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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.

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.

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- 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 groO
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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 in small T c biomS gffom fh ieuter ac

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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.



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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 our sales and marketing personnel in the United States and other key markets. We are currently in the process of establishing a sales and marketing infrastructure in the United States and other key markets. We are currently in the process of establishing a sales and marketing infrastructure in the United States and other key markets. We are currently in the process of establishing a sales and marketing infrastructure in the United States and other key markets.



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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 of

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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:

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- our ability to establish and maintain adequate infrastructure to support the commercial launch and sale of our diagnostic tests
- ourself or through a CISA certified laboratory. We are currently establishing adequate laboratory space, information technology infrastructure, and a diagnostic infrastructure, as well as regulatory compliance, to support the commercial launch and sale of our diagnostic tests.
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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.

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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 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.

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 recroúgh gsure’a s ch

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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 result in a material adverse effect on our business, results of operations and financial condition.

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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 price
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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 “n bño

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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 obtained, o s m^{the thi}

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



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Third parties 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 party successfully claim that we have improperly obtained or used its confidential or proprietary information, we could be liable for damages and attorneys' fees. Furthermore, we could be liable for costs incurred in connection with litigation 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.

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.

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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. nufa

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:

	<u>High</u>	<u>Low</u>
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.

Our company has not declared or paid any cash dividends on its common stock and does not intend to do so for the foreseeable future.



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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.

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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.

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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 c t sn, t n i.le **Re**

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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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

	December 31,	
	2010	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	<u>\$ 77,846</u>	<u>\$ 87,430</u>
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	<u>\$ 77,846</u>	<u>\$ 87,430</u>

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.

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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

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\$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	<u>\$ 1,319</u>

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.

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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 carryforwards. Deferred tax assets and liabilities are recognized on the balance sheet at the amount of the deferred tax assets and liabilities expected to be realized in the future.

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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 lik i

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On May 26, 2009, May 29, 2009, and June 1, 2009, we entered into stock purchase agreRe

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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 (i) of any meet r h t w R a n e s i o r e o e s r u i d e n d s e r e c e i v e , w h e i o r o f 4.80, p b y o p t e e s r s p i t a n z t i m e

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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 against all of our net deferred income tax assets that we do not expect to be utilized by the end of the reporting period.

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	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	<u>(0.8)%</u>	<u>1.0%</u>	<u>0.2%</u>

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

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

Note 10 Supplemental Cash Flow Information

Supplemental cash flow information is summarized as follows:

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

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.

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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 F

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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, initially to

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connection with the increase of the borrowing availability/



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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	—	—	—
	<u>\$ 30,149</u>	<u>\$ 13,147</u>	<u>\$ 9,440</u>
Operating income (loss)			
Pharmaceutical	\$ 373	\$(11,920)	\$(19,437)
Instrumentation	(5,971)	(6,843)	(9,704)
Corporate	(11,631)	(9,257)	(9,422)
	<u>\$(17,229)</u>	<u>\$(28,020)</u>	<u>\$(38,563)</u>
Depreciation and amortization			
Pharmaceutical	\$ 2,082	\$ 507	\$ 29
Instrumentation	1,673	1,797	1,753
Corporate	115	53	41
	<u>\$ 3,870</u>	<u>\$ 2,357</u>	<u>\$ 1,823</u>
Net loss of investees			
Pharmaceutical	\$ (714)	\$ (353)	\$ —
Instrumentation	—	—	—
Corporate	—	—	—
	<u>\$ (714)</u>	<u>\$ (353)</u>	<u>\$ —</u>
Product revenue			
United States	\$ 827	\$ 813	\$ 112
China	17,977	4,418	—
Other	4,110	24	1
	<u>7,235</u>	<u>7,892</u>	<u>9,327</u>
	<u>\$ 30,149</u>	<u>\$ 13,147</u>	<u>\$ 9,440</u>
		As of December 31,	
		2010	2009
Assets			
Pharmaceutical		\$ 51,599	\$ 28,813
Instrumentation		8,637	12,262
Corporate		17,610	46,355
		<u>\$ 77,846</u>	<u>\$ 87,430</u>

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 Meas- Ueb t

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Note 19 Selected Quarterly Financial Data (Unaudited)

(in thousands)	For the 2010 Quarters Ended			
	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)

(in thousands)	For the 2009 Quarters Ended			
	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	(9,155) A	(5,734)		



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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 in the SEC's EDGAR system.

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., Froprix 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.

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Exhibit Number	Description
10.9(3)	Stock Purchase 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 FR

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.

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

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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-1 (NK-1) 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

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.

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 with the Licensed Product, or by the Third Party, less the amount actually paid by the 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 on the sale, delivery or use of Licensed Product).



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

- 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 L s sublin ~~to~~ ~~develop~~ ~~the~~
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TESARO) (“Right to Match”). OPKO’s Right to Match with regard to Latin AmericaWi



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 additional 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:

<u>Event Milestone</u>	<u>Event Milestone Payment</u>
(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
<u>Event Milestone</u>	<u>Event Milestone Payment</u>
(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) F (b) will be 2n w be 2n w be a + s

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 a 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

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 purp a fh

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 proceeding§ta

(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 Invalidation 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. s on Subliare, ili

**ARTICLE VI
CONFIDENTIALITY**

6.1. Confidential Information. The Term and for a period of ~~***~~ after any termination or expiration of this Agreement, each Party shall keep confidential and shall not disclose to any Third Party any Confidential Information of the other Party, except as may be required by law or as may be necessary to enforce the terms of this Agreement or to protect the other Party's intellectual property rights. The obligation of confidentiality shall survive the termination or expiration of this Agreement.



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 to 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

9.3. Termination for Cause. This Agreement may ~nâma

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 a provi ation

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

Party's current or future patents, trade secrets, copyrights, mora



(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 B

Description of SCH 900978

Chemical Structure of SCH 900978:

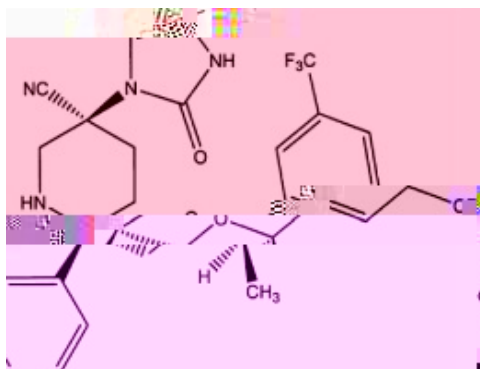


Exhibit C
OPKO Patent Rights
[Attached]

Patent Status by Division

Division: OPKO OPKO

Docket Country	Status	Application Number	Filing Date
<hr/>			
<hr/>			

Sort Order: by Division

Print Remarks?: No

Print Inventors?: No

Print Abstract: No

Action

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 ~~the s ~ â~~

OPKO Representatives

<i>Functional Area Represented</i>	<i>Role</i>	<i>Initial Designee</i>
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

<i>Functional Area Represented</i>	<i>Role</i>	<i>Initial Designee</i>
Team Leader	Act as primary interface with respect to TESSARO 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 TESSARO'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 TESSARO and/or any of TESSARO'S designees. Provide reasonable explanation to TESSARO and/or any of TESSARO'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 TESSARO and/or any of TESSARO'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, pharmacokinetics) 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:



Func

Function
Regulat

Service to be Provided by OPKO

Comments



Table 1
Technology Transfer Schedule

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Date: _____ (or such later

<u>OPKO Know-how</u>	<u>Delivery Time (or such later time as TESARO may request)</u>	<u>Delivery Method</u>	<u>Discussion/Comments</u>
• ****	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	
• ****			§ s

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• ****	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	****

<u>OPKO Know-how</u>	<u>Delivery Time (or such later time as TESARO may request)</u>	<u>Delivery Method</u>	<u>Discussion/Comments</u>
****	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	
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Delivery Tim

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-1 (NK-1) 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 HCl), 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 of NK-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.

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 ****.

SUBSIDIARIES OF OPKO HEALTH, INC.

<u>NAME</u>	<u>JURISDICTION OF INCORPORATION</u>
OPKO Instrumentation, LLC	Delaware
OPKO Pharmaceuticals, LLC	Delaware
Froptix LLC	Florida
Ophthalmics Technology, Inc.	Ontario, Canada

Consent of Independent Registered Public Accounting Firm

internal ;f
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 ;f

I. 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

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**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT**
