system back-up media.

ARTICLE VII
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

7.1. Mutual Representations. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows:

(a) It is duly organized and validly existing under the laws of its jurisdiction of incorporation and has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

(b) The execution, delivery and performance of this Agreement by such Party has been duly and validly authorized and approved by proper corporate action on the part of such Party. Such Party has taken all other action required by applicable law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party.

(c) The execution and delivery of this Agreement, and the performance as contemplated hereunder, by such Party will not violate any applicable law.

(d) Neither the execution and delivery of this Agreement nor the performance hereof by such Party requires such Party to obtain any permit, authorization or consent from any governmental authority (except for any Regulatory Approvals, pricing or reimbursement approvals, manufacturing-related approvals or similar approvals necessary for development, manufacture or commercialization of Licensed Products), or from any other person, and such execution, delivery and performance by such Party, including the granting of the licenses granted under this Agreement, will not result in the breach of or give rise to any conflict, termination of, rescission, renegotiation or acceleration under or trigger any

other rights under any agreement or contract to which such Party may be a party existing as of the Effective Date.

(e) Neither Party nor any of its Affiliates has been debarred or is subject to debarment, and OPKO has not used in any capacity in connection with the development or manufacture of Licensed Product prior to the Effective Date, any person or entity who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or who is the subject of a conviction described in such section.

7.2. OPKO's Representations and Warranties. OPKO hereby makes the following representations and warranties to TESARO as of the Effective Date:

(a) OPKO has the right to grant to TESARO the rights and licenses described in this Agreement.

(b) Exhibit C contains a complete and correct list of all existing OPKO Patent Rights.

(c) To OPKO's knowledge, no Third Party is infringing any of the OPKO Patent Rights identified on Exhibit C.

(d) To OPKO's knowledge, except as discussed with TESARO, the making, using or selling of a Licensed Product will not infringe any Third Party Patent Rights.

(e) OPKO has not received any written notice of (i) any claim that any patent or trade secret right owned or controlled by a Third Party would be infringed or misappropriated by the manufacture, use, sale, offer for sale or importation of Licensed Products in the Field, or (ii) any threatened claims or litigation seeking to invalidate or otherwise challenge the OPKO Patent Rights or OPKO's rights therein.

(f) OPKO's rights to OPKO Patent Rights and OPKO Know-how are held free and clear of any liens, security interests and similar encumbrances.

(g) None of the OPKO Patent Rights owned by OPKO are the subject of any pending re-examination, opposition, interference or litigation proceedings.

(h) To OPKO's knowledge, there have been no inventorship or ownership challenges with respect to any of the OPKO Compound Patent Rights.

(i) The OPKO Patent Rights that are pending patent applications as of the Effective Date are being diligently prosecuted at the respective patent offices. To OPKO's knowledge, the OPKO Patent Rights that are issued patents have been maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

(j) There are no agreements pursuant to which a Third Party has licensed to OPKO any OPKO Patent Rights or OPKO Know-how or pursuant to which OPKO or any of its Affiliates has otherwise acquired any OPKO Patent Rights or OPKO Know-how from a Third Party other than the Asset Purchase Agreement or other Third Party Agreements.

(k) A complete list of material agreements to which OPKO or any of its Affiliates is a Party related to the development, manufacture, use or sale of Licensed Product or under which OPKO may otherwise be required to make payments to Third Parties related to this Agreement is attached as Exhibit F (the "Third Party Agreements"). OPKO will not amend, allow to terminate, or waive any of its

rights or obligations under the Asset Purchase Agreement in a manner which would adversely impact the rights licensed to TESARO under this Agreement, except as approved in writing in advance by TESARO.

(l) To OPKO's knowledge, the research, development and manufacture of Licensed Product in the Territory on or before the Effective Date has been conducted by OPKO and its Affiliates and its subcontractors, in compliance (in all material respects) with all applicable laws.

(m) Neither OPKO nor its Affiliates has received written notice from any Regulatory Authority threatening any proceedings with respect to the research, development or manufacture of any Licensed Product in the Field in the Territory.

(n) To OPKO's knowledge, OPKO has not intentionally withheld any material information relating to the subject matter of this Agreement.

7.3. No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY HERETO MAKES ANY REPRESENTATIONS AND NEITHER PARTY EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT (INCLUDING ANY LICENSED PRODUCT), INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, OPKO MAKES NO WARRANTY OR REPRESENTATION AS TO THE VALIDITY OR SCOPE OF THE OPKO PATENT RIGHTS OR OPKO KNOW HOW, OR THAT ANY LICENSED PRODUCT WILL BE FREE FROM AN INFRINGEMENT ON PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR THAT NO THIRD PARTIES ARE IN ANY WAY INFRINGING OR NOT INFRINGING THE OPKO PATENT RIGHTS OR OPKO KNOW HOW COVERED BY THIS AGREEMENT. TESARO DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF LICENSED PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT, IF COMMERCIALIZED, ANY PARTICULAR SALES LEVEL WILL BE ACHIEVED.

ARTICLE VIII
INDEMNIFICATION

8.1. Indemnification by TESARO. TESARO will indemnify, hold harmless, and defend OPKO, its Affiliates, and their respective directors, officers, employees and agents (the "OPKO Indemnitees") from and against any and all damages, liabilities, costs, expenses and amounts paid in settlement (collectively, "Losses") incurred in connection with any Third Party claim arising out of or resulting from, directly or indirectly; (i) any breach of, or inaccuracy in, any representation or warranty made by TESARO in this Agreement, or any breach or violation of any term of this Agreement by TESARO; (ii) the negligence or willful misconduct of TESARO, its Affiliates and their respective Sublicensees, and their respective directors, officers, employees and agents; and (iii) the research, development, manufacture, commercialization, or use of Licensed Product by TESARO and its Affiliates and Sublicensees in the Territory in the Field under this Agreement. Notwithstanding the foregoing or anything in this Agreement to the contrary, TESARO will have no obligation to indemnify the OPKO Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by OPKO in this Agreement; any breach or violation of any term of this Agreement by OPKO; the negligence or willful misconduct of any of the OPKO Indemnitees or any other Losses as to which OPKO is obligated to indemnify TESARO under Section 8.2.

8.2. Indemnification by OPKO. OPKO will indemnify, hold harmless, and defend TESARO, its Affiliates and their respective directors, officers, employees and agents (the "TESARO Indemnitees")

from and against any and all Losses incurred in connection with any Third Party Claim arising out of or resulting from, directly or indirectly, (i) any breach of, or inaccuracy in, any representation or warranty made by OPKO in this Agreement, or any breach or violation of any term of this Agreement by OPKO; (ii) the negligence or willful misconduct of any OPKO Indemnitee; (iii) the research, development, manufacture or use of Licensed Product by or on behalf of OPKO or any of its Affiliates prior to commencement of the Term; or (iv) the research, development, manufacture, commercialization, or use of Licensed Product by OPKO or any of its Affiliates or licensees (other than TESARO) or any other activities of OPKO and its Affiliates and licensees (other than TESARO) outside the Field. Notwithstanding the foregoing, or anything in this Agreement to the contrary, OPKO will have no obligation to indemnify the TESARO Indemnitees for any Losses as to which TESARO is obligated to indemnify OPKO under Section 8.1.

8.3. Indemnification Procedure. In the event of any such claim against any TESARO Indemnitee or OPKO Indemnitee (individually, an "Indemnitee"), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the defense of the claim and its settlement. The indemnified Party will cooperate with the indemnifying Party and may, at the indemnifying Party's option and expense, be represented in any such action or proceeding. The indemnifying Party will not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party's prior written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in this Article 8 may apply, the indemnifying Party will promptly notify the Indemnitees, who shall then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party will be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party.

8.4. Limitation of Liability. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A PARTY'S WILLFUL MISCONDUCT. NOTHING IN THIS SECTION 8.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

8.5. Insurance. During the Term and for a period of at least **** years after the last commercial sale of a Licensed Product in the Field under this Agreement, TESARO will maintain insurance, with a reputable, solvent insurer in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement, including, commencing immediately prior to the first human clinical trial, product and clinical trial liability insurance of at least **** per occurrence and **** in the aggregate on a worldwide basis.

ARTICLE IX
TERM AND TERMINATION

9.1. Term. This Agreement will become effective as of the Effective Date, and will continue in full force and effect until the last to expire Royalty Term and Japan Income Sharing Term, unless earlier terminated in accordance with this Article IX ("Term"). Upon expiration of the Term under the preceding sentence (but not earlier termination of this Agreement) the licenses granted to TESARO under Section 2.1 will convert to perpetual, fully paid-up, non-royalty-bearing licenses with the same scope as set forth in such Section.

9.2. Termination for Convenience. TESARO will have the right to terminate this Agreement at any time and for any reason upon at least three (3) months' prior written notice to OPKO.

9.3. Termination for Cause. This Agreement may be terminated at any time during the Term upon written notice by either Party if the other Party is in material breach of its obligations hereunder, and has not cured such material breach within sixty (60) days after written notice describing the nature of such material breach is provided to the breaching Party.

9.4. OPKO Termination. To the extent permitted by applicable law, OPKO may terminate this Agreement by giving written notice of termination to TESARO within thirty (30) days of the filing of bankruptcy or bankruptcy of TESARO or the making by TESARO of any assignment for the benefit of creditors. Termination shall be effective upon the date specified in such notice.

9.5. Effect of Termination.

(a) Pre-Termination Obligations; Transfer of Information and Filings. Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. TESARO shall remain obligated to provide an accounting for and to pay Royalties earned. In the event of termination, (i) the licenses granted hereunder shall terminate; (ii) TESARO shall have no further right under OPKO Patent Rights or OPKO Know-how to develop, manufacture or market the Licensed Product or any product containing Licensed Product for use in the Field, or otherwise to use the OPKO Patent Rights or OPKO Know How; (iii) all rights granted hereunder shall revert to OPKO for the benefit of OPKO; and (iv) TESARO shall, as promptly as practicable, transfer to OPKO or OPKO's designee: (a) possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Marketing Approvals and pricing and reimbursement approvals) relating to the development, manufacture or commercialization of the Licensed Product in the Field and all product trademarks then being used in connection with Licensed Product, other than TESARO's corporate trademarks; and (b) all safety data and other adverse event data in TESARO's possession or Control. In addition, OPKO shall have the right to purchase all API and Licensed Product in TESARO'S possession or control at **** or Licensed Product (other than **** pursuant to this Agreement, which will be ****). Notwithstanding the foregoing, TESARO shall be entitled to sell any completed inventory of Licensed Product which remain on hand as of the date of the termination, and to sell new inventory to the extent necessary to satisfy its contractual and legal obligations, so long as TESARO pays to OPKO the royalties applicable to said subsequent sales in accordance with the terms and conditions as set forth in this Agreement; provided that no sales shall be permitted after the expiration of six (6) months after the date of termination. TESARO will execute all documents and take all such further actions, as may be reasonably requested by OPKO in order to give effect to the preceding sentences as soon as practicable.

(b) License Grant. In the event of termination of this Agreement by OPKO under Section 9.3 or 9.4 or termination by TESARO under Section 9.2, TESARO will be deemed to have granted to OPKO a royalty-bearing (but solely to the extent set forth below), worldwide, exclusive, sublicensable, license under any TESARO Improvement Patent Rights and TESARO Improvement to the extent necessary or reasonably useful to manufacture, market, sell or use Licensed Product in the Field in the Territory and solely for such purpose. Except in the event of termination by OPKO under Section 9.3 or 9.4, OPKO will pay to TESARO a royalty on the sale of any Licensed Product in the Field that incorporates a TESARO Improvement and is Covered by a Valid Claim of a TESARO Improvement Patent Right, as follows:

Development Stage as of Date of Termination	Royalty Rate
**** filing of a Licensed Product in the US or EU but **** of a Licensed Product in the US or EU	****
**** of a Licensed Product in the US or EU	****

In addition, in the event TESARO or any of its Affiliates or Sublicensees is required to make payments to any Third Party by reason of the licenses granted to OPKO under this paragraph (b) and based on the development, manufacture or sale of Licensed Product by or on behalf of OPKO or any of its Affiliates or sublicensees, OPKO will pay such amounts due by TESARO or any of its Affiliates or Sublicensees to such Third Party by reimbursing TESARO or paying such amounts directly to such Third Party, as directed by TESARO, in each case based on supporting documentation provided by TESARO. OPKO may elect not to accept the grant of the license to TESARO Improvement Patent Rights upon thirty (30) days written notice to TESARO from the date of termination.

9.6. Survival. Any expiration or termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including payment obligations arising prior to such expiration or termination. The provisions of Articles VI, VIII, IX, X and XI will survive any expiration or termination of this Agreement and all other provisions contained in this Agreement that by their explicit terms survive expiration or termination of this Agreement, will survive. Except as set forth in this Article IX, upon termination or expiration of this Agreement all other rights and obligations of the Parties under this Agreement terminate.

ARTICLE X
DISPUTE RESOLUTION

10.1. Continuance of Rights and Obligations During Pendency of Dispute Resolution. If there are any disputes in connection with this Agreement, including disputes related to termination of this Agreement under Article IX, all rights and obligations of the Parties shall continue until such time as any dispute has be resolved in accordance with the provisions of this Article X.

10.2. Referral of Unresolved Matters to Senior Executives. In the event that the Parties are unable to resolve a dispute within fifteen (15) days from the date such dispute is first brought to the other Party's attention, the matter shall be referred to a senior executive of each Party to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral.

10.3. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which the Parties have not resolved under Section 10.2, will be decided by arbitration in accordance with the Rules of the American Arbitration Association for Commercial Arbitration in effect at the time the dispute arises, unless the Parties hereto mutually agree otherwise. To the extent such rules are inconsistent with this provision, this provision will control. The following rules will apply to any such arbitration:

(a) Any demand for arbitration must be made in writing to the other Party.

(b) There will be three arbitrators, one of whom shall be appointed by each party and a third of whom shall be the chairman of the panel and be appointed by mutual agreement of the two arbitrators appointed by the Parties. If the two arbitrators cannot agree on the appointment of the third arbitrator within thirty (30) days, then the AAA shall select the arbitrator. Any arbitration involving patent rights, other intellectual property rights or intellectual property will be heard by arbitrators who are expert in such areas.

(c) The arbitration will be held in the State of Delaware, or such other place as the Parties agree. The arbitrators will apply the substantive law of the State of Delaware in accordance with Section 11.1, without regard to conflicts of laws and except that the interpretation and enforcement of this arbitration provision will be governed by the Federal Arbitration Act, 9 U.S.C. Section 1 et. seq.

(d) Neither Party will have the right independently to seek recourse from a court of law or other authorities in lieu of arbitration, but each Party has the right before or during the arbitration to seek and obtain from the appropriate court provisional remedies to avoid irreparable harm, maintain the

status quo or preserve the subject matter of the arbitration. There shall be a stenographic record of the proceedings. The decision of the arbitrators will be final and binding upon both Parties. The arbitrators will render a written opinion setting forth findings of fact and conclusions of law.

(e) The expenses of the arbitration will be borne by the Parties in proportion as to which each Party prevails or is defeated in arbitration. Each Party will bear the expenses of its counsel and other experts.

10.4. Equitable Relief. Notwithstanding anything to the contrary, each of the Parties hereby acknowledges that a breach of their respective obligations under this Agreement may cause irreparable harm and that the remedy or remedies at law for any such breach may be inadequate. Each of the Parties hereby agrees that, in the event of any such breach, in addition to all other available remedies hereunder, the non-breaching Party shall have the right, through the arbitration process described in Section 10.3, to seek equitable relief to enforce the provisions of this Agreement.

ARTICLE XI
MISCELLANEOUS

11.1. Governing Law and Jurisdiction. The validity, construction and performance of this Agreement will be governed by and construed in accordance with the substantive laws of the State of Delaware excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

11.2. Force Majeure. Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term, other than an obligation to make payments hereunder, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, acts of God or any other cause beyond the reasonable control of the affected Party to anticipate, prevent, avoid or mitigate (a "Force Majeure Event"); provided that (i) the affected Party provides prompt written notice to the other Party of such failure or delay, (ii) the affected Party uses Commercially Reasonable Efforts to mitigate the effects of the Force Majeure Event, and (iii) the affected Party immediately resumes performance upon cessation of the Force Majeure Event. Notwithstanding the foregoing, any failure or delay in fulfilling a term shall not be considered a result of a Force Majeure Event if it arises from a failure of TESARO or OPKO to comply with applicable laws.

11.3. Further Assurances. Each Party hereto agrees to perform such acts, execute such further instruments, documents or certificates, and provide such cooperation in proceedings and actions as may be reasonably requested by the other Party in order to carry out the intent and purpose of this Agreement.

11.4. Notices. Any notice required or permitted to be given under this Agreement will be in writing and will be deemed to have been properly given if delivered in person by a internationally recognized overnight courier, or by fax (and promptly confirmed by overnight courier), to the addresses given below or such other addresses as may be designated in writing by the Parties from time to time during the Term.

In the case of TESARO:

TESARO, Inc.
309 Waverley Oaks Rd., Suite 101
Waltham, MA 02452
Attention: Chief Financial Officer
Fax No.: 339-469-8966

With a copy to:

Anne Marie Cook
Choate, Hall & Stewart LLP
Two International Place
Boston, MA 02110
Fax No.: 617-248-4000

In the case of OPKO:

OPKO Health Inc.
4400 Biscayne Blvd.
Miami, FL 33137
Attention: Executive Vice President
Fax No.: 305-575-6444

With a copy to: Deputy General Counsel

11.5. Assignment. This Agreement may not be assigned or otherwise transferred by either Party, without the written consent of the other Party such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that either Party may, without such consent, assign this Agreement, in whole or in part, (i) to any of its Affiliates, and (ii) to a Third Party successor or purchaser of all or substantially all of its business or assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other similar transaction, provided that, (i) the Third Party successor or purchaser provides written notice to the other Party that such Third Party agrees to be bound by the terms of this Agreement, and (ii) OPKO will not assign this Agreement unless the assignee is also assigned ownership owns or Controls of the OPKO Patent Rights and OPKO Know-how. Any purported assignment in violation of this Section 11.5 will be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

11.6. Affiliate Performance. Any obligation of TESARO under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at TESARO's sole and exclusive option, either by TESARO directly or by any Affiliate or Sublicensee of TESARO that TESARO causes to satisfy, meet or fulfill such obligation, in whole or in part.

11.7. Amendment. The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but only by a written instrument duly executed by both Parties hereto.

11.8. Entire Agreement. This Agreement, along with all schedules and exhibits attached hereto, contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements, whether written or oral. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement.

11.9. No Benefit to Third Parties. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons.

11.10. Waiver. The failure of a Party to enforce at any time for any period any of the provisions of this Agreement will not be construed as a waiver of such provisions or of the rights of such Party thereafter to enforce each such provision.

11.11. No Implied Licenses. Except as expressly and specifically provided under this Agreement, the Parties agree that neither Party is granted any implied rights to or under any of the other

Party's current or future patents, trade secrets, copyrights, moral rights, trade or service marks, trade dress, or any other intellectual property rights.

11.12. Relationship of the Parties. The Parties agree that their relationship established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically provided in this Agreement, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

11.13. Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction in a final unappealable order because it is invalid or conflicts with any law of any relevant jurisdiction, then such provision will be inoperative in such jurisdiction and the remainder of this Agreement shall remain binding upon the Parties hereto.

11.14. Interpretation.

(a) General. Unless the context of this Agreement otherwise requires, (a) words of one gender include the other gender; and (b) words using the singular or plural number also include the plural or singular number, respectively. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days.

(b) Other Definitional and Agreement References. References to any agreement, contract, statute, act, or regulation are to that agreement, contract, statute, act, or regulation as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof.

(c) Capitalization. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement.

(d) Date References. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

(e) Schedules and Exhibits. All Schedules and Exhibits annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein.

(f) Person References. References to any Person include the successors and permitted assigns of that Person.

(g) References to Parts of this Agreement. References to Articles, Sections, Schedules, and Exhibits are to Articles, Sections, Schedules, and Exhibits of this Agreement unless otherwise specified.

(h) Other Definitional and Interpretative Provisions. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. The word "or" is used in the inclusive sense (and/or). "Writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form.

(i) Headings. The Article and Section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

(j) Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

11.15. Counterparts. This Agreement may be executed in any number of counterparts (including by facsimile), each of which shall be deemed an original, but all of which together shall constitute one and the same document.

[Signature Page Follows]

IN WITNESS WHEREOF, TESARO and OPKO have caused this Agreement to be duly executed by their authorized representatives under seal, in duplicate on the Effective Date.

TESARO, Inc.

By: _____
Name: _____
Title: _____

OPKO Health, Inc.

By: _____
Name: _____
Title: _____

Exhibit A

Description of SCH 619734 (Rolapitant)

Chemical Structure of Rolapitant:

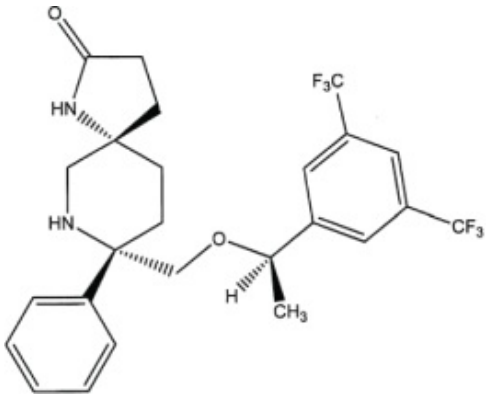

Exhibit B

Description of SCH 900978

Chemical Structure of SCH 900978:

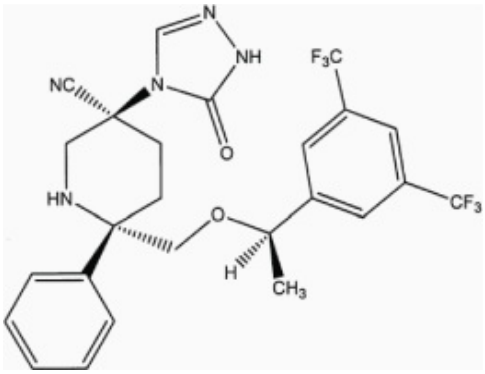

Exhibit C
OPKO Patent Rights

[Attached]

Patent Status by Division

Division: OPKO OPKO

Docket Country	SubCase	Case Type	Status Division Reference	Application Number Patent Number	Filing Date Issue Date	Next Action(s)	Due Date(s)
****							

Sort Order: by Division

Print Remarks?: No

Print Inventors?: No

Print Abstract: No

Actions Due: All

Filing Date: **From:** **To:**

Docket Number: **Status Code:** All

Division: OPKO **Case Type(s):** **Status(es):**

Agent:

Attorney:

Assignee:

Country:

Area:

Inventor:

Exhibit D
Technology Transfer Plan

[Attached]

TECHNOLOGY TRANSFER PLAN

This Technology Transfer Plan is an exhibit to the Exclusive License Agreement entered into between TESARO, Inc. ("TESARO") and OPKO Health, Inc. ("OPKO") (the "Agreement"), and is incorporated by reference into the Agreement. Capitalized terms used in this Technology Transfer Plan will have the meaning set forth in the Agreement.

Part A -General

1. Technology Transfer Services. OPKO will transfer to TESARO (or TESARO's designees) all OPKO Know How and related technical information, and provide such support, as is reasonably necessary to enable TESARO to assume responsibility for the research, formulation, development, testing and manufacture of Licensed Product, and, during the period commencing on the Effective Date and continuing until the later of the completion of all Technical Transfer Services (as defined below) or **** from the Effective Date (such period being hereafter referred to as the "Transfer Period"), will provide reasonable ongoing assistance to TESARO in connection with such transfer and use of the OPKO Know-how. In connection with the foregoing, OPKO will perform the activities set forth in Parts Band C of this Technology Transfer Plan (the "Technology Transfer Services"). In addition, during the Transfer Period, OPKO will make its personnel reasonably available to TESARO to respond to questions related to the OPKO Know-how in connection with any of the activities described in this Technology Transfer Plan, and will provide such ongoing support and assistance as TESARO may reasonably request in the transition of development and manufacturing responsibility for Licensed Products to TESARO. TESARO acknowledges that OPKO and OPKO personnel were not involved in the discovery, manufacture, formulation, sourcing, research or development of the Licensed Product or any API and have only gained information relating to the Licensed Product in connection with the Asset Purchase Agreement and its research and development efforts undertaken since the consummation of the Asset Purchase Agreement in November 2009, much of which has been undertaken through the assistance of Third Party consultants. OPKO intended to use Third Parties for, and therefore had not engaged in, the development or formulation of dosage forms or the manufacture of drug product or API in support of the clinical development program or commercialization of Licensed Product. Accordingly, OPKO's efforts, support and assistance and TESARO's expectations under this Technology Transfer Plan must be considered in light of OPKO' s limited level of expertise, knowledge and familiarity with Licensed Product. Additionally, in making the decision to enter into the Exclusive License Agreement, TESARO has conducted its own independent investigation, review and analysis of the Licensed Product, OPKO Patent Rights and OPKO Know-how, and has had complete access to all of OPKO's files, information, materials and data, and records relating to the Licensed Product. In connection with the foregoing, at the request of TESARO, OPKO will seek the assistance of Merck & Co., Inc. to the extent such support continues to be available under Section 2.5 of the Asset Purchase Agreement, and any other Third Party support, as specified in paragraph 2 of this Part A. To the extent information, data or materials referred to in this Technology Transfer Plan are not in the possession of OPKO, or cannot be obtained from Merck under the Asset Purchase Agreement pursuant to OPKO's rights thereunder, OPKO will have no obligations hereunder or in the Agreement to provide or transfer such requested information, data or materials. Notwithstanding anything herein to the contrary, this Technology Transfer Plan will not be considered a limitation on, or a narrowing of, the obligations of either Party under the Agreement.

2. Third Party Support. If any materials or information to be provided under this Technology Transfer Plan or otherwise under the Agreement are in the possession or control of Merck & Co., Inc. or any other Third Party who provided services to OPKO, OPKO will use Commercially Reasonable Efforts to obtain such materials and information from Merck & Co., Inc. or such other Third Party, as the case may be. In the case of materials and information in the possession or control of Merck & Co., Inc., "Commercially Reasonable Efforts" under the preceding sentence will include an obligation on the part of

OPKO to enforce its rights under the Asset Purchase Agreement. With respect to any provision under this Technology Transfer Plan requiring OPKO to provide support or information from, or access to, personnel, OPKO will, at the request of TESARO, arrange for, and facilitate, direct communication between TESARO and any Third Party who was responsible for generating or implementing the applicable OPKO Know-how. In particular, and especially with respect to the development, implementation, transfer, provision or explanation of production manufacturing or formulation processes for API or drug substance (for which OPKO has no direct knowledge), OPKO will, within ten (10) days of the Effective Date, send written notice to Merck & Co., Inc. under which OPKO shall specify TESARO as its designee under Section 2.5 of the Asset Purchase Agreement and authorizing Merck & Co., Inc. to provide information, support and assistance to TESARO to the same extent as available to OPKO under Section 2.5 of the Asset Purchase Agreement.

3. Technical Transfer Team. Commencing as of the Effective Date, the Parties will form a technical transfer team (the "Technical Transfer Team") comprised of the functions and individuals identified below to coordinate and oversee the Technology Transfer Services.

OPKO Representatives

Functional Area Represented	*Role*	*Initial Designee*
Team Leader	Act as primary interface with respect to OPKO's technology transfer activities	****
Regulatory	Implement transfer of the INDs, IMPDs and correspondence with health authorities	****
Clinical Research	Address questions related to completed clinical studies and those under planning or in start-up; oversee transfer of all clinical data (including but not limited to efficacy, safety, PK, ECG and pharmacovigilence), study documentation, safety reports, advisory meeting minutes, and inventoried biospecimens	****
Chemistry, Manufacturing, and Controls	Oversee transfer of all pharmaceutical development data, technical and manufacturing documentation and inventoried non-GMP and GMP materials (Role is inclusive of API, starting materials, raw materials, retains, and stability programs in OPKO's possession or control)	****

OPKO Representatives

Functional Area Represented	*Role*	*Initial Designee*
Preclinical Research	Address questions related to completed nonclinical studies and those under planning or in start-up; oversee transfer of all nonclinical data, study documentation and inventoried specimens (Role is inclusive of all toxicology, pharmacology, and pharmacokinetic and other preclinical activities)	****
Analytical Methods	Oversee transfer of all clinical, nonclinical and pharmaceutical analytical method development reports, final SOPs and associated reference standards	****
Quality	Oversee transfer of all quality audit and inspection reports, quality release documentation and other all associated quality memorandums in support of completed and planned development activities	****
General	Oversee transfer of all agreements, if any, to be assigned; transfer of any general program information and commercial information; and transfer of project team meeting minutes	****
Commercial	Oversee transfer of all market survey data and reports	****
IT (electronic files)	Information transfer	****
Patents	Oversee transfer of OPKO Patent Rights	****

TESSARO Representatives

Functional Area Represented	*Role*	*Initial Designee*
Team Leader	Act as primary interface with respect to TESARO activities under Technology Transfer Plan	****
Regulatory	Receipt of IND and other regulatory docs	****
Clinical Research	Oversee receipt of technology related to clinical development	****
Chemistry, Manufacturing and Controls	Oversee receipt and implementation of technology related to TESARO's CMC efforts and activities	****
Preclinical Research	Oversee receipt of technology transfer related to preclinical research activities	****
Analytical Methods	Act as primary interface with respect to transfer of analytical methods	****
Quality	Act as primary interface with respect to quality matters	****
General	Oversee transfer of all agreements, if any, to be assigned; transfer of any general program information and commercial information; and transfer of project team meeting minutes	****
Commercial	Act as primary interface	****
IT	Oversee information transfer	****
Patents	Oversee transfer of OPKO Patent Rights	****

Either Party may replace its representatives on the Technical Transfer Team, provided that the OPKO representatives on the Technical Transfer Team will have comparative level of expertise, knowledge and familiarity with Licensed Product to the listed representative.

The responsibilities of the Technical Transfer Team will include, but not be limited to the following:

a. Establish a complete and reasonably detailed accounting of all materials, samples, documents, data, contracts, CD/DVDs and other electronic files that constitute the technical information embodying the OPKO Know-how, and assist in the complete and accurate transfer of all items to TESARO and/or any of TESARO'S designees. Provide reasonable explanation to TESARO and/or any of TESARO'S designees how items are related, filed, and what supportive software programs are required to enable any of the electronic files and data sets.

b. Facilitate the reasonable assistance of OPKO's then current employees and reasonable access to its other internal resources and to Third Parties who generated or possess or control OPKO Know-how, to provide TESARO and/or any of TESARO's designees with a reasonable level of technical assistance and consultation in connection with the transfer of the OPKO Know-

how to TESARO and/or any of TESARO'S designees, including the provision and explanation, upon request, to TESARO and/or any of its designees of all relevant technology, materials, reports, data, documents and materials describing or embodying the OPKO Know How.

c. Facilitate the provision and explanation to TESARO and/or any of TESARO's designees, of all production outlines, materials sourcing, specifications, and testing, standard testing requirements (release, in process, characterization and stability), standard operating procedures (e.g. analytical testing, equipment cleaning), technology, documents (e.g. Certificates of Analysis, Specifications, technical reports, development reports and memorandums, Material Safety Data Sheets, qualification and validation reports, master manufacturing batch records, executed batch records), data, notebooks or other information that constitutes the OPKO Know-how for manufacture of starting materials, API and Licensed Product and intermediates of any of the foregoing.

d. Facilitate the development and implementation of a technology transfer protocol for the transfer of the manufacturing process (including in-process methods) and formulation process for API, final drug substance and final drug product for the Licensed Products to TESARO and/or its designees.

e. Implement transfer of clinical drug assay methodologies and know-how for the Licensed Products, including parent and metabolites, inventoried samples and completed or partial analyses (e.g. toxicokinetics, pharmarcokinetics) to TESARO and/or its designees.

f. Implement transfer of all regulatory filings and sponsor of the INDs as promptly as practicable following the Effective Date.

g. Establish a plan for and implement transfer of all electronic data and confirmation of data integrity and completeness and accuracy following transfer.

h. Introduce TESARO and/or any of TESARO'S designees, at TESARO's request, to consultants, contractors or other vendors currently engaged or involved in future planning activities related to the Licensed Products.

i. Implement transfer to TESARO's designee all patent files related to OPKO Patent Rights in accordance with Section 5.1 of the License Agreement as necessary to allow TESARO to assume prosecution and maintenance of such OPKO Patent Rights without any loss of rights in the transition.

4. Costs. **** associated with technology transfer activities to be provided under this Technology Transfer Plan, including, but not limited to the ****. To the extent any Technology Transfer Services to be provided under this Section require external resources, including consultation with Third Party consultants, **** of such external resources, provided that such activities and costs are expressly set forth in this Technology Transfer Plan or are otherwise approved in writing in advance by ****.

Part B -Activities.

The activities to be performed by OPKO under this Technology Transfer Plan, by technical area, are as follows:

Function	Service to be Provided by OPKO	Comments
Technical Operations	OPKO shall provide the reasonable assistance of OPKO's then current employees and reasonable access to its other internal resources to provide TESARO (and/or TESARO's designees)with a reasonable level of technical assistance and consultation in connection with the transfer and implementation of OPKO Know How to TESARO, including the provision and explanation, on request, to TESARO and its Affiliates of all technology, electronic files, materials, reports, data, documents, standard testing requirements, standard operating procedures, notebooks and materials describing or embodying the OPKO Know How. TESARO will be given the reasonable opportunity to meet with, and receive assistance and services of, the OPKO's knowledgeable personnel in connection with TESARO gaining competent knowledge of the contents of the OPKO Know How and OPKO's activities related to Licensed Product. As stated above, OPKO personnel were not involved in the discovery, manufacture, formulation, sourcing, research or development of the Licensed Product or any API and have only gained information relating to the Licensed Product in connection with the Asset Purchase Agreement and its research and development efforts undertaken since the consummation of the Asset Purchase Agreement in November 2009, much of which has been undertaken through the assistance of Third Party consultants. OPKO intended to use Third Parties for, and therefore had not engaged in, the development or formulation of dosage forms or the manufacture of drug product or API in support of the clinical development program or commercialization of Licensed Product. OPKO will seek the assistance of Merck & Co., Inc. to the extent such support continues to be available under Section 2.5 of the Asset Purchase Agreement to provide the Technical Operations Support, including discussion with appropriate Merck & Co., Inc. personnel, as outlined in the Technical Transfer Services included as Schedule 2.5 to the Asset Purchase Agreement, to: • Identify the identity and location of all archived development samples for transfer to TESARO and/or TESARO designees	

Function	Service to be Provided by OPKO	Comments
	• Discuss regulatory files and correspondence with regulatory authorities, including an outline of open obligations • Discuss the rationale of Phase 3 dose and formulation and clinical utility of the current IV formulation. Personnel shall also identify the identity and location of all archived study samples for transfer to TESARO and/or TESARO designees. - Discuss key completed toxicology studies including but not limited to carcinogenicity studies, oral chronic toxicology, development and reproductivity studies, and IV studies, as well as safety pharmacology studies,. Personnel shall also identify the identity and location of all archived study samples for transfer to TESARO and/or TESARO designees. - Discuss past and current research and development efforts specific for the Licensed Product, including the status of study reports, data and analyses for each study completed as well as available biospecimens for transfer to TESARO and/or TESARO designees. - Assist in the transfer of the current bioanalytical methods to TESARO and/or any of TESARO'S designees, as well as available biospecimens for transfer to TESARO and/or TESARO designees. - Provide relevant information particularly audit reports related to the Licensed Products to ensure all studies were conducted in accordance with GLP, GMP & GCP, to provide certification that appropriate storage conditions for all inventoried materials has been met at all locations of storage and during all periods of transit, and to provide appropriate documentation to support the chain of custody to OPKO and then to TESARO and/or any of TESARO'S designees. - IT personnel to discuss format, systems utilized and transfer of nonclinical, clinical and CMC data. (Note: all such meetings and communication will be coordinated through the Team Leaders).	

Function	Service to be Provided by OPKO	Comments
Regulatory Services	OPKO and TESARO shall establish a prompt communication and interaction process to ensure the orderly transfer of all regulatory filings related to Licensed Product ("Regulatory Filings") as promptly as practicable following the Effective Date. Within thirty (30) days following the Effective Date, or as otherwise agreed by the Parties, the Parties shall file with the FDA and any other applicable Regulatory Authority, such information as may be required to transfer the Regulatory Filings from OPKO to TESARO. Both OPKO and TESARO agree to use Commercially Reasonable Efforts to take any actions required by the FDA or other applicable Regulatory Authority to affect the transfer of the Regulatory Filings to TESARO.	
Manufacturing Process	Seek the assistance of Merck & Co., Inc. under Section 2.5 of the Asset Purchase Agreement towards the development and implementation of a technology transfer protocol for the transfer of the manufacturing process (including in-process methods) and formulation process for API and formulated drug substance for the Licensed Product to TESARO and/or its designees. Seek the assistance of Merck & Co., Inc. under Section 2.5 of the Asset Purchase Agreement to provide training to TESARO and/or TESARO'S designees in the manufacturing and testing of the Licensed Product.	
Intellectual Property	OPKO shall transfer to TESARO responsibility for filing and prosecuting any patent applications and patents included in the OPKO Patent Rights and maintaining any patents included in the OPKO Patent Rights, and shall (a) execute any legal documents, such for recordation in any U.S. or foreign offices or agencies, to evidence TESARO's control of prosecution and maintenance of the applicable OPKO Patent Rights, (b) performing all reasonable actions that may be necessary or useful to complete the assignment to TESARO of such responsibilities, and (c) provide reasonable cooperation to TESARO in connection with such activities in accordance with Section 5.1 of the Exclusive License Agreement.	

Part C-Technology Transfer Schedule.

The schedule for performance of certain specified Technology Transfer Services and form of transfer of certain OPKO Know-how are set forth in the Table I below (the "Technology Transfer Schedule"). The

Parties' representatives comprising the Technical Transfer Team will have the ability, by mutual written agreement of the Team Leaders from both Parties, to modify in writing the Technology Transfer Schedule, provided that no such modification shall amend the terms of the Agreement other than to specifically amend the timelines and format set forth in the Technology Transfer Schedule unless both Parties agree in writing to amend this Agreement in accordance with Section 11.7 of the Agreement.

Table 1
Technology Transfer Schedule

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
Records related to Licensed Product in the Data Room	OPKO will provide within **** calendar days of the Effective Date	To be delivered in such form as currently exists via commercial carrier.	Will contain the entire contents of the data room that was available to TESARO during due diligence.
IND 77,044	OPKO will provide within **** calendar days of the Effective Date	To be delivered on CD or DVD via commercial carrier.	**** which shall, in no event, be greater than 60 calendar days after the Effective Date.
IND 72,754	OPKO will provide within **** calendar days of the Effective Date	To be delivered on CD or DVD via commercial carrier.	**** which shall, in no event, be greater than 60 calendar days after the Effective Date.
Regulatory Documents			
• ****	To be delivered within **** days of the Effective Date.	Hard copy (and electronic as may be available) of all correspondence to and from regulatory agencies and attachments arranged in chronological order. The original IND and IMPD to be delivered on CD or DVD.	
Pharmacovigilance			
• ****	To be transferred to TESARO within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	****
Discovery Biology			
• ****	To be delivered within **** days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process.

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
Drug Metabolism & Pharmacokinetics			
• ****	• To be delivered within **** days of the Effective Date. •	• To be delivered on CD or DVD via commercial carrier	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process, as well as associated raw data analyses.
Drug Safety			
• ****	• To be delivered within **** days of the Effective Date.	• To be delivered on CD or DVD via commercial carrier	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process, as well as associated raw data analyses.
****	• To be delivered within **** days of the Effective Date.	• To be delivered on CD or DVD via commercial carrier	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process, as well as associated raw data analyses.

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
• ****	To be delivered within **** days of the Effective Date.	To be delivered on CD or DVD as electronic transport file via commercial carrier	Software that may be required to access the data will need to be specified by OPKO.
Early Clinical Research & Experimental Medicine			
• ****	• To be delivered within **** days of the Effective Date.	• To be delivered on CD or DVD via commercial carrier	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process, as well as associated raw data analyses.
• ****	To be delivered within **** days of the Effective Date.	To be delivered on CD or DVD as a SAS transport file via commercial carrier	Software that may be required to access the data will need to be specified by OPKO.

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
Clinical Research			
• ****	**** - To be delivered within **** calendar days of the Effective Date **** • To be delivered within **** calendar days of the Effective Date **** • To be delivered within **** calendar days of the Effective Date.	• To be delivered on CD or DVD via commercial carrier • Delivery conditions to be specified per sample requirements	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process, as well as associated raw data analyses.
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD as a SAS transport file via commercial carrier	Software that may be required to access the data will need to be specified by OPKO.
Chemistry, Manufacturing, and Controls			
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	If hard copy signatures were obtained for final report, the original signed report should be provided. Should include any draft reports that may be in process, as well as associated raw data analyses.

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	****
•			
Occupational & Environmental Toxicology			
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
Market Research	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
• ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD via commercial carrier	
Physical chemical inventory			
API ****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	****

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	
****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	
****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	
****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	
****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	

OPKO Know-how	Delivery Time (or such later time as TESARO may request)	Delivery Method	Discussion/Comments
****	To be delivered within **** calendar days of TESARO providing OPKO with the shipping instructions and location, or as otherwise agreed by the parties.	OPKO will ship via commercial carrier under appropriate sample storage and control conditions per sample requirements	
Samples			
****	At TESARO's direction, to be provided with **** days of the Effective Date or retained by OPKO	Delivery conditions to be specified per sample requirements	
OPKO Patent Rights			
All **** art (whether **** prosecution counsel relating to any or all OPKO Patent Rights, all **** tile each issued patent under the OPKO Patent Rights).	Transfer of the patent portfolio will occur within **** calendar days of the Effective Date	To be delivered on CD or DVD or hard copy via commercial carrier	
Notebooks or all other relevant data or material (even draft form).			
Originals or copies of ****	To be delivered within **** calendar days of the Effective Date.	To be delivered on CD or DVD or hard copy via commercial carrier	Materials will need to be redacted for information not relevant to the OPKO Know How.

Exhibit E

Form of Press Release

[Attached]

FOR IMMEDIATE RELEASE

TESARO and OPKO Health Sign Exclusive License Agreement for Rolapitant

- Rolapitant is a Phase III-ready neurokinin-l (NK-l) receptor antagonist in development for chemotherapy induced nausea and vomiting (CINV)
- TESARO responsible for worldwide development and commercialization of rolapitant

Boston, MA and Miami, FL -December 13, 2010 -TESARO, Inc. and OPKO Health, Inc. (NYSE Amex:OPK), today announced that they have signed a definitive agreement granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Rolapitant is a potent and selective neurokinin-1 (NK-1) receptor antagonist with an extended plasma half-life that has the potential to improve the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy. Rolapitant, which is Phase III ready, demonstrated promising efficacy in Phase II testing for prevention of nausea and vomiting in patients undergoing highly emetogenic chemotherapy.

Under the terms of the agreement, OPKO will acquire an approximately 10% equity investment in TESARO. OPKO is eligible for payments of up to over $120 million, including an up-front payment and additional payments based upon achievement of specified regulatory and commercialization milestones; in addition, OPKO will receive tiered royalties on sales. Under the agreement, OPKO and TESARO will share future profits from the commercialization of licensed products in Japan and OPKO will have an option to market the products in Latin America.

“TESARO is very pleased to announce this agreement with OPKO and to advance the development of this important product candidate, rolapitant,” said Lonnie Moulder, Chief Executive Officer of TESARO. “Our leadership team has a deep understanding of the unmet need that still exists in oncology supportive care, given our successful commercialization of the market-leading therapy for CINV prevention at the helm of MGI PHARMA. We believe that rolapitant is a differentiated product with great potential to help cancer patients undergoing chemotherapy.”

TESARO was co-founded by former executives of MGI PHARMA, an oncology and acute-care focused specialty biopharmaceutical company that Eisai Co., Ltd. acquired in 2008 for $3.9 billion. While at MGI PHARMA, TESARO executives led the clinical development and commercialization of numerous drugs, including commercialization of Aloxi® (palonosetron HCI), the leading drug in the 5-HT3 receptor antagonist class for prevention of CINV.

“We are pleased to complete this important transaction and look forward to seeing rolapitant progress towards registration in key markets throughout the world,” said Phillip Frost, M.D., OPKO’s Chairman and Chief Executive Officer. “The TESARO team’s successful experience with the development and commercialization of oncology supportive care products will be of special benefit in making rolapitant a commercial success.”

About Rolapitant:

Rolapitant, a potent and selective neurokinin-1 (NK-1) receptor antagonist with an extended plasma half-life, has completed Phase II clinical testing for prevention of chemotherapy induced nausea and vomiting indications. NK-1 receptors are highly concentrated in the brain and bind substance P, a neurokinin that elicits an emetogenic response. Activation ofNK-1 receptors plays a central role in nausea and vomiting induced by emetogenic cancer chemotherapy.

About Chemotherapy Induced Nausea and Vomiting (CINV):

CINV is estimated to afflict over 70% of cancer patients undergoing chemotherapy and, if not prevented, may possibly result in a delay or even discontinuation of chemotherapy treatment. NK-1 receptor antagonists have been demonstrated to improve the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy.

About OPKO Health, Inc.

Miami-based OPKO is a specialty healthcare company involved in the discovery, development, and commercialization of proprietary pharmaceutical products, medical devices, vaccines, diagnostic technologies and imaging systems. Initially focused on the treatment and management of ophthalmic diseases, OPKO has since expanded into other areas of major unmet medical need. For more information, visit www.opko.com.

About TESARO, INC.

Founded in 2010, TESARO is a privately held oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients by developing and commercializing safer and more effective therapeutics. Earlier this year, TESARO secured $60 million in start-up funding from New Enterprise Associates (NEA) and the TESARO founders. TESARO is headquartered in Boston, Massachusetts. For more information, visit www.tesarobio.com.

For Further Information Contact:

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This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding product development efforts, including the ability to develop and commercialize rolapitant for chemotherapy-induced nausea and vomiting, the ability to obtain registration for rolapitant in key markets and the timing thereof, and the potential for rolapitant to help cancer patients undergoing chemotherapy, as well as other non-historical statements about expectations, beliefs or intentions regarding business, technologies and products, financial condition, strategies or prospects. These forward-looking statements are not guarantees of OPKO's or TESARO's future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Many factors could cause either Company's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include, an inability to successfully develop and commercialize rolapitant and the NK-1 program assets, that rolapitant may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of this product, that others may develop products, including other NK-1 receptor antagonists, which are superior to rolapitant, and that the acquired compounds may not have advantages over presently marketed products. In addition, forward-looking statements may also be adversely affected by risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and OPKO and TESARO do not undertake any obligation to update forward-looking statements. The Companies' intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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Exhibit F

Material Agreements

Asset Purchase Agreement, dated October 12,2009, by and among Schering Corporation and OPKO Health, Inc., as amended by letter agreement dated June 29, 2010

Clinical Research Services Agreement, dated October 7,2010, by and among OPKO Health, Inc. and ****.

Clinical Research Services Agreement, dated October 7, 2010, by and among OPKO Health, Inc. and ****.

Clinical Research Services Agreement, dated October 7, 2010, by and among OPKO Health, Inc. and ****.

****

Cost Proposal Regarding Retention of Radiolabeled and Stable Isotope Labeled Test Articles, dated June 7, 2010, by and among OPKO Health, Inc. and ****.

Consulting Agreement, dated October 9, 2009, as amended on October 15,2010, by and among OPKO Health, Inc. and ****.

Consulting Agreement, dated October 9,2009, as amended on October 15,2010, by and among OPKO Health, Inc. and ****.

Consulting Agreement, dated November 30,2009, by and among OPKO Health, Inc. and ****.

Consulting Agreement, dated February 11,2010, by and among OPKO Health, Inc. and ****.

Consulting Agreement, dated September 15,2010, by and among OPKO Health, Inc. and ****.

Consulting Agreement, dated October 11, 2010, by and among OPKO Health, Inc. and ****.

Exhibit 21

SUBSIDIARIES OF OPKO HEALTH, INC.

NAME	JURISDICTION OF INCORPORATION
OPKO Instrumentation, LLC	Delaware
OPKO Pharmaceuticals, LLC	Delaware
Froptix LLC	Florida
Ophthalmics Technology, Inc.	Ontario, Canada
Vidus Ocular, Inc.	Delaware
Pharma Genexx, S.A.	Chile
Pharmacos Exakta S.A. de C.V.	Mexico

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-172168) of OPKO Health, Inc. and subsidiaries, and
2. Registration Statement (Form S-8 No. 333-144040) pertaining to the 2007 Equity Incentive Plan of OPKO Health, Inc. and subsidiaries;

of our reports dated March 16, 2011, with respect to the consolidated financial statements of OPKO Health, Inc. and subsidiaries and the effectiveness of internal control over financial reporting of OPKO Health, Inc. and subsidiaries included in this Annual Report (Form 10-K) of OPKO Health, Inc. and subsidiaries for the year ended December 31, 2010.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida
March 16, 2011

Exhibit 31.1

CERTIFICATIONS

I, Phillip Frost, certify that:

(1) I have reviewed this Annual Report on Form 10-K of OPKO Health, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2011

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Rao Uppaluri, certify that:

(1) I have reviewed this Annual Report on Form 10-K of OPKO Health, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2011

/s/ Rao Uppaluri
Rao Uppaluri
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OPKO Health, Inc. (the "Company") on Form 10-K for the year ended December 31, 2010 (the "Report"), and pursuant to pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Frost, Chief Executive Officer of the Company, certify that to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.
Chief Executive Officer
March 16, 2011

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OPKO Health, Inc. (the "Company") on Form 10-K for the year ended December 31, 2010 (the "Report"), and pursuant to pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, I, Rao Uppaluri, Chief Financial Officer of the Company, certify that to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Rao Uppaluri

Rao Uppaluri
Chief Financial Officer
March 16, 2011