

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

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**FORM 10-K**

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

For the fiscal year ended December 31, 2012

OR

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

For the transition period from            to            .

Commission file number 001-33528

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**OPKO HEALTH, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**DELAWARE**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**75-2402409**  
(I.R.S. Employer  
Identification No.)

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

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

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

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

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

None

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

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

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

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

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

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

Large Accelerated filer

Accelerated filer

Non-Accelerated filer  (Do not check if a smaller reporting company)

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EX-101.INS XBRL Instance Document

EX-101.SCH XBRL Taxonomy Extension Schema Document

EX-101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

EX-101.DEF XBRL Taxonomy Extension Definition Linkbase Document

EX-101.LAB XBRL Taxonomy Extension Label Linkbase Document

EX-101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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- In September 2009, we acquired a minority equity interest in Cocrystal Discovery, Inc. (“Cocrystal”), a privately-held biopharmaceutical company focused on the discovery and development of novel small molecule antiviral therapeutics tailored for the treatment of serious and chronic viral diseases. In September 2011, Teva signed a collaboration option to license and share purchase agreements to invest in Cocrystal. Dr. Phillip Frost, our Executive Officer and Chairman of our Board of Directors, is Chairman of the Board of Directors of Teva. Teva agreed to initially invest \$7.5 million in Cocrystal, and Cocrystal will develop an antiviral drug targeting the polymerase enzyme of the Hepatitis C virus for Teva. <sup>1</sup>/<sub>1</sub>

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- our ability to secure reimbursement for our product candidates,
- the price of the products we may develop and commercialize relative to competing products;
- our ability to accurately forecast and meet demand for our product candidates if regulatory approvals are achieved;
- our ability to develop a commercial scale infrastructure either on our own or with a collaborator, which would include expansion of existing facilities, including our manufacturing facilities, development of a sales and distribution network, and other operational and financial systems necessary to support our increased scale;
- our ability to maintain a proprietary position in our technologies; and
- our ability to rapidly expand the existing information technology infrastructure and configure existing operational, manufacturing, and financial systems (on our own or with third party collaborators) necessary to support our increased scale, which would include existing or additional facilities and or partners.

**REGULATORY OVERSIGHT**

The U.S. government regulates healthcare through various agencies. The U.S. Food and Drug Administration (FDA) is the primary regulatory agency for the development, manufacture, and distribution of pharmaceuticals. The FDA is responsible for ensuring that drugs are safe, effective, and of high quality. The FDA also regulates medical devices, biologics, and off-investigational drugs. The U.S. Department of Health and Human Services (HHS) is responsible for the overall health and welfare of the United States. HHS oversees the FDA and other agencies, including the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). The U.S. Department of Justice (DOJ) is responsible for enforcing federal laws, including those related to healthcare. The DOJ also oversees the Federal Bureau of Investigation (FBI) and the Department of Health and Human Services Inspector General (OIG). The U.S. Department of Treasury (DOE) is responsible for managing the federal government's finances. The DOE also oversees the Internal Revenue Service (IRS) and the Social Security Administration (SSA). The U.S. Department of Education (DOE) is responsible for overseeing the federal government's education programs. The DOE also oversees the National Endowment for the Arts (NEA) and the National Endowment for the Humanities (NEH). The U.S. Department of Agriculture (DOE) is responsible for overseeing the federal government's agricultural programs. The DOE also oversees the National Aeronautics and Space Administration (NASA) and the National Science Foundation (NSF). The U.S. Department of Energy (DOE) is responsible for overseeing the federal government's energy programs. The DOE also oversees the National Energy Laboratory (NEL) and the National Energy Research Scientific Center (NERSC). The U.S. Department of the Interior (DOI) is responsible for overseeing the federal government's land and natural resources. The DOI also oversees the National Park Service (NPS) and the Bureau of Land Management (BLM). The U.S. Department of the Environment (DOE) is responsible for overseeing the federal government's environmental programs. The DOE also oversees the Environmental Protection Agency (EPA) and the National Oceanic and Atmospheric Administration (NOAA). The U.S. Department of State (DOE) is responsible for overseeing the federal government's foreign relations. The DOE also oversees the United States Agency for International Development (USAID) and the United States Agency for Global Media (USAGM). The U.S. Department of Veterans Affairs (DOE) is responsible for overseeing the federal government's veterans programs. The DOE also oversees the National Cemetery Administration (NCA) and the Department of Veterans Affairs Medical Center (VAMC). The U.S. Department of Housing and Urban Development (DOE) is responsible for overseeing the federal government's housing and urban development programs. The DOE also oversees the Federal Housing Administration (FHA) and the Department of Housing and Urban Development Inspector General (OIG). The U.S. Department of Labor (DOE) is responsible for overseeing the federal government's labor programs. The DOE also oversees the Occupational Safety and Health Administration (OSHA) and the National Labor Relations Board (NLRB). The U.S. Department of Transportation (DOE) is responsible for overseeing the federal government's transportation programs. The DOE also oversees the Federal Aviation Administration (FAA) and the National Transportation Safety Board (NTSB). The U.S. Department of Justice (DOE) is responsible for overseeing the federal government's justice programs. The DOE also oversees the Federal Bureau of Investigation (FBI) and the Department of Justice Inspector General (OIG). 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might previously have been cleared under the 510(k) process may be require approval under the PMA process. Similarly, the Medical User Fee Amendments of 2012 authorized the FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2012, including 510(k)s. These fees are intended to improve the device review process, but the actual impact on the industry is still unknown.

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

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

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

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

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



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

### *State and Federal Security and Privacy Regulations*

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

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

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

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

We are also subject to various federal, state, and international laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. The federal Anti-Kickback Statute prohibits anyone from knowingly and willfully soliciting, receiving, offering, or paying any remuneration with the intent to refer, or to arrange for the referral or order of, services or items payable under a federal health care program, including the purchase or prescription of a particular drug or the use of a service or device. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the U.S. Department of Health and Human Services Office of Inspector General to issue guidance on the application of the statute to certain arrangements. The guidance is not binding on the courts, but it is highly influential in the way the statute is enforced. The guidance also provides that the statute does not apply to certain arrangements, including those that are approved by the Office of Inspector General. The guidance is available at <http://www.oig.hhs.gov/oea/whistleblower/anti-kickback/>.





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*Foreign Corrupt Practices Act*

We are also subject to the U.S. Foreign Corrupt Practices Act (“FCPA”), which prohibits corporate





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

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

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

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

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

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

### ***Our product development activities could be delayed or stopped.***

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

- a limited number of, and competition for, suitable patients with the particular types of disease required for enrollment in our clinical trials or that otherwise meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;
- a limited number of, and competition for, suitable serum samples from patients with particular types of disease required for our validation studies;
- a limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA or other non-U.S. regulatory authorities' approval or agreement to commence a clinical trial;



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

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

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved or cleared drugs and diagnostic products. The commercial success of our existing and future product candidates in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors. The government and other third-party payors are increasingly attempting to contain their expenditures on pharmaceuticals.

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We have scientific and clinical advisors who assist us in formulating our research, development, and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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

*As we evolve from a company primarily involved in development frofrofrofi*

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

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

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

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

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

***We currently have limited marketing staff and no pharmaceutical or device sales staff. Although we have a sales and marketing team, we currently have limited marketing staff and no pharmaceutical or device sales staff.***



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

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

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

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

The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, unenforceable, or circumvented. Moreover, the U.S. Patent and Trademark Office (“USPTO”) may commence interference proceedings involving our patents or patent applications. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology, pharmaceutical, and medical device companies. Any challenge to, finding of unenforceability or invalidation or circumvention of, our patents





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*We license patent rights to certain of our technology*





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*Non-U.S. governments often in*

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

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

### ***We are subject to risks associated with doing business globally.***

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

## **RISKS RELATED TO ACQUISITIONS AND INVESTMENTS**

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

- difficulty integrating acquired technologies, products, services, operations, and personnel with the existing businesses;
- diversion of management's attention in connection with both negotiating the acquisitions and integrating the businesses;
- strain on management

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

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

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

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

## **RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK**

### ***The market price of our Common Stock may fluctuate significantly.***

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

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

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

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

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

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

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

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

### ***Directors, executive officers, principal stockholders and affiliated entities ow***



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

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm on the effectiveness of internal control over financial reporting as of December 31, 2012. p of Decemb012.n



**PART II**

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

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

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

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

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



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

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- In February 2012, we purchased from Biozone Pharmaceuticals, Inc. (“BZNE”), a publicly-traded company that specializes in drug development, manufacturing, and marketing, \$1.7 million of 10% secured convertible promissory notes (the “BZNE Notes”), and ten year warrants (the “BZNE Warrants”) to purchase 8.5 million shares of BZNE common stock. In July 2012, we exercised the BZNE Warrants using their cashless net exercise feature and received 7,650,000 shares of BZNE common stock. We also entered into a license agreement pursuant to which we acquired a world-wide license for the development and commercialization of products utilizing BZNE’s proprietary drug delivery technology, including a technology called QuSomes, exclusively for OPKO in the field of ophthalmology and non-exclusive for all other therapeutic fields, subject in each case to certain excluded products.
- In February 2012, we made a \$1.0 million investment in ChromaDex Corporation (“ChromaDex”), a publicly-traded company and leading provider of proprietary ingredients and products for the dietary supplement, nutraceutical, food and beverage, functional food, pharmaceutical and cosmetic markets. We also entered into a license, supply and distribution agreement with ChromaDex pursuant to which we obtained exclusive distribution rights to certain of its products in Latin America.

## **RECENT DEVELOPMENTS**

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

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









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

*Amortization of intangible assets*

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In connection with the acquisition of ALS, we paid (i) \$2.4 million in cash at the closing, less certain liabilities, and (ii) \$0.8 million in cash at the closing into a separate escrow account to satisfy possible indemnity claims. We agree

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

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

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

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

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

We believe the cash, cash equivalents and marketable securities on hand at December 31, 2012, the net proceeds of \$170.5 million from our January 2013 convertible debt offering, and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates. If we aai for or

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

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

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

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

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

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

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

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

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

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Interest Rate Risk – Our exposure to market risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of theæres



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### *FineTech acquisition*

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

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

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

### *OPKO Diagnostics acquisition*

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





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

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### *Series C Preferred Stock*

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

### *8% Series D Cumulative Convertible Preferred Stock*

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

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

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

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

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

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

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

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

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

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

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

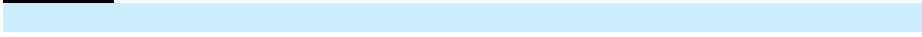
During 2008, we conducted a study to determine the impact of the various ownership changes that occurred during 2007 and 2008. As a result, we have concluded that the annual utilization of our net operating loss carryforwards (“NOLs”) and tax credits is subject to a limitation pursuant to Internal Revenue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

### ***Uncertain Income Tax Positions***

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







We also entered into a research funding and option agreement to provide funding of approximately \$0.2 million annually over three years to support further development of the technology. Dr. Frost serves as a Trustee for TSRI and Dr. Lerner served as its President until December 2011.

In February 2012, we made a \$1.0 million investment in ChromaDex. **D** v

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

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

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

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

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

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

In July 2009, we entered into a worldwide exclusivity agreement with Academia Sinica for a new technology to develop protein vaccines against influenza and other viral infections. Effective in March 2010, the Frost Group assigned two license agreexclus



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

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

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

**Note 15 Strategic Alliances**

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

**Note 16 Leases**

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












[Redacted text block 1]

[Redacted text block 2]



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On March 1, 2013, we entered into an asset purchase agreement (the “Asset Purchase Agreement”) with RXi Pharmaceuticals Corporation (“RXi”). On March 12, 2013, pursuant to the Asset Purchase Agreement, we sold to RXi substantially all of our assets in the field of RNA interference (the “RNAi Assets”). As consideration for the RNAi Assets, at the closing of the Asset Purchase Agreement, RXi issued to us 50 million shares of its common stock (the “APA

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On January 29, 2013, we entered into note purchase agreements, dated January 25, 2013, with various purchasers (collectively, the “Purchasers”) for the sale of \$175.0 million aggregate principal amount of 3.00% convertible senior notes due 2033 (the “Notes”) to qualified institutional buyers and accredited investors (collectively, the “Note Purchase Agreement”) in a private placement in reliance on exemptions from registration under cer

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

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

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

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

**ITEM 9B. OTHER INFORMATION.**

None.

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**PART 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. I .
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4.2	Form of Common Stock Warrant.
10.1	Form of Lockup Agreement.
10.2	License Agreement, dated as of March 31, 2003, by and between the Trust and Marp Agr









[\*] CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS. ASTERISKS DENOTE SUCH OMISSIONS.

**Exhibit 2.9**

**Execution Copy**

**AGREEMENT AND PLAN OF MERGER**

This Agreement and Plan of Merger (the "Agreement") is entered into as of October 18, 2012, among Prost-Data, Inc., a corporation organized under the laws of Oklahoma and d/b/a Our Lab, Our Labs, Endo Labs and Gold Lab (the "Company"), Jonathan Oppenheimer, M.D., the sole shareholder of the Company (the "Shareholder"), OPKO Health, Inc., a Delaware corporation

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“Agreement” means this Agreement together with all exhibits and schedules referred to herein.

“Cash Holdback” means the \*\*\* of \$4,000,000 or \*\*\* of the \*\*\* in the \*\*\* as of the Closing Date.

“Closing Date” means the date upon which the Closing actually occurs.

“Closing Financial Statements” means (A) the audited balance sheet of the Company as of December 31, 2011, and the audited statement of operations, statement of change in shareholder’s equity, and statement of cash flow for the fiscal year ended on December 31, 2011, including any related notes, certified by the Company’s independent certified public accountan







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“Subsidiary” of a specified Person means a Person in which such Person ofñ

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powers and franchises of the Interim Surviving Corporation shall vest in Merger Sub II as the surviving entity in the Second Step Merger, and all debts, liabilities and duties of the Interim Surviving Corporation shall become the debts, liabilities and duties of Merger Sub II as the surviving entity in the Second Step Merger.

### **2.3 Conversion of Securities of Company; Merger Consideration.**

(a) At the Effective Time, by virtue of the First Step Merger and without any action on the part of Buyer, Merger Sub I, the Company or their respective shareholders, all of the Securities of the Company issued and outstanding immediately prior to the Effective Time shall be canceled and converted automatically into the right to receive an aggregate of Forty Million Dollars (\$40,000,000) payable as follows:

(i) Nine Million Three Hundred and Seventy Five Thousand Dollars (\$9,375,000) shall be payable in cash at Closing by wire transfer of immediately available funds to an account designated by Shareholder, less the Cash Holdback, subject to the provisions of Section 6.4(i) hereof (the "Cash Consideration"); and

(ii) Thirty Million Six Hundred and Twenty Five Thousand Dollars (\$30,625,000) shall be payable by delivering that number of shares of OPKO Common Stock calculated by dividing 30,625,000 by \$4.33, which represents the average closing price ("Average Closing Sales Price") of a share of OPKO Common Stock for the fifteen trading days preceding the date on which this Agreement is executed (the "Stock Consideration," and together with the Cash Consideration, the "Merger Consideration"). At the Closing, Buyer shall (a) deposit shares representing Seven Million Five Hundred Thousand Dollars (\$7,500,000) of the Stock Consideration with the Escrow Agent to be held, until the eighteen-month anniversary of the Closing Date, in escrow pursuant to the Escrow Agreement to secure the Company's and Shareholder's indemnification obligations pursuant to this Agreement (the "Escrow Shares"); and (b) deliver Twenty Three Million One Hundred and Twenty Five Thousand Dollars (\$23,125,000) of the Stock Consideration to the Shareholder (the "Closing Shares").

### **2.4 Certificate of Formation; Bylaws.**

(a) At and as of the Effective Time, the Certificate of Incorporation of Merger Sub I as in effect immediately prior to the Effective Time shall be the Certificate of Incorporation of the Interim Surviving Corporation. At and as of the Effective Time, the bylaws of the Merger Sub I as in effect immediately prior to the Effective Time shall be the bylaws of the Interim Surviving Corporation until amended or repealed in accordance with the provisions thereof and applicable law.

(b) At and as of the effective time of the Second Step Merger, the Certificate of Formation of Merger Sub II as in effect immediately prior to the effective time of the Second Step Merger shall be the Certificate of Formation of the Final Surviving Entity; *provided, however*, that at the effective time of the Second Step Merger, the appropriate section of such Certificate of Formation shall be amended and restated in its entirety to read as follows: "The name of this limited liability company is OPKO OURLab, LLC". At and as of the Effective Time, the limited liability company agreement of Merger Sub II as in effect immediately prior to the effective time of the

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Second Step Merger shall be the limited liability company agreement of the Final Surviving Entity until amended or repealed in accordance with the provisions thereof and applicable law; *provided, however*, that at the effective time of the Second Step Merger, the appropriate section of such limited liability company agreement shall be amended and restated in its entirety to read as follows: “The name of this limited liability company is OPKO OURLab, LLC”.

### **2.5 Directors/Managers and Officers**

(a) At and as of the Effective Time, the directors of Merger Sub I immediately prior to the Effective Time shall be the directors of the Interim Surviving Corporation and shall serve in such capacities until their respective successors are duly elected and qualified. The Final Surviving Entity shall initially be managed by Buyer, as its sole member.

(b) At and as of the Effective Time, the officers of Merger Sub I immediately prior to the Effective Time shall be the officers of the Interim Surviving Corporation immediately after the Effective Time and the officers of the Final Surviving Entity immediately after the effective time of the Second Step Merger, and shall serve in such capacities until their respective successors are duly elected and qualified.

## **ARTICLE 3**

### **REPRESENTATIONS AND WARRANTIES OF BUYER AND MERGER SUBS**

In order to induce the Company and the Shareholder to enter into this Agreement and to consummate the transactions contemplated hereby, Buyer and Merger Subs make the representations and warranties set forth below to the Company and the Shareholder.

**3.1 Organization.** Buyer is a corporation duly organized, validly existing and in good standing under the laws of Delaware. Merger Sub I is a corporation duly organized, validly existing and in good standing under the laws of Oklahoma. Merger Sub I is newly formed and was formed solely to effectuate the First Step Merger. Merger Sub II is a limited liability company duly organized, validly existing and in good standing under the laws of Florida. Merger Sub II is newly formed and was formed solely to effectuate the Second Step Merger. Buyer and Merger Subs are duly qualified or licensed to do business, and are in good standing, in each jurisdiction where the character of the properties owned, leased or operated by their or the nature of their businesses makes such qualification or licensing necessary. Buyer and Merger Subs have all requisite right, power and authority to (a) own or lease and operate their properties, (b) conduct their businesses as presently conducted and (c) engage in and consummate the transactions contemplated hereby. Merger Subs are each a directly held 100-percent owned subsidiary of Buyer.

**3.2 Authorization; Enforceability.** Each of Buyer and Merger Subs has all requisite right, power and authority to execute and deliver the Transaction Documents and to consummate the transactions contemplated thereby. The execution and delivery of the Transaction Documents by Buyer and Merger Subs and the consummation by Buyer and Merger Subs of the transactions contemplated thereby have been duly authorized by all requisite corporate or other action. The Transaction Documents have been duly executed and delivered by Buyer and Merger Subs, and constitute the legal, valid and enforceable obligations of Buyer and Merger Subs, and constitute the legal, valid and enforceable obligations of Buyer and Merger Subs, and constitute the legal, valid and enforceable obligations of Buyer and Merger Subs.



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**3.9 Brokers.** Neither Buyer nor Merger Subs has employed any financial advisor, broker or finder and has not incurred and will not incur any broker's, finder's, investment banking or similar fees, commissions or expenses, in connection with the transactions contemplated by this Agreement, which would be payable by the Company.

**3.10 Absence of Certain Changes or Events.** Except as disclosed in the Buyer SEC Reports, (a) since December 31, 2011, there has not occurred any Material Adverse Effect on Buyer, and (b) Buyer and its subsidiaries have carried on and operated their respective businesses in all material respects in the ordinary course of business consistent with past practices.

**3.11 Compliance with Laws.** Except as discussed in the Buyer SEC Reports, Buyer is in compliance in all material respects with all Laws and other legal requirements applicable to it or its properties, and Buyer has not received written notification from any governmental or regulatory authority asserting that it is not in compliance with or has violated any of the Laws, which such governmental or regulatory authority enforces, or threatening to revoke any Permit (as hereinafter defined), and Buyer is not subject to any agreement or consent decree with any governmental or regulatory authority arising out of previously asserted violations, except in each case, for matters which have not, and are not reasonably expected to result in, a Material Adverse Effect on Buyer.

**3.12 Consent of Governmental Authorities.** Except for compliance with federal Securities laws and NYSE requirements, no consent, approval or authorization of, or registration, qualification or filing with any governmental or regulatory authority is required to be made by Buyer in connection with the execution, delivery or performance of this Agreement by Buyer or the consummation by Buyer of the transactions contemplated hereby.

#### ARTICLE 4

##### REPRESENTATIONS AND WARRANTIES OF THE COMPANY AND THE SHAREHOLDER

In order to induce Buyer and Merger Subs to enter into this Agreement and to consummate the transactions contemplated hereby, the Company and the Shareholder make the representations and warranties set forth below to Buyer and Merger Subs.

**4.1 Organization.** The Company has been duly organized and is validly existing and in good standing under the laws of the jurisdiction of its incorporation. The Company is duly qualified or licensed to do business, and is in good standing, in each jurisdiction where the character of the properties owned, leased or operated by it or the nature of its business makes such qualification or licensing necessary. Except as set forth on Schedule 4.25(c)(ii), the Company has all requisite right, power and authority to (a) own or lease and operate its properties, (b) conduct its business as presently conducted and (c) engage in and consummate the transactions contemplated hereby. The Company is not in default under its Organizational Documents.

**4.2 Authorization; Enforceability.** The Company and the Shareholder have all requisite right, power and authority to execute and deliver the Transaction Documents and consummate the transactions contemplated thereby. The execution and delivery of the Transaction Documents by the Company and the Shareholder and the consummation by it of the transactions contemplated hereby have been duly authorized by all requisite corporate and other required action. The Transaction Documents have been duly executed and delivered and constitute the legal, valid

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#### **4.8 Financial Statements.**

(a) Schedule 4.8(a) includes a complete copy of the Company's unaudited (i) Statement of Assets, Liabilities & Equity as of December 31, 2011; (ii) Statement of Revenue, Expenses, & Retained Earnings for the one-month and twelve months ending December 31, 2011; (iii) Statement of Assets, Liabilities & Equity as of July 31, 2012; and (iv) Statement of Revenue, Expenses, & Retained Earnings for the one-month and seven months ending July 31, 2012 (collectively, the "Company Financial Statements"). Except as set forth on Schedule 4.8(a), the Company Financial Statements: (a) have been prepared in accordance with the books of account and records of the Company; (b) fairly present, and represent in all material respects true, correct and complete statements of the financial condition of the Company and the results of its operations at the dates and for the periods specified in those statements; and (c) have been prepared on the cash basis of accounting, consistently applied with prior periods.

#### **4.9 Absence of Undisclosed Liabilities.**

(a) Except as set forth on Schedule 4.9(a)R





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(n) enter into any transaction, commitment or agreement, or amend or terminate any existing Contract material to the Company or where the amount involved exceeds \$10,000 per transaction, commitment or agreement or amendments of \$20,000 in the aggregate;

(o) acquire (including, without limitation, by merger, consolidation or acquisition of stock or assets) any interest in any corporation, partnership, other business organization, Person or any division thereof or any assets thereof other than capital expenditures within the limits described in subsection (i) hereof;

(p) alter the manner of keeping its books, accounts or records, or change in any manner the accounting practices, methods or assumptions therein reflected;

(q) agree to accelerate or delay collection of notes or accounts receivable in advance of or beyond their regular dates or the date when the same could have been collected in the ordinary course of business consistent with past practices;

(r) waive, release, assign, settle or compromise any claims or litigation;

(s) make any Tax election or settle or compromise any federal, state or local or federal income Tax liability;

(t) take or omit to take any action which is intended to render any of the Company's representations or warranties untrue or misleading, or which would be a material breach of any of the covenants of this Agreement;

(u) take any action which could have a Material Adverse Effect; or

(v) agree, whether in writing or otherwise, to do any of the foregoing.

**4.13 List of Accounts.** Set forth on Schedule 4.13 is: (a) the name and address of each bank or other institution in which the Company maintains an account (cash, securities or other) or safe deposit box; (b) the name and phone number of the Company's contact person at such bank or institution; (c) the account number of the relevant account and a description of the type of account; and (d) the persons authorized to transact business in such accounts.

**4.14 Tax Matters.**

(a) All Tax returns and other similar documents required to be filed with respect to the Company have been timely filed (after taking into account any extensions to file) with the appropriate governmental authorities in all jurisdictions in which such returns and documents are required to be filed prior to the Closing Date, all of the foregoing as filed are true, correct and complete and reflect accurately all liabilities for Taxes of the Company for the periods to which such returns and documents relate, and all amounts shown as owing thereon have been paid. No claims or deficiencies have been asserted against the Company with respect to any Taxes which have not been paid or otherwise satisfied or for which accruals or reserves have not been made in the Financial Statements, and to the Knowledge of the Company, there exists no reasonable basis for the making of any such claim. The Company has not waived any restrictions on assessment or collection of Taxes or consented to the extension of any statute of limitations relating to taxation.

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(b) During the last 5 years (or any open tax year), there has been no, and as of the date hereof, there are no presently pending audits or other administrative proceedings or court proceedings with respect to any Taxes of the Company. No claim has ever been made by a governmental entity in a jurisdiction where the Company does not file a Tax Return that the Company is or may be subject to taxation by that jurisdiction.

(c) All Taxes required to be paid (

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all of the assets and rights required to operate the business of the Company as conducted on the date of this Agreement. All of the Assets are in reasonable operating condition and repair, ordinary wear and tear excepted. Schedule 4.16 sets forth a full and complete list of the material Assets owned by the Company.

#### **4.17 Intellectual Property.**

(a) Schedule 4.17(a) sets forth a true and complete list of (i) all patents and patent applications, registered trademarks and trademark applications, registered copyrights and copyright applications and domain names included in the Company Intellectual Property, (ii) all Company IP Agreements, and (iii) other Company Intellectual Property material to the Company's business.

(b) Except as disclosed in Schedule 4.17(a), the Company is the exclusive owner of the entire right, title and interest in and to the Company Intellectual Property, and has a valid license to use the Licensed Intellectual Property in connection with the Company's business. The Company is entitled to use all Company Intellectual Property and Licensed Intellectual Property in the continued operation of the Company's business without limitation, subject only to the terms of the Company IP Agreements. The Company Intellectual Property and the Licensed Intellectual Property have not been adjudged invalid or unenforceable in whole or in part, and, to the Knowledge of the Company, are valid and enforceable.

(c) The conduct of the Company's business as currently conducted does not infringe or misappropriate the Intellectual Property of any third party, and no Action alleging any of the foregoing are pending, and no Action has been threatened or asserted against Shareholder or the Company alleging any of the foregoing. To the Knowledge of the Company, no Person is engaging in any activity that infringes the Company Intellectual Property.

(d) No Company Intellectual Property is subject to any outstanding Governmental Order restricting the use of such Intellectual Property or that would impair the validity or enforceability of such Intellectual Property.

#### **4.18 Real Property.**

(a) The Company does not own any real property.

(b) Schedule 4.18(b) sets forth the street address of each parcel of real property leased by the Company (the "Leased Real Property"). The Company has previously delivered to Buyer true and complete copies of all lease agreements, as amended to date (the "Leases") relating to the Leased Real Property. The Company enjoys peaceable and undisturbed possession of the Leased Real Property.

**4.19 Compliance with Environmental Laws.** The Company is in compliance with all applicable Environmental Laws. To the Knowledge of Company, there are no pending governmental claims, citations, notices of violation, judgments, decrees or orders issued against the Company for impairment or damage, injury or adverse effect to the environment or public health and, to the Knowledge of the Company and there have been no private complaints with respect to any such matters. To the Knowledge of the Company, there is no condition relating to any properties of the Company that would require any type of remediation, clean-up, response or other

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action under applicable Environmental Laws. The Company has complied with all applicable Environmental Laws in the generation, treatment, transportation, storage and disposal of Hazardous Materials.

**4.20 Employment Matters.**

(a) Employment Agreements. Schedule 4.20(a) sets forth all employment, consulting, severance, and indemnification arrangements, agreements and understandings between the Company and any officer, director, advisory board member, consultant or employee ("Employment Agreements"). The Company has delivered to the Buyer true and complete copies of all of the Employment Agreements. No Employment Agreement (i) will require any payment by the Company or Buyer to any director, officer or employee of the Company, or any other party, by reason of the change in control of the Company resulting from the transactions contemplated by this Agreement, or (ii) provides for the acceleration or change in the award, grant, vesting or determination of options, warrants, rights, severance payments, or other contingent obligations of any nature whatsoever of the Company in favor of any such parties. Except as set forth on Schedule 4.20(a), the terms of employment or engagement of all directors, officers, employees, agents, consultants and professional advisers of the Company are such that their employment or engagement may be terminated at any time without liability for payment of compensation or damages (other than, with respect to employees of the Company, the payment of the statutory minimum compensation) and the Company has not entered into any agreement or arrangement for the management of its business or any part thereof other than with its directors or employees.

(b) Personnel. Schedule 4.20(b) contains the names and job descriptions of all officers, directors, advisory board members, consultants, and employees of the Company. The Company previously has delivered to the Buyer the annual salary rates and other compensation of any kind of such person.

(c) Employment Laws. Except as set forth on Schedule 4.20(c), the Company has complied with all applicable employment Laws, including payroll, withholding and related obligations, benefits, social security, and does not have any obligation in respect of any amount due to employees of the Company, other than normal salary, fringe benefits and contributions accrued but not payable on the date hereof.

(d) Policies. Schedule 4.20(d) contains a list of all employee policies (written or otherwise), employee manuals or other written statements of rules or policies concerning employment, including working conditions, vacation and sick leave, a complete copy of each of which (or, if oral, an accurate written summary thereof) has been previously delivered to Purchasers.

(e) Employee Benefit Plans. Except as set forth on Schedule 4.20(e), the Company does not maintain any "employee benefit plans" for its employees.

**4.21 Labor Relations**. Except as set forth on Schedule 4.21, there is no strike or dispute pending or, to the Knowledge of the Company, threatened involving any employees of the Company. None of the employees of the Company is a member of any labor union, and the Company is not a party to, otherwise bound by or, to the Knowledge of the Company, threatened





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or permit, and the Company is not subject to any agreement or consent decree with any governmental or regulatory authority arising out of previously asserted violations.

(b) Except as set forth on Schedule 4.25(b), without limiting the generality of the foregoing clause (a), the Company (A) is in material compliance with any and all of the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), including all material requirements of the Transactions Rule and the Privacy and Security Rules and (B) is not subject to, and would not reasonably be expected to become subject to, any civil or criminal penalty or any investigation or claim in connection with any violation by such Person of the requirements of HIPAA.

(c) Except as set forth in Schedule 4.25(c), without limiting the generality of clause (a) above, neither the Company, nor to the Company's Knowledge, any of the Company's officers, directors, managing employees or agents, have engaged in any activity, whether alone or in concert with one or more of their business associates, which would constitute a violation of:

(i) The federal Medicare or Medicaid Statutes, Public Contracts Anti-Kickback Act, 41 U.S.C. § 51, et seq., the federal statutes relating to health care fraud and abuse and kickbacks, including 42 U. S.C. § 1320a-7b, 42 U.S.C. § 1320a-7a, 42 U.S.C. § 1395nn and the federal Civil False Claims Act, or related or similar statutes pertaining to any other federal health care program;

(ii) state Laws pertaining to the operation of clinical laboratories and the provision of services by the Company; or

(iii) CLIA Laws including 42 U.S.C. § 263a *et seq* and 42 C.F.R. § 493 *et seq*, or related or similar statutes.

(d) Without limiting the generality of clause (a) above, neither the Company nor, to the Knowledge of the Company, its officers, directors, managing employees, agents or persons with direct or indirect ownership interests of the Company (as those terms are used in 42 C.F.R. § 1001.1001):

(i) has had a civil monetary penalty assessed against it under Section 1128A of the Social Security Act or any regulations promulgated thereunder;

(ii) except as set forth on Schedule 4.25(d)(ii), has been excluded from participation in any manner under the Medicare or Medicaid program or any other federal health care program (as defined in the Social Security Act Section 1128B(f)) or a state health care program (as defined in the Social Security Act Section 1128(h)) or any regulations promulgated thereunder;

(iii) has been convicted of any criminal offense relating to the delivery of an item or service under Medicare, Medicaid, any other federal health care program or state health care program;





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all applicable Laws and regulations, including those relating to investigational use, premarket clearance or marketing approval (or exemptions therefrom) to market a Product or Service, good manufacturing practices, labeling, advertising, record keeping and filing of reports and security. Except as set forth on Schedule 4.29(a), no Product or Service sold, provided or delivered by the Company is subject to any guaranty, warranty (other than warranties imposed by Law) or other indemnity.

(b) Except as set forth on Schedule 4.29(b), at no time have any of the Products been recalled, withdrawn or Products or Services suspended by the Company, voluntarily or otherwise; nor are there any pending Actions or ~~in~~ ~~pro~~ ~~cess~~

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**4.30 Brokers.** The Company has not employed any financial advisor, broker or finder and have not incurred and will not incur any broker's, finder's, investment banking or similar fees, commissions or expenses in connection with the transactions contemplated by this Agreement, which would be payable by the Company or Buyer.

**4.3**

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(b) Buyer shall file or cause to be filed all Tax returns of the Company due after the Closing Date other than the final income Tax return of the Company for the short S Corporation taxable year which shall be the responsibility of Shareholder. Buyer shall have the opportunity to review and comment on each such tax return prepared by Shareholder prior to filing and Shareholder shall have the opportunity to review and comment on each such tax return prepared by Buyer prior to filing with respect to which Shareholder may be responsible for such taxes reported on such return under this Agreement.

(c) Buyer, Shareholder and the Company shall cooperate fully, as and to the extent reasonably requested by the other party, in connection with the preparation and filing of Tax Returns pursuant to this Agreement and any audit, litigation or other proceeding relating to Taxes. Buyer, Shareholder and the Company shall retain all books and records with respect to Tax matters pertinent to the Company relating to any Tax period beginning before the Closing Date until the expiration of the applicable statute of limitations and to abide by all record retention agreements entered into with any taxing authority.

**6.9 Continuing Company Employees.** As of and following the Closing Date, Buyer shall permit employees of Company who continue employment with Buyer or any of its subsidiaries following the closing Date, and, as applicable, their eligible dependents, to participate in the employee welfare benefit plans, programs or policies of Buyer, any plan of Buyer intended to qualify within the meaning of Section 401(a) of the Code and any equity compensation plans sponsored or maintained by Buyer for similarly situated employees of Buyer. These employees shall also be eligible to continue in their current paid time off plan or the Buyer's paid time off plan, at the discretion of the Buyer. Such continuing employees (i) shall receive credit for purposes of eligibility and vesting for years of service with the Company prior to the Closing date in the applicable welfare benefit plans and pension plan (intended to qualify within the meaning of Section 401(a) of the Code) of Buyer, and (ii) shall receive credit for the purpose of vacation accrual levels after the Closing date for years of service with the Company prior to the Closing Date. Notwithstanding anything to the contrary, any such credit and waiver will not result in duplication of benefits.

## ARTICLE 7

### INTERIM COVENANTS

#### 7.1 Interim Operations of the Company.

(a) The Company and the Shareholder The CTG <sup>fitsot</sup> f



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(x) grant any guaranty;

(xi) waive, release, assign, settle or compromise any material claim or litigation;

(xii) except as required by Law, increase the compensation payable or to become payable to directors, officers, employees, consultants or agents or grant any rights to severance or termination pay to, or enter into any employment or severance agreement with any of the foregoing Persons or establish, adopt, enter into or amend any collective bargaining, bonus, profit sharing, thrift, compensation, stock option, restricted stock, pension, retirement, deferred compensation, employment, termination, severance or other plan, agreement, trust, fund, policy or arrangement for the benefit of any of the foregoing Persons;

(xiii) acquire (including, without limitation, by merger, consolidation or acquisition of stock or assets) any interest in any corporation, partnership, other business organization, Person or any division thereof or any assets;

(xiv) alter the manner of keeping its books, accounts or records, or change in any manner the accounting practices therein reflected, except for adoption and preparation of the Closing Financial Statements and Closing Trial Balance in accordance with U.S. GAAP;

(xv) make any Tax election or settle or compromise any material federal, state or local or federal income Tax Liability;

(xvi) write down any of its assets;

(xvii) enter into any commitment or transaction, which would survive the Closing Date, except in the ordinary course of business consistent with past practice;

(xviii) accelerate, terminate, modify or cancel any Contract;

(xix) grant any license or sublicense of any right under or with respect to any Intellectual Property or disclose any proprietary or confidential information to any third party;

(xx) take or omit to take any action which would render any of the Company's or the Shareholder's representations or warranties untrue or misleading, or which would be a breach of any of the Company's or the Shareholder's covenants;

(xxi) enter into any Contract, transaction or arrangement with any Affiliate;

(xxii) take any action which could have a Material Adverse Effect; or

(xxiii) agree, whether in writing or otherwise, to do any of the foregoing.

**7.2 Consent of Governmental Authorities and Others.** Each of Buyer, on the one hand, and the Company and the Shareholder, on the other, agree to file, submit or request (or cause to be filed, submitted or requested) promptly after the date of this Agreement and to prosecute diligently any and all (a) applications or notices required to be filed or submitted to

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provided that the failure of any such condition is not the result of any action, or failure to act, by the Company or Shareholder which occurs subsequent to the date of this Agreement:

(a) Representations and Warranties True. The representations and warranties of Buyer and Merger Subs contained in this Agreement or in any certificate or other document delivered pursuant to this Agreement shall be true and correct in all material respects (except for representations and warranties which are by their terms qualified by materiality, which shall be true and correct to the extent of such materiality) as of the Closing Date with the same force and effect as though made on and as of such date and shall have been true as of the date hereof.

(b) Covenants Performed. The covenants of Buyer and Merger Subs contained in this Agreement to be performed or complied with on or before the Closing Date shall have been duly performed or complied with.

(c) No Material Adverse Effect on Buyer. There shall not have occurred any Material Adverse Effect on Buyer, the impact of which the parties have not been able to resolve to the satisfaction of both parties, acting in good faith and in a commercially reasonable manner.

(d) No Material Adverse Effect on the Company. There shall not have occurred any Material Adverse Effect on the Company.

(e) No Litigation. No litigation, arbitration or other proceeding shall be pending or threatened by or before any court, arbitration panel or governmental authority; no law or regulation shall have been enacted after the date of this Agreement; and no judicial or administrative decision shall have been rendered; in each case, which enjoins, prohibits or materially restricts, or seeks to enjoin, prohibit or materially restrict, the consummation of the transactions contemplated by this Agreement.

(f) Buyer's Certificate. Buyer shall have delivered to the Sellers a certificate executed by an authorized officer of Buyer dated the Closing Date certifying that the conditions specified in this Section above have been fulfilled.

(g) Escrow Agreement. Buyer shall have executed and delivered to the Shareholder the Escrow Agreement.

(h) Employment Agreement. The Company shall have entered into an Employment Agreement on substantially the terms and in the form set forth on Schedule B.

(i) Release from Guaranteed Obligations. Shareholder shall have been released from any personal guarantees of any Company obligations which are set forth on Schedule 8.2 hereto.

### **8.3 Termination**

(a) Anything herein or elsewhere to the contrary notwithstanding, this Agreement may be terminated at any time before the Closing Date on the Esc the











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the State of Florida, and further irrevocably w

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IN WITNESS WHEREOF, the parties hereto have each executed and delivered this Agreement as of the day and year first above written.

**BUYER:**

**OPKO Health, Inc.**

By: /s/ Steven D. Rubin

Name: Steven D. Rubin

Title: Executive VP-Administration

4400 Biscayne Boulevard

Miami, Florida 33131

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USA  
Attn: Legal Department

Facsimile: (305) 575-4140

**SHAREHOLDER:**

**JONATHAN OPPENHEIMER, M.D.**

By: /s/ Jonathan Oppenheimer

Address: PO Box 50207  
Nashville, TN 37205

Facsimile:

**COMPANY:**

**Prost-Data, Inc.**

By: /s/ Jonathan Oppenheimer

Name: Jonathan Oppenheimer, M.D.

Title:

Address: PO Box 50207  
Nashville, TN 37205

Attn:  
Facsimile:

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**The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplementally any of the omitted schedules upon request by the Securities and Exchange Commission. Following is a list briefly identifying the contents of all omitted schedules:**

Schedule A - Escrow Agreement

Schedule B - Employment Agreement

The Company's Disclosure Schedules

Schedule 7.10 - Contributed Assets

Schedule 8.2 - Released Guarantees

Exhibit 1 - Certificate of Merger

Exhibit 2 - Second Step Certificate of Merger (OK)

Exhibit 3 - Second Step Certificate of Merger (FL)



SUBSIDIARIES OF OPKO HEALTH, INC.

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**CERTIFICATIONS**

I, Phillip Frost, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of OPKO Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in ~~the~~ **this** report;
- (4) The registrant's other certifying officer(s) ~~is~~ **are** ~~not~~ **is** a ~~financial~~ **financial** officer.

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**CERTIFICATIONS**

I, Juan F. Rodriguez, 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 internal control and m
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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of OPKO Health, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012 (the "Report"), and pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Frost, Chief Executive Officer of the Company, certify that to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Dr. Phillip Frost, M.D.

Dr. Phillip Frost, M.D.  
Chief Executive Officer  
March 18, 2013

