Opko Health, Inc.
Form 10-K
March 31, 2008

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, DC 20549**

**FORM 10-K**

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

For the fiscal year ended December 31, 2007

OR

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

Commission file number 000-26648

**OPKO HEALTH, INC.**
(Exact Name of Registrant as Specified in Its Charter)

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

4400 Biscayne Blvd., Suite 1180, Miami, FL 33137
(Address of Principal Executive Offices, Zip Code)

Registrant's Telephone Number, Including Area Code: (305) 575-4138

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

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, $.01 par value per share | American Stock Exchange |

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

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 þ

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 þ

Indicate by check mark if disclosures 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 (as defined in Rule 12b-2 of the Exchange Act).

| Large Accelerated filer ¨ | Accelerated filer ¨ | Non-Accelerated filer þ | Smaller Reporting Company ¨ |
|---|---|---|---|

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of the last business day of the Registrant's most recently completed second fiscal quarter was: $236,986,298.

As of March 21, 2008 the registrant had 182,150,969 shares of common stock outstanding.

**Documents Incorporated by Reference**

Portions of the registrant's definitive proxy statement for its 2008 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

**TABLE OF CONTENTS**


| | | Page |
|---|---|---|
| **Part I.** | | |
| Item 1. | Business | 6 |
| Item 1A. | Risk Factors | 23 |
| Item 1B. | Unresolved Staff Comments | 39 |
| Item 2. | Properties | 39 |
| Item 3. | Legal Proceedings | 39 |
| Item 4. | Submission of Matters to a Vote of Security Holders | 39 |
| **Part II.** | | |
| Item 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 41 |
| Item 6. | Selected Financial Data | 42 |
| Item 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 43 |
| Item 7A. | Quantitative and Qualitative Disclosures about Market Risk | 49 |
| Item 8. | Financial Statements and Supplementary Data | 50 |
| Item 9. | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure | 73 |
| Item 9A(T). | Controls and Procedures | 73 |
| Item 9B. | Other Information | 74 |
| **Part III.** | | |
| Item 10. | Directors, Executive Officers and Corporate Governance | |
| Item 11. | Executive Compensation | |
| Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | |
| Item 13. | Certain Relationships and Related Transactions, and Director Independence | |

| | | |
|---|---|---|
| Item 14. | Principal Accountants Fees and Services | |
| **Part IV.** | | |
| Item 15. | Exhibits, Financial Statement Schedules | 76 |
| **Signatures** | | 78 |
| **Certifications** | | |

**CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS**

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

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

- We have a history of operating losses and we do not expect to become profitable in the near future.
- Our technologies are in an early stage of development and are unproven.
- Our drug research and development activities may not result in commercially viable products.
- We are highly dependent on the success of our lead product candidate, bevasiranib, and we cannot give any assurance that it will receive regulatory approval or be successfully commercialized.
- The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-United States regulatory authorities.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.
- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.
- Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.
- Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.
- We may not meet regulatory quality standards applicable to our manufacturing and quality processes.
- We may be unable to resolve issues relating to an FDA warning letter in a timely manner.

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

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

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

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

- We have no experience manufacturing our pharmaceutical product candidates and we therefore rely on third parties to manufacture and supply our pharmaceutical product candidates, and would need to meet various standards necessary to satisfy FDA regulations when we commence manufacturing.

- We currently have no pharmaceutical marketing, sales or distribution organization. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates.

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

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

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

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

- We will rely heavily on licenses from third parties.

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

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

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

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

- Acquisitions may disrupt our business, distract our management and may not proceed as planned; and we may encounter difficulties in integrating acquired businesses.

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

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

- The market price of our common stock may fluctuate significantly.

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

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

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

- We may be unable to maintain our listing on the American Stock Exchange, which could cause our stock price to fall and decrease the liquidity of our common stock.

- Future issuances of common stock and hedging activities may depress the trading price of our common stock.

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

- We do not intend to pay cash dividends on our common stock in the foreseeable future.

## PART I

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

## ITEM 1. BUSINESS

### OVERVIEW

We are a specialty healthcare company focused on the discovery, development and commercialization of proprietary pharmaceuticals, drug delivery technologies, diagnostic systems, and instruments for the treatment, diagnosis and management of ophthalmic disorders. Our business presently consists of the development of ophthalmic pharmaceuticals and the development, commercialization and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Our objective is to establish industry-leading positions in large and rapidly growing segments of ophthalmology by leveraging our preclinical and development expertise and our novel and proprietary technologies. We actively explore opportunities to acquire complementary pharmaceuticals, compounds, and technologies, which could, individually or in the aggregate, materially increase the scale of our business. We also intend to explore strategic opportunities in other medical markets that would allow us to benefit from our business and global distribution expertise, and which have operational characteristics that are similar to ophthalmology, such as dermatology. We intend to expand under the following strategic objectives.

*Leverage R&D strengths to develop our pharmaceutical product pipeline*. We plan to leverage our strengths in siRNA drug development, RNAi technology, and all phases of pharmaceutical research and development to further develop and commercialize a pipeline of pharmaceutical products used in the treatment of ophthalmic disorders with unmet medical needs, such as Age-Related Macular Degeneration, or AMD, glaucoma, diabetic retinopathy, and dry eye, among others.

*Develop novel diagnostic and disease management technologies*. We plan to invest in and develop novel technologies and products to diagnose ophthalmic disorders at the earliest stages and to monitor the disease state and track the impact of intervention over time and during the course of treatment. We believe these technologies will improve our understanding of disease processes, help individualize treatment options, improve clinical decision making and enhance clinical outcomes and quality of life for patients with a variety of ocular disorders, including AMD, diabetic retinopathy and glaucoma.

*Utilize expertise and resources to develop other ophthalmic products*. We also plan to use our expertise and resources to develop and commercialize other types of ophthalmic products beyond pharmaceutical products and diagnostic and imaging systems, including without limitation, drug delivery systems and other ophthalmic devices which aid in the management of ocular disorders.

*Acquire additional ophthalmic businesses, therapies and technologies and expand into complementary businesses*. We continue to seek to expand our current operations by acquiring additional ophthalmic businesses and therapeutic and diagnostic technologies. We also intend to explore strategic opportunities in other medical markets that would allow us to benefit from our business and global distribution expertise, and which have operational characteristics that are similar to ophthalmology, such as dermatology. While we have not yet made any definitive plans to acquire any dermatology-related businesses, we believe that there are opportunities to apply our expertise to this field.

*Utilize expertise and resources to enhance our competitive position*. We intend to utilize our wide-ranging technological innovation and proprietary position to enhance our competitive position in the ophthalmic products market. For example, we intend to utilize our diagnostic and instrumentation products to measure disease progression and treatment outcomes of our pharmaceutical products in clinical trials.

Key elements of our strategy are to:

- Obtain regulatory approval for our lead product candidate, bevasiranib, for Wet AMD;
- Develop a focused commercialization capability in the United States;
- Strategically utilize our R&D resources to advance our product pipeline;

- Develop and grow our instrumentation business beyond diagnostic and imaging systems to include drug delivery devices and other therapeutic devices and technologies;

- Utilize our ophthalmic expertise to identify and acquire companies with innovative ophthalmic technologies; and

- Expand into other medical markets, including dermatology, which we believe are complementary to and synergistic with our ophthalmology business.

**Corporate Information**

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

On November 28, 2007, we acquired Ophthalmic Technologies, Inc., or OTI, an Ontario corporation pursuant to a definitive share purchase agreement with OTI and its shareholders. As a result of this agreement, we have entered into the ophthalmic instrumentation market and have begun generating revenue from this business.

Our shares are publicly traded on the American Stock Exchange under the ticker “OPK”. Our principal executive offices are located in Miami, Florida. Our clinical operations are based in Morristown, New Jersey. OTI has offices in Toronto, Ontario, Canada, with a research and development branch office in Kingston, Ontario, Canada. OTI also maintains a research and development office in the United Kingdom at the University of Kent. We maintain a website at www.OPKO.com.

**BUSINESS**

We presently have eight compounds and technologies in research and development for the ophthalmic pharmaceutical market. Our most advanced drug candidate is bevasiranib, which we are developing for the treatment of Wet AMD. In July 2007, we initiated the first of two required pivotal Phase III trials for bevasiranib. Bevasiranib is the first therapy in late stage clinical development based on the Nobel Prize-winning RNA interference, or RNAi technology, and we believe it is the most advanced siRNA-based drug currently in development. Bevasiranib is administered locally to the eye through an intravitreal injection, and is designed to require administration every eight to 12 weeks. Lucentis®, an FDA approved treatment for the treatment of Wet AMD currently on the market, is recommended to be administered through intravitreal injection every four weeks. We are also researching and developing several novel pharmaceutical products for ophthalmic disorders, including Dry AMD, diabetic retinopathy and Diabetic Macular Edema, or DME, dry eye, viral conjunctivitis, and prevention of ocular infection. The following table lists our most advanced pharmaceutical product candidates, the initial indications that we plan to address through their development, and their development stage.

| Product Candidate | Initial Indication | Development Stage |
|---|---|---|
| Bevasiranib | Wet AMD | Phase III |
| Bevasiranib | Diabetic Retinopathy/DME | Phase I / II |
| Civamide | Dry Eye | Phase I/II |

| | | |
|---|---|---|
| ACU-HHY-011 | Wet AMD, Diabetic Retinopathy/DME | Pre-Clinical |
| ACU-XSP-001 | Allergy and Inflammation | Pre-Clinical |
| Wound Dressing | Post-surgical Wound Healing | Late Stage Research |
| ACU-HTR-028 | Wound-Healing-Antifibrotic | Pre-Clinical |
| Dry-AMD Compound | AMD | Pre-Clinical |
| N-Chlorotaurine | Viral Conjunctivitis | Late Stage Research |

In April 2007, we acquired 33% of Ophthalmic Technologies, Inc., or OTI, and in November 2007, we acquired the remaining 67% of OTI. Through OTI, we presently market four ophthalmic diagnostic systems and instrumentation products in over 60 countries worldwide. We offer innovative systems with advanced imaging capabilities and tools designed to meet the needs of eye care professionals.

We offer a full line of advanced imaging products and ultrasound used by eye care professionals for both routine and specialized care. These technologically advanced systems are routinely used in the screening and management of major eye diseases, provide key information for treatment decisions, and complement our therapeutic products. In the future, for example, we expect that patient outcomes will be significantly optimized by the use of our instrumentation products in individualizing treatment as well as monitoring and tracking disease progression and treatment outcomes. We believe our OCT / SLO system is an innovative product offering significant advantages over current technology and providing a flexible platform that can process a wide variety of diagnostic tests. OTI has offices in Canada and the United Kingdom, and a growing distributor network that currently covers more than 60 countries.

**OPHTHALMIC PHARMACEUTICAL MARKET**

In the developed world, major vision threatening disorders include cataracts, glaucoma, AMD, and diabetic retinopathy/DME. To date, we have primarily focused our resources on developing drugs to prevent and treat AMD, as well as diabetic retinopathy/DME.

The ophthalmic pharmaceutical market in the developed world is driven by:

- An aging population and increased life expectancy;
- Increased incidence of chronic and age-related disorders with vision destroying characteristics, such as Diabetes (Type I and II), and other metabolic syndromes;
- Better understanding of the pathophysiology of diseases;
- Emerging technologies to diagnose, treat and manage ophthalmic diseases; and
- Improved access to medical care.

***Age Related Macular Degeneration ("AMD")***

AMD is a back-of-the-eye disease involving the retina, macula and fovea, which is characterized by loss of central visual acuity. AMD affects the central part of the retina, known as the macula. The extent of vision loss is dependent on the degree to which the center of the macula, the fovea, is affected. The fovea is responsible for vision acuity. The rest of the retina outside of the macular area is responsible for peripheral vision, which is usually unaffected in AMD patients. Untreated AMD can significantly impact an affected individual's quality of life.

AMD accounts for approximately 55% of blindness in the United States. Direct and indirect costs attributed to the treatment of AMD in the United States are approximately $30 to $40 billion annually, according to the National Eye Institute, a division of the National Institutes of Health. Age is the primary risk factor for AMD, and the number of cases of AMD is expected to increase significantly as the population ages. AMD afflicts approximately 9 million Americans, and the current Wet AMD treatment market is approaching 2 million patients in the United States. There are two forms of AMD, Dry and Wet. Wet AMD is the result of the formation of new, leaky, poorly organized blood vessels under the retina, which is known as neovascularization. The blood vessels are delicate and break easily, causing bleeding, swelling and the formation of scar tissue, which results in visual impairment and/or blindness. Although more common than Wet AMD, Dry AMD typically results in a less severe, more gradual loss of vision. Wet AMD is considered a more serious disease, with clinically demonstrated vision loss occurring within three to six months of diagnosis. Currently there is no known proven pharmaceutical therapy for Dry AMD.

***Diabetic Retinopathy/Diabetic Macular Edema***

Diabetic retinopathy is the most common diabetic eye disease. It is caused by damage to blood vessels in the retina. Diabetic Macular Edema, or DME, a medical condition which occurs when the damaged blood vessels leak fluid and lipids onto the macula, the portion of the retina that allows us to see detail, is present in approximately 25% of all diabetic retinopathy cases. DME can occur at any stage in diabetic retinopathy development, and it is possible for advanced diabetic retinopathy and DME to occur simultaneously in the same patient. DME is the leading cause of visual impairment for people with diabetic retinopathy, and the population suffering from DME is expected to grow as a result of an increasing incidence of Type II diabetes in the United States.

**OPHTHALMIC PHARMACEUTICAL BUSINESS**

We have concentrated significant resources to address ophthalmic disease in large and growing markets by employing a powerful and rapidly progressing technology, known as RNAi, to develop our lead product candidate, bevasiranib. In October 2006, the Nobel prize in Medicine was awarded to the two individuals who discovered RNAi. We have taken advantage of this major scientific breakthrough by inventing and developing siRNAs that shut down the production of proteins that cause ophthalmic diseases. We believe we are a pioneer in this area as we conducted the first clinical trials ever with an siRNA and obtained the first clinical proof of concept with a siRNA. We intend to market bevasiranib, which is our most advanced therapeutic compound, as a treatment for Wet AMD. Bevasiranib is a first in class siRNA drug designed to silence the genes that cause vascular endothelial growth factor, or VEGF, which is believed to be largely responsible for the vision loss associated with Wet AMD and other related ocular conditions. We believe that bevasiranib is the most advanced siRNA-based drug currently in development. We believe that RNA-interference based drugs have the potential to be a significant advancement over the VEGF inhibitors presently on the market because they block the synthesis of VEGF as opposed to merely neutralizing existing VEGF. In addition, RNA-interference based drugs should require less frequent administration than VEGF inhibitors and have a better safety profile.

We have utilized our expertise in ophthalmology and RNAi technology to take bevasiranib from the laboratory through animal models into clinical trials. We have completed two Phase II clinical trials studying the use of bevasiranib as a treatment for Wet AMD and DME. Bevasiranib demonstrated safety and potential to show efficacy in our Phase II clinical trial for Wet AMD in 129 patients. Results showed bevasiranib to be safe and well-tolerated, with a dose-related effect evident across multiple endpoints including near vision, choroidal neovascularization, or CNV, size and time to rescue.

In July 2007, we commenced our pivotal multi-national Phase III COBALT, or Combining Bevasiranib And Lucentis® Therapy, clinical trial of bevasiranib for the treatment of Wet AMD. The trial will include more than 330 Wet AMD patients and will assess whether bevasiranib administered every eight or 12 weeks is safe and has equivalent efficacy in preventing vision loss as Lucentis® administered every four weeks. Interim analysis of safety and efficacy will be made at week 60.

We believe that bevasiranib will be an improvement over existing and anticipated therapies for Wet AMD as it addresses the underlying source of VEGF production, rather than merely neutralizing existing VEGF. Currently marketed drugs for the treatment of Wet AMD are antagonist-based and are only designed to neutralize existing VEGF. We also believe bevasiranib has a better safety profile than VEGF inhibitors in that we do not believe it has the serious systemic side effects associated with VEGF inhibitors in some patients.

We are also developing product candidates for additional ophthalmic disorders, including the treatment of dry eye, diabetic retinopathy and DME, complications of ocular surgery, viral conjunctivitis, and the fibrotic component of Wet AMD and Dry AMD. In order to treat these disorders, we are using compounds that induce lacrimation, are anti-angiogenic, anti-inflammatory, anti-fibrotic and anti-Drusen. These products address eye diseases with large markets and major unmet medical needs, and range in developmental stage from clinical to preclinical.

***Bevasiranib Commercial Potential***

We have an exclusive license to commercialize bevasiranib. We believe there are three primary potential therapeutic profiles for bevasiranib in the marketplace: maintenance therapy, primary therapy and preventative treatment.

*Maintenance Therapy*. We anticipate that bevasiranib will be used by itself as a maintenance therapy to inhibit VEGF production following an initiation therapy with an approved VEGF antagonist drug. After the antagonist has absorbed extracellular VEGF, bevasiranib could be used to suppress the formation of new VEGF and maintain a patient's vision.

*Primary Therapy*. It is possible that not all patients will require the VEGF antagonist initiation regimen due to low VEGF load at time of diagnosis. These patients may get the full benefit from bevasiranib alone. Additionally, not all patients respond favorably to the currently marketed VEGF antagonist. Finally, when used in combination with other therapies bevasiranib's sustained VEGF suppression may add to the antagonist's activity and provide a better outcome than that of the VEGF antagonist alone.

*Preventative Therapy*. Certain patients who do not yet have the wet form of AMD may be determined to be at high-risk for progressing to the wet form. Bevasiranib may prevent these high-risk patients from progressing to Wet AMD. The current VEGF antagonist products will not likely provide any benefit to this type of patient because of the lack of any VEGF to absorb.

***Clinical Results and Program Status of Bevasiranib***

The following table summarizes the status of our material clinical trials of bevasiranib to date:

| Indication | Trial Name | Phase | Objectives | Number of Patients | Enrollment Status |
|---|---|---|---|---|---|
| Wet AMD | CARBON study | Phase III | Dose ranging, Safety and Efficacy | ~500 | Initiation planned for 2009 |
| Wet AMD | COBALT study | Phase III | Safety and Efficacy | ~330 | Initiated July 2007 |
| Wet AMD | CARE Trial | Phase II | Safety / Dosage / Efficacy | 129 | Complete |
| Wet AMD | NA | Phase I | Safety | 15 | Complete |
| DME | RACE Trial | Phase II | Safety / Dosage / Efficacy | 48 | Complete |

***Clinical Trials for the Treatment of Wet AMD***

*The COBALT Study.* In July 2007, we initiated this pivotal Phase III study of bevasiranib for the treatment of Wet AMD. The multi-national COBALT study is currently open and enrolling patients. The trial will include approximately 330 wet AMD patients and will assess whether bevasiranib administered every eight or 12 weeks is safe and has equivalent efficacy in preventing vision loss as Lucentis® administered every four weeks. This study has been designed to show that bevasiranib is safe and efficacious for the treatment of wet AMD following an initiation with Lucentis®. Additionally, the study has been designed to demonstrate that in patients that receive an initiation therapy with Lucentis®, a less frequent administration of bevasiranib is equivalent or superior to monthly treatments of Lucentis®.

We currently anticipate initiating a second Phase III clinical trial of bevasiranib in or around 2009. This clinical trial of bevasiranib for the treatment of Wet AMD will be referred to as the CARBON study. The trial will include more than ~500 Wet AMD patients and will compare the safety and efficacy of three doses of bevasiranib administered every eight weeks to Lucentis®, an approved treatment for Wet AMD, administered every four weeks.

*The CARE™ Trial, a Phase II Clinical Trial for Wet AMD*. The "Cand5 Anti-VEGF RNAi Evaluation, or CARE study," a 129 patient Phase II clinical study in patients with predominantly and minimally classic Wet AMD, was completed successfully. The results of the CARE study demonstrated that bevasiranib is safe and well-tolerated for doses up to 3.0 mg/eye. An important measure of Wet AMD is choroidal neovascularization, or CNV. In the CARE study, bevasiranib was shown to inhibit the growth of CNV, and demonstrated the effects of RNA interference-based VEGF suppression.

*Phase I Clinical Trial for Wet AMD*. This Phase I trial was an open label, dose escalation study that included 15 patients and tested five dose levels administered by intravitreal injection at six-week intervals. Bevasiranib was shown to be safe and well-tolerated following repeated administration of escalating doses, up to 3.0 mg per eye. Further, this study indicated that the study drug was below the limit of detection in the peripheral blood at any of the doses tested. The absence of systemic exposure to bevasiranib is significant because anti-VEGF agents have been shown to have serious systemic side effects in some patients.

***Clinical Trials for the Treatment of DME***

*The R.A.C.E.™ Trial*, a Pilot Phase II Clinical Trial for DME. The RNAi Assessment of bevasiranib in Diabetic Macular Edema, or R.A.C.E. trial, was a pilot phase II investigation of the safety and preliminary efficacy of bevasiranib in patients with DME. This 48 patient multi-center, double-masked and randomized trial studied three dose levels of bevasiranib.

In this pilot study, there was a trend showing a decrease in macular thickness between weeks eight and twelve, where the higher doses result in a larger reduction in thickness than the lowest dose. This trial also showed no detectable levels of bevasiranib in patients at all doses and time-points. These results further support the findings of the CARE study and serve as a confirmation of the safety and biologic activity in a second VEGF-driven ocular condition.

***ACU-HHY-011 for the Treatment of Wet AMD***

We have a worldwide exclusive license to commercialize ACU-HHY-011, which is an siRNA targeting HIF-1 , believed to be the most important transcription factor involved in the cellular response to hypoxia, a key step in the neovascularization process which occurs in Wet AMD. HIF-1 is upstream of the target for bevasiranib and preclinical data suggests that targeting HIF-1 may have advantages over other approaches to treating Wet AMD. HIF-1 modulates the expression of more than 60 genes, including multiple angiogenic factors under hypoxic conditions, such as VEGF, angiopoietin-1, angiopoietin-2, placental growth factor, and platelet-derived growth factor-B.

***ACU-HTR-028 for the Treatment of Fibrosis***

We have a worldwide exclusive license to commercialize siRNAs targeting transforming growth factor-b receptor Type II, or TbRII, which is an important mediator of wound healing and has been shown to play a significant causative role in ocular inflammation and scarring. This compound may have a therapeutic application as an eye drop to prevent complications from ocular surgery, and will also be developed as an adjunct therapy to bevasiranib or ACU-HHY-011 in Wet AMD patients to reduce the damage caused by the fibrotic component of Wet AMD.

***Compounds for the Treatment of Dry AMD***

We have worldwide exclusive licenses to commercialize compounds from the University of Florida Research Foundation which have potential to treat Dry AMD by eliminating disease-causing accumulations of protein molecules at the back of the eye. Proteins must fold into their correct three-dimensional conformation to achieve their biological function. The loss of vision associated with Dry AMD is thought to be caused by the destructive effects of the misfolded protein and debris aggregates likes lipofuscin. Autophagy is a cellular process by which cellular protein aggregates and dysfunctional organelles like mitochondria are degraded. If methods for increasing autophagy were available, they might enhance the elimination of misfolded proteins, and eliminate the destructive effects associated with their accumulation. These compounds may mitigate retinal degeneration by causing the elimination or reduction of drusen in patients with Dry AMD.

***Civamide for the Treatment of Dry Eye***

In September 2007, we acquired worldwide rights to commercialize products containing civamide for the treatment of ophthalmic conditions in humans, particularly dry eye. There is only one FDA approved prescription product available for dry eye. Dry eye syndrome is caused by a variety of conditions, such as insufficient tear production. Nine million Americans are estimated to suffer from moderate to severe dry eye. An additional 20 to 30 million people may have a mild form of the condition. Dry eye syndrome is more common with advancing age and the incidence appears to be increasing with our aging population and the increasing popularity of procedures that can cause dry eye, such as vision-correction surgery and cosmetic eyelid surgery.

***Wound Dressing***

In October 2007, we acquired worldwide rights to commercialize an ocular product for use following invasive retinal procedures to prevent the development of endophthalmitis, a devastating complication that can lead to blindness and loss of the affected eye. There are estimated to be over 1.5 million invasive retinal procedures, including both surgeries and intravitreal injections, being currently performed in the U.S. alone. While most patients suffer no adverse effects from intravitreal injections, all patients who receive invasive retinal procedures are at risk of developing endophthalmitis. The product is in late-stage research.

***N-chlorotaurine***

In April 2006, we entered into a license agreement with Pathogenics, Inc. (“Pathogenics”) under which we were granted an exclusive, irrevocable license, with the right to sublicense, under Pathogenics intellectual property to make, have

made, use, sell, offer for sale, import, or otherwise commercialize N-chlorotaurine and licensed products for the treatment of ophthalmic disease or infection in any territory. We were also granted non-exclusive rights to all data resulting from a phase I clinical trial with N-chlorotaurine in Austria. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed product, including commercially reasonable efforts to initiate pre-clinical activities necessary to file an IND with the FDA to initiate a phase I clinical trial for N-chlorotaurine for an ophthalmic indication. Pathogenics will have a non-exclusive right to such information for the treatment of non-ophthalmic diseases or infections.

**OPHTHALMIC INSTRUMENTATION MARKET**

The market for ophthalmic instrumentation, including imaging systems and other devices, is approximately $1.5 billion and growing at a rate of approximately 10% annually. This growth is primarily driven by an aging patient population, technological innovation and improvement in treatment options, as well as improved awareness in patients actively seeking treatment. Ophthalmic instruments, imaging products, and other medical devices are sold to a variety of eye care practitioners, including retinal and glaucoma specialists, ophthalmologists, optometrists, retail optometry chain outlets, teaching institutions, and military hospitals.

**OPHTHALMIC INSTRUMENTATION BUSINESS**

Our instrumentation business consists of the development, commercialization and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Currently, the instrumentation business is primarily based on the technology platform established by Ophthalmic Technologies, Inc. (OTI), which offers innovative systems with advanced diagnostic imaging capabilities and tools that meet the needs of eye care professionals. We continue to build our presence in the international marketplace currently covering more than 60 countries using the distributor network built by OTI. Additionally, we are developing our own direct sales force in the United States to sell our products primarily to retinal and glaucoma specialists and ophthalmologists.

We plan to utilize our expertise and resources to expand our business to include other types of ophthalmic products. These efforts may lead to our acquiring or developing products which aid in the prevention, diagnosis, treatment, and management of ocular disorders. The product types may include diagnostic and imaging instruments, other instrumentation products, and drug delivery systems and technologies.

We plan to develop and sell novel technologies utilized to diagnose ophthalmic diseases at the earliest stages and track them for change over time, and during the course of treatment. We expect these technologies to improve physician treatment decisions and enhance outcomes for a variety of ocular disorders, including AMD, diabetic retinopathy, and glaucoma, among others.

***Optical Coherence Tomography / Confocal Scanning Ophthalmoscopy***

We have developed a spectral imaging system which combines Spectral Optical Coherence Tomography, together with a Confocal Scanning Ophthalmoscope, or OCT / SLO, in a single platform that is used in the diagnosis of a variety of ocular disorders. We believe this is an innovative product that offers significant advantages over current technology in resolution and functionality. OCT technology is being rapidly adopted by the eye care community for diagnosing AMD and diabetic retinopathy and also tracking the course of treatment. The OCT / SLO is unique in that it offers microperimetry capability, which provides the physician with the ability to correlate loss of visual function with abnormalities in the retina. Additionally, the OCT / SLO diagnostic platform offers a foundation upon which to build a multitude of diagnostic tests. In the future, we plan to incorporate a number of imaging and other diagnostic test modalities into the OCT / SLO platform.

***Ultrasound***

We develop, manufacture, market and sell a full line of advanced ophthalmic ultrasound systems used by eye care professionals for both routine and specialized care. Our ultrasound systems include A-scans, B-scans, and Ultrasound Bio-microscope, or UBM, high frequency B-scan systems. A-scan technology is principally used for eye axial length measurement in the calculation of the power for an intraocular lens implant. These systems are routinely used prior to cataract surgery.

The B-scan system displays internal structures of the eye, often when these structures are not visible by traditional light-based imaging methods. This system has the ability to pass through opacities and reveal internal structures.

The UBM system is a high frequency ultrasound device that provides detailed structural assessment of the anterior segment of the eye and is typically used in glaucoma evaluation and certain refractive surgeries that require precise positioning of lens implantation.

***Research and development program expenses***

To date, the majority of our research and development expenses have been incurred to develop our bevasiranib programs. During 2006, our research and development expenses of $0.5 million reflect the sponsored research between Froptix and the University of Florida. During 2007, we incurred $10.9 million in research and development expenses, a majority of which reflects costs to develop bevasiranib. In addition, during 2007 we recorded $243.8 million for acquired in process research and development related to our acquisition of Acuity.

**INTELLECTUAL PROPERTY**

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

We actively seek, when appropriate and available, protection for our products and proprietary information by means of United States and foreign patents, trademarks, trade secrets, copyrights, and contractual arrangements. Patent protection in the pharmaceutical field, however, can involve complex legal and factual issues. Moreover, broad patent protection for new formulations or new methods of use of existing chemical entities is sometimes difficult to obtain, primarily because the active ingredient and many of the formulation techniques have been known for some time. Consequently, some patents claiming new formulations or new methods of use for old drugs may not provide meaningful protection against competition. There can be no assurance that any steps taken to protect such proprietary information will be effective.

We own or have exclusively licensed more than eight issued patents in the United States and five foreign patents, as well as more than 100 United States and foreign patent applications. Our acquisition of OTI has given us access to an additional seven U.S. patents in the field of ophthalmic instrumentation, as well as ten U.S. patent applications and 18 foreign patent applications.

We have exclusively licensed technology, patents, and patent applications from the University of Pennsylvania related to siRNA directed to specific mRNA targets for therapeutic use. These applications include targeting VEGF, HIF-1 , and intracellular adhesion molecules, or ICAM, among other therapeutic targets. In particular, we have exclusively licensed two issued U.S. patents that cover bevasiranib and methods of using bevasiranib.

In addition, we have exclusively licensed technology, patents, and patent applications related to (i) the treatment of ophthalmic disorders characterized by excessive neovascularization, angiogenesis or leakage, (ii) siRNA targeting TGF-bRI; and (iii) compounds or technologies to treat a variety of ocular disorders, including without limitation, Dry AMD and retinitis pigmentosa, viral conjunctivitis, dry eye, and ocular infection. See “Licenses and Collaborative Relationships”.

**LICENSES AND COLLABORATIVE RELATIONSHIPS**

Our strategy is to develop a portfolio of product candidates through a combination of internal development and external partnerships. Collaborations are key to our strategy and we continue to build relationships and forge partnerships with companies both inside and outside of ophthalmology. We have completed strategic deals with the Trustees of the University of Pennsylvania, the University of Illinois, the University of Florida Research Foundation, Pathogenics, Inc., and Intradigm Corporation, among others.

***The Trustees of the University of Pennsylvania***

In March 2003, we entered into two world-wide exclusive license agreements with The Trustees of the University of Pennsylvania to commercialize siRNA targeting VEGF, HIF-1 , ICAM, and other therapeutic targets. In consideration for the licenses, we are obligated to make certain milestone payments to the University of Pennsylvania. We also agreed to pay the University of Pennsylvania earned royalties based on the number of products we sell that use the inventions claimed in the licensed patents. We agreed to use commercially reasonable efforts to develop, commercialize, market, and sell such products covered by the license agreements.

The term of the agreements is for the later of the expiration or abandonment of the last patent or ten years after the first commercial sale of the first licensed product. We may terminate either of the agreements upon 60 days’ prior written notice. The University of Pennsylvania may terminate either of the agreements if we are more than 90 days late in a payment owed to the University of Pennsylvania, we breach the agreements and do not cure within 90 days after receiving written notice from the University of Pennsylvania, if we become insolvent or we are involved in bankruptcy proceedings.

***Intradigm Corporation***

In June 2005, we entered into a license and collaboration agreement with Intradigm Corporation, or Intradigm, for intellectual property covering the treatment of ophthalmic diseases characterized by excessive neovascularization, angiogenesis, or leakage. Under the terms of the agreement, we have agreed to jointly develop a topical siRNA compound. After selection the topical siRNA compound, we are obligated to use commercially reasonable efforts to market, distribute, and sell the topical siRNA in the United States and any selected foreign country. We have agreed to pay to Intradigm certain milestone payments upon the achievement of specified milestones and royalty payments on all net sales of the topical siRNA and other licensed products.

The term of the agreement is 20 years, unless earlier terminated in accordance with the agreement. Either party may terminate upon mutual written consent, upon written notice by a party if the other party dissolves or enters into bankruptcy or insolvency proceedings, or upon 90 days prior written notice of a material breach of the agreement without cure.

***The Board of Trustees of the University of Illinois***

In August 2006, we entered into an exclusive worldwide license agreement with The Board of Trustees of the University of Illinois to commercialize intellectual property related to ophthalmic siRNA targeting TGF-bRII for the treatment of ophthalmic disease. In September 2007, the license was amended to include all other fields of use beyond the treatment of ophthalmic disease. The license agreement obligates us to pay to the University of Illinois certain milestone payments and royalty payments on all net sales of licensed products and an annual license fee payment.

***University of Florida Research Foundation***

In April 2006, we entered into three world-wide exclusive license agreements with the University of Florida Research Foundation. The license agreements obligate us to pay to University of Florida Research Foundation royalty payments on all net sales of licensed products. We agreed to use our commercially reasonable activities to commercialize products. The technology licensed from the University of Florida Research Foundation includes autophagy inducing compounds which are designed to enhance the elimination of misfolded proteins, and eliminate the destructive effects associated with their accumulation, compounds that affect important intracellular pathways which lead to the accumulation of properly folded mutant proteins, and potential drug candidates that are designed to recruit stem cells which may aid in delaying or reversing the damage at the back of the eye associated with several retinal diseases including Dry AMD and retinitis pigmentosa. The term of each of the agreements is for the earlier of the date that no licensed patent remains an enforceable patent or the payment of earned royalties under the agreement once begun, ceases for more than two calendar quarters. We may terminate any of the agreements upon 60 days' prior written notice. The University of Florida Research Foundation may terminate any of the agreements if we are more than 60 days late, after written demand, for a payment owed to the University of Florida Research Foundation, if we breach the agreements and do not cure within 60 days after receiving written notice from the University of Florida Research Foundation, or if we become involved in bankruptcy proceedings.

***Civamide License***

In September 2007, we entered into an exclusive worldwide license to commercialize intellectual property related to pharmaceutical compositions or preparations containing civamide for the treatment of ophthalmic conditions in humans, particularly dry eye. The license agreement obligates us to pay the licensor certain milestone payments and royalty payments on all net sales of licensed products thereunder and all costs of research and development necessary to obtain marketing authorizations for such licensed products. There is only one FDA approved prescription product available for dry eye. Dry eye syndrome is caused by a variety of conditions, such as insufficient tear production. Nine million Americans are estimated to suffer from moderate to severe dry eye. An additional 20 to 30 million people may have a mild form of the condition. Dry eye syndrome is more common with advancing age and the incidence appears to be increasing with our aging population and the increasing popularity of procedures that can cause dry eye, such as vision-correction surgery and cosmetic eyelid surgery. We intend to evaluate the safety and efficacy of civamide in patients with moderate to severe dry eye. A Phase I/II proof of principal study in moderate to severe dry eye is being planned in 2008.

***Theta Research Consultants***

In October 2007, we entered into an exclusive worldwide license to commercialize intellectual property related to an ocular product for use following invasive retinal procedures to prevent the development of endophthalmitis, a

devastating complication that can lead to blindness and loss of the affected eye. The license agreement obligates us to make royalty payments on all net sales of licensed products thereunder and all costs of research and development necessary to obtain marketing authorizations for such licensed products. Experts believe that the incidence of endophthalmitis is growing as a result of the rising number of ocular surgeries being performed, the widespread adoption of sutureless surgical techniques, and a significant increase in the number of intravitreal injections. While most patients suffer no adverse effects from intravitreal injections, all patients who receive invasive retinal procedures are at risk of developing endophthalmitis.

***Pathogenics***

In April 2006, we entered into a license agreement with Pathogenics under which we were granted an exclusive, irrevocable license, with the right to sublicense, under Pathogenics' intellectual property to make, have made, use, sell, offer for sale, import, or otherwise commercialize N-chlorotaurine and licensed products for the treatment of ophthalmic disease or infection in any territory. We were also granted non-exclusive rights to all data resulting from a phase I clinical trial with N-chlorotaurine in Austria. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed product, including commercially reasonable efforts to initiate pre-clinical activities necessary to file an IND with the FDA to initiate a phase I clinical trial for N-chlorotaurine for an ophthalmic indication. Pathogenics will have a non-exclusive right to such information for the treatment of non-ophthalmic diseases or infections.

We are obligated to pay to Pathogenics certain milestone payments upon the achievement of specified milestones and royalty payments on all net sales of licensed products. We are also obligated to pay Pathogenics an annual minimum payment if the total payments made for such year are less than a specified minimum amount. The term of the agreement is for the shorter of twenty years or the last to expire of the Pathogenics intellectual property. We may terminate the agreement for any reason upon written notice. The agreement may be terminated upon mutual written consent of the parties, by either party upon written notice if either party dissolves or is involved in a bankruptcy or insolvency proceeding or upon ninety days prior written notice if the other party is in material breach and fails to cure.

**COMPETITION**

***Wet AMD***

The Wet AMD treatment market is highly competitive with each competitive company eager to expand market share. Several pharmaceutical and biotechnology companies are actively engaged in research and development related to new treatments for Wet AMD. We intend to leverage our technological innovation and proprietary position utilizing RNAi and other platform technologies to effectively compete in the ophthalmic drug market. Additionally, we intend to couple diagnostic tests together with therapeutics in clinical trials to further enhance our competitive position.

Genentech, Allergan, Alcon Laboratories, Novartis, Alnylam, Regeneron and QLT all have products or development programs for Wet AMD. For Wet AMD, we currently believe that Genentech and Allergan are or will be our primary competitors. Genentech's Lucentis® and Avastin® products are both based on antibody technology to block VEGF protein after it is produced. While both of the drugs provide most patients with an effective treatment, we believe that bevasiranib has distinct advantages over these approaches, which will result in its use and contribute to a significant market share.

Lucentis® and Avastin® block VEGF protein only after it is produced. Additionally, Lucentis® and Avastin® are designed to require monthly injections for optimal effectiveness and include cautions about potential arterial thromboembolic events. Bevasiranib is designed to reduce injection frequency to bi-monthly or quarterly, and we do not believe it has the systemic side effect risks associated with anti-VEGF antibodies. By using siRNA and stopping the production of VEGF, we believe bevasiranib will provide a Wet AMD patient with a longer-lasting and safer maintenance treatment following an initiation therapy with either Lucentis® or Avastin®.

Allergan is presently developing an siRNA based therapy with a product licensed from Merck (formerly Sirna). This siRNA based therapy targets a particular VEGF receptor and due to the fact that there are multiple receptors for VEGF, it is unclear whether that approach will yield a clinical benefit in Wet AMD. Additionally this program is at an earlier stage than our bevasiranib program.

***Diabetic Retinopathy***

We believe that the primary competitors in the diabetic retinopathy/DME market include Bausch & Lomb with its Fluocinolone acetonide product, Allergan with its Dexamethasone product, Surmodics with its Triamcinolone acetonide product, and Psividia/Alimeira Sciences with its Fluocinolone acetonide product. Many of these competitors have significantly greater financial resources than we do to fund further research and development.

***Optical Coherence Tomography***

We have several competitors located in the United States and abroad. These include companies with a far more diverse product offering than ours with significantly greater market presence. Our primary competition for medical devices include Carl Zeiss Meditec, Topcon Corporation, and Heidelberg Engineering. There are a number of competitors and smaller start-up companies that may also have competing technologies and products.

The ophthalmic device market is highly competitive. We intend to leverage our technological innovations to effectively compete in the ophthalmic device market. We differentiate our products on the basis of scan quality, precise image registration, software functionality, and on a diagnostic test known as microperimetry. Microperimetry allows the clinician to obtain both structure and function from a single device. Additionally, in the future we intend to utilize diagnostic tests to further refine and guide therapeutic treatments in clinical trials in order to further enhance our competitive position.

**GOVERNMENT REGULATION OF OUR DRUG AND DEVICE DEVELOPMENT ACTIVITIES**

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

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

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

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

human clinical trials of an investigational drug can commence.

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

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

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

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

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

The second, more comprehensive, approval process applies to a new device that is not substantially equivalent to a pre-1976 product or that is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices. For example, most implantable devices are subject to the approval process. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to

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

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

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

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

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

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

The levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of

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

Our instrumentation products are subject to regulation by the FDA and similar international health authorities. We also have an obligation to adhere to the FDA's cGMP regulations. Additionally, we are subject to periodic FDA inspections, quality control procedures, and other detailed validation procedures. If the FDA finds deficiencies in the validation of our manufacturing and quality control practices, they may impose restrictions on marketing specific products until corrected. On March 25, 2008, OTI received a warning letter in connection with an inspection of OTI's facilities. The warning letter cited several deficiencies in OTI's quality systems. We intend to fully cooperate with the FDA and have immediately begun to take corrective actions to remedy these deficiencies. See "Manufacturing and Quality" below.

We are also subject to various federal, state, and international laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug or the use of a service or device. Federal and state false claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on us, including our stock price. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, which could have a materially adverse effect on our business, results of operations and financial condition. We will consult counsel concerning the potential application of these and other laws to our business and our sales, marketing and other activities and will make good faith efforts to comply with them. However, given their broad reach and the increasing attention given by law enforcement authorities, we cannot assure you that some of our activities will not be challenged or deemed to violate some of these laws.

**MANUFACTURING AND QUALITY**

We currently have no pharmaceutical manufacturing facilities. We have entered into agreements with various third parties for the formulation and manufacture of our pharmaceutical clinical supplies. These suppliers and their manufacturing facilities must comply with FDA regulations, current good laboratory practices, or cGLPs, and current good manufacturing practices, or cGMPs. We plan to outsource the manufacturing and formulation of our clinical supplies.

OTI has an instrumentation manufacturing facility in Toronto, Canada which predominantly performs high level assembly. Certain of OTI's components and optical subsystems are produced by sub-contracted vendors that specialize in optical device manufacturing.

On March 25, 2008, OTI received a warning letter in connection with a FDA inspection of OTI's facilities in July and August of 2007. The warning letter cited several deficiencies in OTI's quality, record keeping, and reporting systems relating to certain of OTI's products, including the OTI Scan 1000, OTI Scan 2000, and OTI OCT/SLO combination imaging system. Based upon the observations noted in the warning letter, OTI is not currently in compliance with cGMP. The FDA indicated that it has issued an Import Alert and may refuse admission of these products. As a result, we will not be permitted to sell these devices in the United States, and the pre-market approval application for the Company's OCT/SLO product will be delayed until the violations have been corrected.

We plan to cooperate fully with the FDA, and upon receipt of the warning letter, we immediately began to take corrective action to address the FDA's concerns and to assure the quality of OTI's products. We are committed to providing high quality products to our customers, and we plan to meet this commitment by working diligently to remedy these deficiencies and to implement updated and improved quality systems and concepts throughout the OTI organization.

**SALES & MARKETING**

We currently do not have pharmaceutical sales or marketing personnel. In order to commercialize any pharmaceutical products that are approved for commercial sale, we must either build a sales and marketing infrastructure or collaborate with third parties with sales and marketing experience.

Our instrumentation division presently has an eight-person sales and marketing staff, including three salespersons calling on retinal specialists and ophthalmologists, that is beginning to market our OTI products. OTI has offices in Canada, the United States and the United Kingdom and a growing distributor network that currently covers more than 60 countries. Our strategy is to increase sales of existing products through expansion of our sales channel in the United States and to provide additional marketing resources to our international distributor network.

**SERVICE & SUPPORT**

We currently offer service and telephone support for all of our marketed instrumentation products. Warranties are given on all products against defects and performance for a period of one year. Extended Service Contracts are available for purchase. Product repairs are performed at our Toronto facility.

**EMPLOYEES**

As of December 31, 2007, we have 57 full-time employees. We plan to add to our headcount in key functional areas that will allow us to further the development of our product candidates. None of our employees are represented by a collective bargaining agreement.

**MANAGEMENT**

***Executive Officers***

The following table sets forth information concerning our current executive officers, including their ages:

| Name | Age | Title |
|---|---|---|
| Phillip Frost, M.D. | 71 | Chief Executive Officer and Chairman of the Board |
| Jane H. Hsiao, Ph.D., MBA | 60 | Chief Technical Officer and Vice Chairman |
| Steven D. Rubin | 47 | Executive Vice President - Administration and Director |
| Rao Uppaluri, Ph.D. | 58 | Senior Vice President and Chief Financial Officer |
| Naveed K. Shams, M.D., Ph.D. | 51 | Senior Vice President - Research and Development and Chief Medical Officer |

*Phillip Frost, M.D.* Dr. Frost became the CEO and Chairman of OPKO Health, Inc. upon the consummation of the merger of Acuity Pharmaceuticals Inc., Froptix Corporation and eXegenics, Inc. on March 27, 2007 (referred to as the "Acquisition"). Dr. Frost was named the Vice Chairman of the Board of Teva Pharmaceutical Industries, Limited, or Teva, in January 2006 when Teva acquired IVAX Corporation, or IVAX. Dr. Frost had served as Chairman of the Board of Directors and Chief Executive Officer of IVAX Corporation since 1987. He was Chairman of the Department of Dermatology at Mt. Sinai Medical Center of Greater Miami, Miami Beach, Florida from 1972 to 1986. Dr. Frost was Chairman of the Board of Directors of Key Pharmaceuticals, Inc. from 1972 until the acquisition of Key Pharmaceuticals by Schering Plough Corporation in 1986. Dr. Frost was named Chairman of the Board of Ladenburg Thalmann Financial Services Inc., an investment banking, asset management, and securities brokerage firm providing services through its principal operating subsidiary, Ladenburg Thalmann & Co. Inc., in July 2006 and has been a director of Ladenburg Thalmann since March 2005. Dr. Frost also serves as Chairman of the Board of Directors of Ideation Acquisition Corp., a special purpose acquisition company formed for the purpose of acquiring businesses in digital media, and Modigene Inc., a development stage biopharmaceutical company. He serves on the Board of Regents of the Smithsonian Institution, a member of the Board of Trustees of the University of Miami, a Trustee of each of the Scripps Research Institutes, the Miami Jewish Home for the Aged, and the Mount Sinai Medical Center and is Co-Vice Chairman of the Board of Governors of the American Stock Exchange. Dr. Frost is also a director of Continucare Corporation, a provider of outpatient healthcare and home healthcare services, and Northrop Grumman Corp., a global defense and aerospace company.

*Jane H. Hsiao, Ph.D., MBA.* Dr. Hsiao has served as Vice-Chairman and Chief Technical Officer of the Company since May 2007. Dr. Hsiao served as the Vice Chairman-Technical Affairs of IVAX from 1995 to January 2006, when Teva acquired IVAX. Dr. Hsiao served as IVAX's Chief Technical Officer since 1996, and as Chairman, Chief Executive Officer and President of IVAX Animal Health, IVAX's veterinary products subsidiary, since 1998. From 1992 until 1995, Dr. Hsiao served as IVAX's Chief Regulatory Officer and Assistant to the Chairman. Dr. Hsiao has served as Chairman of the Board of Safestitch Medical, Inc., a medical device company, since September 2007. Dr. Hsiao is also a director of Modigene, Inc., a development stage biopharmaceutical company.

*Steven D. Rubin.* Mr. Rubin has served as Executive Vice President - Administration since May 2007 and a director of the Company since February 2007. Mr. Rubin served as the Senior Vice President, General Counsel and Secretary of IVAX from August 2001 until September 2006. Prior to joining IVAX, Mr. Rubin was Senior Vice President, General Counsel and Secretary with privately-held Telergy, Inc., a provider of business telecommunications and diverse optical network solutions, from early 2000 to August 2001. In addition, he was with the Miami law firm of Stearns Weaver Miller Weissler Alhadeff & Sitterson from 1986 to 2000, in the Corporate and Securities Department. Mr. Rubin had been a shareholder of that firm since 1991 and a director since 1998. Mr. Rubin currently serves on the board of directors of Dreams, Inc., a vertically integrated sports licensing and products company, Safestitch Medical, Inc., a medical device company, Ideation Acquisition Corp., a special purpose acquisition company formed for the purpose of acquiring businesses in digital media, Modigene, Inc., a development stage biopharmaceutical company, and Longfoot Communications Corp., a public shell company seeking to identify a merger or business combination candidate.

*Rao Uppaluri, Ph.D.* Dr. Uppaluri has served as our Senior Vice President and Chief Financial Officer since May, 2007. Dr. Uppaluri served as the Vice President, Strategic Planning and Treasurer of IVAX from 1997 until December 2006. Before joining IVAX, from 1987 to August 1996, Dr. Uppaluri was Senior Vice President, Senior Financial Officer and Chief Investment Officer with Intercontinental Bank, a publicly traded commercial bank in Florida. In addition, he served in various positions, including Senior Vice President, Chief Investment Officer and Controller, at Peninsula Federal Savings & Loan Association, a publicly traded Florida S&L, from October 1983 to 1987. His prior employment, during 1974 to 1983, included engineering, marketing and research positions with multinational companies and research institutes in India and the United States. Dr. Uppaluri currently serves on the board of directors of Ideation Acquisition Corp., a special purpose acquisition company formed for the purpose of acquiring businesses in digital media, and Longfoot Communications Corp., a public shell company seeking to identify a merger or business combination candidate.

*Naveed Shams, M.D., Ph.D.* Dr. Shams has served as Chief Medical Officer and Senior Vice President of Research and Development since January 2008. Prior to joining the Company, Dr. Shams served from September 2003 through November 2007 as Senior Medical Director, Head Ophthalmic Medical Affairs and Post-Marketing Team Leader at Genentech, Inc., a pharmaceutical company, where he led the clinical team responsible for launching Lucentis®. Previously, Dr. Shams was also a Director, Clinical Science for Novartis Ophthalmics, Inc. from April 1998 through September 2003, and Senior Scientist and Glaucoma Group Leader-Discovery for Storz Ophthalmics from January 1995 through March 1998. Before joining industry, Dr. Shams was a member of the Research Faculty at the Schepen's Eye Research Institute and Department of Ophthalmology at Harvard Medical School.

***Code of Ethics***

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

**ITEM 1A. RISK FACTORS.**

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

**RISKS RELATED TO OUR BUSINESS**

The occurrence of any of the events discussed below could significantly and adversely affect our business, prospects, results of operations, financial condition, and cash flows:

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

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

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

We are engaged in the research and development of pharmaceutical products, drug delivery technologies, and diagnostic systems and instruments for the treatment and prevention of ophthalmic diseases. The effectiveness of our technologies is not well-known in, or accepted generally by, the clinical medical community. There can be no assurance that we will be able to successfully employ our technologies as therapeutic, diagnostic, or preventative solutions for any ophthalmic disease. Our failure to establish the efficacy or safety of our technologies would have a material adverse effect on our business.

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

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

Most of our product candidates are in the very early stages of development and are prone to the risks of failure inherent in drug and medical device product development. We will likely be required to complete and undertake

significant additional clinical trials to demonstrate to the FDA that our product candidates are safe and effective to the satisfaction of the FDA and other non-United States regulatory authorities or for their intended uses, or are substantially equivalent in terms of safety and effectiveness to an existing, lawfully marketed non-premarket approved device. Clinical trials are expensive and uncertain processes that often take years to complete. Failure can occur at any stage of the process, and successful early positive results do not ensure that the entire clinical trial or later clinical trials will be successful. Product candidates in clinical-stage trials may fail to show desired efficacy and safety traits despite early promising results.

***We are highly dependent on the success of our lead product candidate, bevasiranib, and our failure to commercialize bevasiranib, or the experience of significant delays in doing so, would have a material adverse effect on our business, results of operation, and financial condition.***

We have invested a significant portion of our efforts and financial resources in the development of bevasiranib. Bevasiranib has been studied in a Phase II clinical drug trial for the treatment of Wet AMD, and we are presently studying bevasiranib in Phase III clinical trials. Our Phase III clinical trials may not be successful, and bevasiranib may never receive regulatory approval or be successfully commercialized. Our clinical development program for bevasiranib may not receive regulatory approval if we fail to demonstrate that it is safe and effective in clinical trials and, consequently, fail to obtain necessary approvals from the FDA, or similar non-United States regulatory agencies, or if we have inadequate financial or other resources to advance bevasiranib through the clinical trial process. Even if bevasiranib receives regulatory approval, its approved labeling may be insufficient to permit adequate marketing. We may not be successful in marketing it for a number of other reasons, including the introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts. Any failure to obtain approval of bevasiranib and successfully commercialize it would have a material and adverse impact on our business.

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

Positive results from pre-clinical studies and early clinical trial experience should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates either (i) are safe and effective for use in a diverse population of their intended uses or (ii) with respect to Class I or Class II devices only, are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under section 510(k) of the Food, Drug and Cosmetic Act. Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other non-United States 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 nor may our device candidates be approved or cleared, as the case may be, even though clinical or other data are, in our view, adequate to support a device approval or clearance. The FDA or other non-United States 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 approval. In addition, 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. In addition, the FDA or other non-United States regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of our product candidates.

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

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals, and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and establishment of risk management programs that may,

for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

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

We are advancing and intend to continue to advance multiple product candidates through clinical and pre-clinical development. We believe that our existing cash and cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least for the next twelve months. We have based this estimate on assumptions that may prove to be wrong or subject to change, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on a number of factors, including the continued progress of our research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

We will need to raise substantial additional capital to engage in and continue our clinical and pre-clinical development, and commercialization activities. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical, biotechnology, and medical device companies that are researching and marketing products designed to address AMD and other ophthalmic diseases and conditions our products are designed to diagnose, treat, or prevent. We are currently developing therapeutic, diagnostic, and preventative products that will compete with other drugs, therapies, and medical devices that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs, therapies, and medical devices. Many of our competitors have significantly greater financial, manufacturing, marketing, and drug development resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals or clearances for drugs or medical devices. These companies also have significantly greater research and marketing capabilities than we do. Some of the pharmaceutical companies we expect to compete with include Genentech, Allergan, Alcon Laboratories, Regeneron, QLT, Pfizer, Alnylam, and Bausch & Lomb. In addition, many universities and private and public research institutions may become active in ophthalmic disease research. 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. The development of other promising drugs for the treatment of Dry AMD, which in certain patients is the precursor to Wet AMD, could materially adversely affect the prospects for bevasiranib and other treatments for Wet AMD.

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 commercialize and market any of our product candidates that may receive regulatory approval or clearance;
- our ability to design and successfully execute appropriate clinical trials;
- the timing and scope of regulatory approvals or clearances;
- 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, both the biopharmaceutical 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 planned clinical trials will be completed on schedule, or at all, and we cannot guarantee that our planned clinical trials 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 ophthalmic disease required for enrollment in our clinical trials or that otherwise meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;
- a limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;
- requirements to provide the drugs or medical devices required in our clinical trial protocols or clinical trials at no cost or cost, which may require significant expenditures that we are unable or unwilling to make;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain institutional review board, or IRB, approval to conduct or renew a clinical trial at a prospective or accruing site.

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

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials;

- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; and
- inability to monitor patients adequately during or after treatment.

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

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

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

- restrictions on the products, manufacturers, or manufacturing process;
- adverse inspectional observations (Form 483), warning letters, or non-warning letters incorporating inspectional observations;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals or clearances;
- product seizures, detentions, or import bans;

- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and

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

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

· a drug candidate may not be deemed safe or effective;

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

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

· the FDA might not approve our or our third-party manufacturer's processes or facilities; or

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

The Company may, at some future date, seek approval of one or more drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, § 505(b)(2) which permits a manufacturer to submit an NDA for an existing drug compound for intended uses that have already been approved by the FDA, but with certain different characteristics, such as a different route of administration. Section 505(b)(2) allows a company to reference the clinical data already collected by the NDA of the drug supplemented by clinical trial results that address the change (e.g., route of administration). The Company is not presently involved in clinical trials for a section 505(b)(2) drug or the submission of an NDA for such a drug, but could be in the future. If the Company were to submit an NDA under that section, the Company could be sued for patent infringement by the pharmaceutical company that owns the patent on the existing approved NDA drug. Such a suit would automatically preclude the FDA from processing our NDA for 30 months and possibly longer. Defending such a suit would be costly. If we were to lose the litigation, we could be precluded from marketing the product until the NDA holder's patent expires. Such an adverse result would interfere without strategic plans and would therefore have adverse financial implications for the company.

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

If a product candidate receives marketing approval and we or others later identify undesirable side effects caused by such products:

·regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;

·regulatory authorities may withdraw their approval of the product and require us to take our approved drug off the market;

.

we may be required to change the way the product is administered, conduct additional clinical trials, or change the labeling of the product;

- we may have limitations on how we promote our drugs;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

***We may be unable to resolve issues related to an FDA warning letter in a timely manner, which could delay the production and sale of our instrumentation products.***

We are currently taking remedial action in response to certain deficiencies in OTI's quality systems as cited by the FDA in a warning letter to OTI dated March 25, 2008. The warning letter noted several deficiencies in OTI's quality control systems relating to certain products. As stated in the warning letter, the FDA issued an Import Alert and may refuse admission of OTI's Scan 1000, Scan 2000, and OCT/SLO combination imaging system products. As a result, we will not permitted to sell these devices in the United States, and pre-market approval applications for the Company's OCT/SLO product will be delayed until the violations have been corrected.

While we intend to work with the FDA to resolve these issues, this work will require the dedication of significant incremental internal and external resources and will impede our ability to sell these products in the United States. There can be no assurances regarding the length of time or cost it will take us to resolve these quality issues to our satisfaction and to the satisfaction of the FDA. If our remedial actions are not satisfactory to the FDA, we may have to devote additional financial and human resources to our efforts, and the FDA may take further regulatory actions against us including, but not limited to, assessing civil monetary penalties or imposing a consent decree on us, which could result in further regulatory constraints, including the governance of our quality system by a third party. Our inability to resolve these issues or the taking of further regulatory action by the FDA may weaken our competitive position and have a material adverse effect on our operations.

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

As a medical device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation (QSR) requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. In addition, most international jurisdictions have adopted regulatory approval and periodic renewal requirements for medical devices, and we must comply with these requirements in order to market our products in these jurisdictions. In the European Community, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Further, some emerging markets rely on the FDA's Certificate for Foreign Government (CFG) in lieu of their own regulatory approval requirements. Our FDA warning letter prevents our ability to obtain CFGs; therefore, our ability to market new products or renew marketing approvals in countries that rely on CFGs may be impacted until the warning letter is resolved.

If we, or our manufacturers, fail to adhere to quality system regulations or ISO requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

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

Once regulatory approval has been granted, the approved or cleared product and its manufacturer are subject to continual review. Any approved or cleared product may only be promoted for its indicated uses. In addition, if the

FDA or other non-United States regulatory authorities approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, and promotion for the product will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with current Good Manufacturing Practicing, or cGMP regulations, or the FDA's QSR regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which reports are publicly available. Further, regulatory agencies must approve manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-United States regulatory authorities, or if previously unknown problems with our products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions.

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

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

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

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

In addition, our efforts to educate the medical community and health care payors on the benefits of our product candidates may require significant resources and may never be successful.

***If our future product candidates fail to achieve market acceptance, 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 or medical devices is uncertain, and failure of our pharmaceutical products and procedures using our medical devices to be adequately covered by insurance and eligible for adequate reimbursement could limit our ability to market any future product candidates we may develop and decrease our ability to generate revenue from any of our existing and future product candidates that may be approved or cleared.

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

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

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

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

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical, medical device, and other similar businesses. If we are unable to attract and retain the necessary personnel to accomplish our business objectives, we

may experience constraints that will impede significantly the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

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

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

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

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

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

We expect that any product candidate to which we acquire rights will require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and other non-United States regulatory authorities. All product candidates are subject to the risks of failure inherent in pharmaceutical or medical device product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Even if the product candidates are approved or cleared, we cannot be sure that they would be capable of economically feasible production or commercial success.

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

We believe we currently have, or can access, sufficient supplies of bevasiranib to conduct and complete our planned Phase III clinical trials. If our manufacturing partners are unable to produce bevasiranib or our other 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-United States regulatory authorities to ensure strict compliance with QSR regulations for devices or cGMPs for drugs, and other applicable government regulations and corresponding standards relating to matters such as testing, quality control, and documentation procedures. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR or cGMPs, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns, or other problems that could seriously harm our business.

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

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

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

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

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

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

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

***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 proposed products. Because certain United States 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 United States Patent and Trademark Office, or USPTO, may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, and could have a material adverse effect on our business. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology, pharmaceutical, and medical device companies.

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

While we believe that our patent rights are enforceable, we cannot assure you that any patents that have issued, that may issue, or that may be licensed to us will be enforceable or valid, or will not expire prior to the commercialization of our product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our product candidates or our future products.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how, and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants, and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants, or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

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

***We will rely heavily on licenses from third parties.***

Many of the patents and patent applications in our patent portfolio are not owned by us, but are licensed from third parties. For example, we rely on technology licensed from the University of Pennsylvania, the University of Illinois, the University of Florida Research Foundation, Pathogenics and Intradigm. Such license agreements give us rights for the commercial exploitation of the patents resulting from the respective patent applications, subject to certain provisions of the license agreements. Failure to comply with these provisions could result in the loss of our rights under these license agreements. Our inability to rely on these patents and patent applications, which are the basis of our technology, would have a material adverse effect on our business.

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

We have obtained licenses from, among others, the University of Pennsylvania, the University of Illinois, the University of Florida Research Foundation, Pathogenics, and Intradigm that are necessary or useful for our business. In addition, we intend to enter into additional licenses of third-party intellectual property in the future.

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

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

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief from an infringement and may be unable to enjoin infringement, which could materially diminish the value of the patent.

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

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products, or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent, or circumvent the

third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition, and results of operations.

Additionally, RNAi is a relatively new scientific technology that has generated many different patent applications from organizations and individuals seeking to obtain important patents in the field. These applications claim many different methods, compositions, and processes relating to the discovery, development, and commercialization of RNAi therapeutics. Because the field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will issue, when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings, such as interference and opposition proceedings in various patent offices, relating to patent rights in RNAi technology. Others may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes among third parties could impact our intellectual property rights.

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

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

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

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

In the United States, there have been a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products profitably. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, extended Medicare, effective January 1, 2006, to cover most outpatient prescription drugs that are not administered by physicians and modified, effective January 1, 2004, the methodology used by Medicare to reimburse for those drugs administered by physicians. Our business could be harmed by the MMA, by the possible effect of this legislation on amounts that private payors will pay, and by other healthcare reforms that may be enacted or adopted in the future. To the extent that our products are deemed to be durable medical equipment, they may be subject to distribution under the new Competitive Acquisition regulations, also part of MMA, and this could adversely affect the amount that patients or medical providers can seek from payors. Non-durable medical equipment devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. As a result, these types of devices are subject to intense price competition that can place a small

manufacturer at a competitive disadvantage.

We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. Any cost containment measures or other health care system reforms that are adopted could have a material adverse effect on our ability to commercialize our existing and future product candidates successfully.

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

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

***Acquisitions may result in disruptions to our business or distractions of our management and may not proceed as planned.***

We intend to continue to expand our business through the acquisition of companies, technologies, products, and services. Acquisitions involve a number of special problems and risks, including, but not limited to:

- difficulty integrating acquired technologies, products, services, operations, and personnel with the existing businesses;

- diversion of management's attention in connection with both negotiating the acquisitions and integrating the businesses;

- strain on managerial and operational resources as management tries to oversee larger operations;

- exposure to unforeseen liabilities of acquired companies;

- potential costly and time-consuming litigation, including stockholder lawsuits;

- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our common stock, or which may have a dilutive effect on our stockholders;

- the need to incur additional debt or use cash; and

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

As a result of these or other problems and risks, businesses we acquire may not produce the revenues, earnings, or business synergies that we anticipated, and acquired products, services, or technologies might not perform as we expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We may not be

able to successfully address these problems and we cannot assure you that the acquisitions will be successfully identified and completed or that, if acquisitions are completed, the acquired businesses, products, services, or technologies will generate sufficient revenue to offset the associated costs or other harmful effects on our business.

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

***Non-United States governments often impose strict price controls, which may adversely affect our future profitability.***

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

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

Our business is subject to risks associated with conducting business internationally, in part due to a number of our suppliers being located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- difficulties in compliance with non-United States laws and regulations;
- changes in non-United States regulations and customs;
- changes in non-United States currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements, or other restrictive actions by United States or non-United States governments;
- negative consequences from changes in tax laws; and
- difficulties associated with staffing and managing foreign operations, including differing labor relations.

***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;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in the biotechnology, pharmaceutical, and medical device industry;

- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- 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, and medical device companies in particular, has recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock.

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

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

A substantial percentage of the outstanding shares of our common stock (including outstanding shares of our preferred stock on an as converted basis) are restricted securities and/or are subject to lockup agreements which limit sales during a two-year period ending March 27, 2009. 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 after April 2, 2008, pursuant to Rule 144. In addition, as described herein, a substantial number of our shares of common stock are subject to lockup agreements expiring on March 27, 2009, provided that (i) one third of the shares subject to the lockup shall be exempt from lockup restrictions beginning March 27, 2008, (ii) one third of the shares subject to lockup shall be exempt from lockup restrictions beginning September 27, 2008, and (iii) the restrictions on the remaining shares subject to lockup shall lapse on March 27, 2009. Future sales of a substantial number of shares of our common stock in the public market pursuant to Rule 144 or after the lockup agreements lapse, or the perception that such sales could occur, could adversely affect the price of our common stock.

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

As of March 21, 2008, our directors, executive officers, principal stockholders, and affiliated entities beneficially owned, in the aggregate a majority of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to control the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed.

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, 2008. We continuously monitor our existing internal control over financial reporting systems to confirm that they are compliant with Section 404, and we may identify deficiencies that we may not be able to remediate in time to meet the deadlines imposed by the Sarbanes-Oxley Act. This process may divert internal resources and will take a significant amount of time and effort to complete.

If, at any time, it is determined that we are not in compliance with Section 404, we may be required to implement new internal control procedures and reevaluate our financial reporting. We may experience higher than anticipated operating expenses as well as increased independent auditor fees during the implementation of these changes and thereafter. Further, we may need to hire additional qualified personnel. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, which could result in our being unable to obtain an unqualified report on internal control from our independent auditors. Failure to maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

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

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

## ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

## ITEM 2. PROPERTIES.

Our principal corporate office is located at 4400 Biscayne Blvd, Suite 1180, Miami, Florida. We lease this space from Frost Real Estate Holdings, LLC, an entity which is controlled by Dr. Phillip Frost, our Chairman of the Board and Chief Executive Officer. Pursuant to the lease agreement with Frost Real Estate Holdings, we lease approximately 8,300 square feet, which encompasses space for our corporate offices, administrative services, preclinical research and development, project management and pharmacology. The lease is for a five-year term and currently requires annual rent of approximately $221,000, which amount increases by approximately 4.5% per year.

We also lease approximately 2,000 square feet of office space in Morristown, New Jersey, where additional clinical research and development is performed, and an animal research facility at Mount Sinai Hospital in Miami Beach, Florida. Our OTI subsidiary maintains offices in Toronto, Ontario, Canada and research and development branch offices in Kingston, Ontario, and in the United Kingdom at the University of Kent.

## ITEM 3. LEGAL PROCEEDINGS.

We are not currently a party to any material litigation. From time to time, we may be involved in litigation arising in the ordinary course of our business.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

Effective as of December 4, 2007, stockholders holding a majority of the voting power of our outstanding stock approved the issuance to members of The Frost Group, LLC, or the Frost Group, a private investment group controlled by Dr. Phillip Frost, M.D., our Chairman and CEO, of an aggregate of 10,869,565 shares of our common stock in exchange for a $20 million investment in the Company. Stockholder approval was in the form of a written consent of stockholders in lieu of a special meeting in accordance with the relevant sections of the Delaware General Corporation Law, and included those of our stockholders holding a majority of the voting power of our issued and outstanding shares of common stock and preferred stock, voting together as a group. Stockholder approval was sought solely in order to comply with applicable rules of the American Stock Exchange, on which our common stock is listed.

The foregoing is merely a summary of those matters submitted to a stockholder vote during the fourth quarter of 2007, and is qualified in its entirety by the full text of our Definitive Information Statement on Schedule 14C, filed with the SEC on January 8, 2008, which is incorporated by reference into this Item 4 to our Annual Report on Form 10-K.

## PART II

### I T E MMARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS 5. AND ISSUER PURCHASES OF EQUITY SECURITIES.

We changed our name from eXegenics, Inc. to OPKO Health, Inc in June 2007. Our common stock has been traded publicly on the American Stock Exchange under the symbol "OPK" since June 11, 2007. Prior to June 11, 2007, our common stock was quoted on the over-the-counter bulletin board, or the OTCBB, under the symbol "EXEG." Quotes on the OTCBB may have reflected inter-dealer prices without retail markups, markdowns, or commissions and may not necessarily have represented actual transactions. 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 OTCBB for the periods from January 1, 2006 through June 8, 2007 and on the American Stock Exchange from June 11, 2007 through December 31, 2007:

| | High | Low |
|---|---|---|
| **2007** | | |
| First Quarter | $ 4.10 | $ 0.87 |
| Second Quarter | 5.50 | 3.20 |
| April 1 - June 8, 2007 | 5.50 | 3.20 |
| June 11, 2007 - June 30, 2007 | 4.33 | 3.42 |
| Third Quarter | 4.94 | 3.36 |
| Fourth Quarter | 4.53 | 2.50 |
| | | |
| **2006** | | |
| First Quarter | $ 0.46 | $ 0.39 |
| Second Quarter | 0.45 | 0.38 |
| Third Quarter | 1.09 | 0.38 |
| Fourth Quarter | 0.99 | 0.72 |

As of March 21, 2008, there were approximately 436 holders of record of our common stock.

The Company has not declared or paid any cash dividends on its common stock. No cash dividends have been previously paid on our common stock and none are anticipated in fiscal 2008.

**Recent Sales of Unregistered Securities**

On December 5, 2007, members of The Frost Group, LLC, a private investment group controlled by Dr. Phillip Frost, M.D., our Chairman and CEO, made a $20 million investment in the Company. Under the terms of the investment, we issued 10,869,565 shares of common stock, par value $.01, at $1.84 per share, representing an approximately 40% discount to the average trading price of the Company's stock on the American Stock Exchange for the five trading days immediately preceding the effective date of board and stockholder approval of the investment. The shares issued in the investment are restricted securities, subject to a two year lockup, and no registration rights were granted. The issuance of the shares was exempt from the registration requirements under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, because the transaction did not involve a public offering.

**Stock Performance Graph**

**ITEM 6. SELECTED FINANCIAL DATA.**

As a result of the reverse merger between Froptix Corporation, or Froptix and eXegenics, Inc., or eXegenics, historical comparative results are those of Froptix. Froptix was incorporated on June 23, 2006. The following selected historical consolidated statement of operations data for the year ended December 31, 2007 and for the period from inception (June 23, 2006) through December 31, 2006 and the consolidated balance sheet data as of December 31, 2007 and December 31, 2006, below are derived from our audited consolidated financial statements and related notes thereto. The results of operations for the period from inception (June 23, 2006) to December 31, 2006 include Froptix's operating results for the full period. The year ended December 31, 2007 includes the results of operations from Froptix for the full year, the operating results of Acuity Pharmaceuticals, Inc., or Acuity, subsequent to our acquisition on March 27, 2007, and the operating results from Ophthalmic Technologies, Inc., or OTI, subsequent to our acquisition on November 28, 2007. In addition, the results for the 2007 period includes the minority interest loss of $0.6 million for a portion of OTI's operating loss from the date of our investment in OTI on April 13, 2007 through the date of our acquisition on November 28, 2007.

This data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our consolidated financial statements and the related notes thereto.

| (in thousands, except share and per shares information) | For the year ended December 31, 2007 (unaudited) | Period from inception (June 23, 2006) to December 31, 2006 (unaudited) |
|---|---|---|
| Statement of operations data | | |
| Revenue | $ 847 | $ - |
| Cost of goods sold | 808 | - |
| Gross margin | 39 | - |
| Operating expenses: | | |
| Selling, general and administrative | 12,466 | 375 |
| Research and development | 10,850 | 508 |
| Write-off of acquired in-process research and development | 243,761 | - |
| Other operating expenses; primarily amortization of intangible assets | 150 | |
| Total operating expenses | 267,227 | 883 |
| Operating loss | (267,188) | (883) |
| Other (expense) income, net | (671) | 6 |
| Loss before income taxes and loss from OTI | (267,859) | (877) |
| Income taxes | 83 | - |
| Net loss before loss from OTI | (267,776) | (877) |
| Loss from OTI | (629) | - |
| Net loss | (267,405) | (877) |
| Preferred stock dividend | (217) | - |
| Net loss attributable to common shareholders | $ (268,622) | $ (877) |
| Loss per share, basic and diluted | $ (2.09) | $ (0.01) |
| Weighted average number of shares outstanding - basic and diluted | 128,772,080 | 58,733,556 |
| Balance sheet data | | |

| | | | | |
|---|---|---|---|---|
| Total assets | $ | 39,568 | $ | 116 |
| Working capital | $ | 19,489 | $ | 21 |
| Notes payable, credit line with related party and capital lease obligations, net | $ | 14,235 | $ | - |
| Stockholders' equity | $ | 16,784 | $ | 21 |

**I T E M 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.**

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

**OVERVIEW**

We are a specialty healthcare company focused on the discovery, development, and commercialization of proprietary pharmaceuticals, imaging and diagnostic systems, and instruments for the treatment, diagnosis, and management of ophthalmic disorders. Our business presently consists of the development of ophthalmic pharmaceuticals and the development, commercialization and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Our objective is to establish industry-leading positions in large and rapidly growing segments of ophthalmology by leveraging our preclinical and development expertise and our novel and proprietary technologies. We actively explore opportunities to acquire complementary pharmaceuticals, compounds, and technologies, which could, individually or in the aggregate, materially increase the scale of our business. We also intend to explore strategic opportunities in other medical markets that would allow us to benefit from our business and global distribution expertise, and which have operational characteristics that are similar to ophthalmology, such as dermatology.

We expect to incur substantial losses as we continue the development of our product candidates, particularly bevasiranib, continue our other research and development activities, and establish a sales and marketing infrastructure in anticipation of the commercialization of our product candidates. We currently have limited commercialization capabilities, and it is possible that we may never successfully commercialize any of our pharmaceutical product candidates. To date, we have devoted substantially all of our efforts towards research and development. As of December 31, 2007, we had an accumulated deficit of $269.3 million. Since we do not generate revenue from any of our pharmaceutical product candidates and have only generated limited revenue from our instrumentation business, we expect to continue to generate losses in connection with the continued clinical development of bevasiranib and the research and development activities relating to our technology and other product candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe that our operating losses are likely to be substantial over the next several years. We will need to obtain additional funds to further develop our research and development programs, and there can be no assurance that additional capital will be available to us on acceptable terms, or at all.

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

On November 28, 2007, we acquired Ophthalmic Technologies, Inc., or OTI, an Ontario corporation pursuant to a definitive Share Purchase Agreement with OTI and its shareholders. As a result of this agreement, we have entered into the ophthalmic instrumentation market and have begun generating revenue from this business.

On March 25, 2008, OTI received a warning letter citing several deficiencies in OTI's quality systems relating to three of its products, including the OCT/SLO combination imaging system. Until we resolve these deficiencies to the satisfaction of the FDA, we will not be permitted to sell these products in the United States.

**RESULTS OF OPERATIONS**

***For The Years Ended December 31, 2007 and From Inception (June 23, 2006) Through December 31, 2006***

The results of operations for the period from inception (June 23, 2006) through December 31, 2006 include only the operating results of Froptix. The results of operations for 2007 include those of Froptix for the full period as well as the results of operations of Acuity from March 27, 2007 through December 31, 2007, and of OTI from November 28, 2007 through December 31, 2007. We had limited operating activities during the 2006 period since our inception was on June 23, 2006. During 2007, we increased the level of activities in our research and development programs to include the initiation of our first of two required Phase III clinical trials for bevasiranib, our lead compound in development and the most clinically advanced siRNA drug in development. Further, during 2007, we began to build a commercial presence in the ophthalmic instrumentation business in the U.S. as we prepared for the acquisition of OTI, and we assumed the operations of OTI for instrumentation sales internationally in November. In addition, our general and administrative expenses have increased in line with the operations of our ophthalmic pharmaceutical and instrumentation business as well as incurring the costs associated with being a public company.

*Revenue.* Revenue for the year ended December 31, 2007 was $0.8 million. All revenue generated relates to product sold after our acquisition of OTI on November 28, 2007. Until the acquisition of OTI, we did not generate any revenue. During 2007, all revenue relates to products that were shipped internationally. There were no product sales in

the U.S.

*Gross margin.* Gross margin for the year ended December 31, 2007 was $39 thousand. The gross margin related to product sold after our acquisition of OTI on November 28, 2007. The gross margin was negatively impacted by manufacturing costs associated with the introduction of our new OCT / SLO model. We anticipate that our margin will increase as we begin manufacturing more components in-house.

*Selling, General and Administrative Expense*. Selling, general and administrative expense in 2007 was $12.5 million and increased from $0.4 million during the 2006 period, primarily as a result of increased personnel costs, including equity-based compensation, directors' and officers' insurance, professional fees and other costs related to building infrastructure as a public company. In addition, during 2007 we incurred professional fees related to various business transactions, including the acquisitions of Acuity and OTI. During 2007, we also incurred expenses related to building a commercial presence in the ophthalmic instrumentation market in the United States, including personnel and tradeshow costs. During the 2006 period, selling, general and administrative expense primarily included equity-based compensation expense related to a consultant and professional fees. We did not have any employees during 2006. Equity based compensation expense for the year ended December 31, 2007 was $7.4 million, of which, $4.4 million was included in selling, general and administrative expense and $3.0 million was included in research and development expense. During the period from our inception (June 23, 2006) through December 31, 2006, equity based compensation expense was $0.3 million, all of which was recorded in selling, general and administrative expense.

*Research and Development Expense*. Research and development expense for 2007 was $10.9 million and increased from $0.5 million during the 2006 period, primarily as a result of the expense related to our Phase III clinical trial for bevasiranib, which was initiated in July 2007. Research and development expenses for the year ended December 31, 2007 include personnel costs, including equity-based compensation and professional fees as we initiated our Phase III clinical trial for bevasiranib. During the third quarter of 2007, a reversal of equity-based compensation expense of $8.1 million was recorded as a result of the termination of a consulting agreement prior to the vesting of any of the equity based awards issued under the consulting agreement. Originally, we accrued $0.3 million for this expense during 2006 and $7.8 million during the first six months of 2007. Research and development expense during 2006 was related to our sponsored research agreement with the University of Florida and costs related to the prosecution of related patents.

We anticipate that research and development expense during 2008 will primarily relate to our bevasiranib program, including on-going costs for our initial Phase III clinical trial. The trial was initiated in July 2007 and is expected to last approximately 60 weeks once the trial is fully enrolled. We currently anticipate enrollment will take approximately eighteen months. We currently expect the total cost of this trial to be approximately $25 million, although this estimate could vary significantly as the Phase III clinical trial progresses.

*Write-off of Acquired In-Process Research and Development*. On March 27, 2007, we acquired Acuity in a stock for stock transaction. We valued our common stock issued to Acuity shareholders at the average closing price of the common stock on the date of the transaction and two days prior to the transaction. We recorded the assets and liabilities acquired at fair value. Approximately $243.8 million of the purchase price was allocated to in-process research and development projects, which was immediately charged to expense. We record expense for in-process research and development projects which have not reached technological feasibility and which have no alternative future use. At the time of our acquisition of Acuity, Acuity's lead product, bevasiranib, had not begun the first of two required Phase III clinical trials and as such, had not reached a stage of technological feasibility and had no alternative future use.

*Other Income and Expenses*. Other expense was $0.7 million, net of $0.3 million of interest income for the year ended December 31, 2007. Other expenses primarily consist of interest expense incurred on our $4.0 million term loan and our $12.0 million line of credit, partially offset by interest earned on our cash and cash equivalents. Other income during the 2006 period reflected the interest earned on our cash and cash equivalents. We did not have any outstanding debt during that period. In addition, the 2007 period includes the minority interest loss of $0.6 million for a prorated portion of OTI's operating loss from the date of our investment in OTI on April 13, 2007 through the date of our acquisition on November 28, 2007.

***Liquidity And Capital Resources***

At December 31, 2007, we had cash and cash equivalents of approximately $23.4 million. Cash used in operations primarily reflects our net loss, offset by our non-cash operating expenses including the write-off of in-process research and development acquired in the acquisition of Acuity and equity-based compensation expense. Since our inception, we have not generated significant revenue and our primary source of cash has been from the private placement of stock and through credit facilities available to us.

In connection with the acquisition of Acuity, we assumed the rights and obligations under Acuity's $4.0 million term loan ($2.4 million outstanding at December 31, 2007) with Horizon Financial Funding Company, LLC. The term loan bears interest at 12.23% and is payable monthly. The principal is payable in 12 equal monthly installments which commenced August 2007. On January 11, 2008, we repaid in full all outstanding amounts and terminated all of our commitments under the term loan with Horizon. The total amount repaid in satisfaction of our obligations under the term loan was $2.4 million. We realized a net savings by avoiding future interest charges over the remaining term of the obligation.

45

We also assumed the rights and obligations of Acuity under the $7 million line of credit with The Frost Group, LLC, or the Frost Group, a related party. The Frost Group members include a trust controlled by Dr. Phillip Frost, who is the Company's Chief Executive Officer and Chairman of the board of directors, Dr. Jane H. Hsiao, who is the Vice Chairman of the board of directors and Chief Technical Officer, Steven D. Rubin who is Executive Vice President - Administration and a director of the Company, and Rao Uppaluri who is the Chief Financial Officer of the Company. At the time of the acquisition of Acuity, we amended and restated the Frost Group line of credit to provide additional available borrowing capacity up to a total of $12 million, and we assumed Acuity's existing obligation to repay $4.0 million outstanding under the line of credit. During 2007, we drew down the available amount under this credit line of $8.0 million for a total of $12.0 million borrowed. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at a 10% annual rate, which is due July 11, 2009. The line of credit is collateralized by all of our personal property except our intellectual property.

On December 5, 2007, in exchange for a $20 million cash investment in the Company, we agreed to issue 10,869,565 shares of our common stock, par value $.01, to members of the Frost Group. The shares were issued at a price of $1.84 per share, representing an approximately 40% discount to the average trading price of our stock on the American Stock Exchange for the five trading days immediately preceding the date the board of directors and stockholders approved the issuance of the shares. The shares issued in the private placement are restricted securities, subject to a two year lockup, and no registration rights have been granted.

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, add infrastructure and incur additional costs related to being a public company, including the costs of directors' and officers' insurance, investor relations programs and increased professional fees.

We believe the cash and cash equivalents on hand at December 31, 2007 will be sufficient to meet our anticipated cash requirements for operations and debt service for at least the next 12 months. We based this estimate on assumptions that may prove to be wrong or subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we 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 the continued progress of our research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs.

We intend to finance additional research and development projects, clinical trials and our future operations with a combination of private placements, payments from potential strategic research and development, licensing and/or marketing arrangements, public offerings, debt financing and revenues from future product sales, if any. There can be no assurance, however, that additional capital will be available to us on acceptable terms, or at all.

The following table provides information as of December 31, 2007 with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations

| (in thousands) | 2008 | 2009 | 2010 | 2011 | 2012 | After 2012 | Total |
|---|---|---|---|---|---|---|---|
| Open purchase orders | $ 1,469 | $ - | $ | $ | $ - | $ - | $ 1,469 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Operating leases | 333 | 351 | 338 | 350 | 226 | - | 1,598 |
| Term loan | 2,392 | - | - | - | - | - | 2,392 |
| Credit line | - | 12,000 | - | - | - | - | 12,000 |
| Total | 4,194 | 12,351 | 338 | 350 | 226 | - | 17,459 |

The preceding table does not include information where the amounts of the obligations are not currently determinable, including contractual obligations in connection with clinical trials, which are payable on a per-patient basis and product license agreements that include payments upon achievement of certain milestones. In addition to the principal balance as shown on our credit line, we also must pay interest upon the maturity of the credit line in July 2009.

***Critical Accounting Policies and Estimates***

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

*Equity Based Compensation.* As of June 23, 2006 (the date of inception), we adopted Statement of Financial Accounting Standards, or SFAS No. 123(R). Share-Based Payments SFAS No. 123(R) replaces SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB No. 25. SFAS No. 123(R) requires that all stock-based compensation be recognized as an expense in the financial statements and that such cost be measured at the fair value of the award. We adopted SFAS No. 123(R) upon our inception. Equity-based compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123(R) and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," which requires that these equity instruments are recorded at their fair value on the measurement date. As prescribed under SFAS 123(R), we estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the "Black-Scholes Model" and allocate the resulting compensation expense over the corresponding requisite service period associated with each grant. The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform significant analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model. We also perform significant analyses to estimate forfeitures of equity-based awards as required by SFAS 123(R). We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates may have a material impact on our Consolidated Financial Statements.

As of December 31, 2007, we had $15.9 million of unrecognized compensation expense related to unvested stock options that is expected to be recognized over a weighted average period of 3 years.

*Goodwill and Intangible Assets*. The allocation of the purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values under the provisions of SFAS No. 141, Business Combinations (SFAS No. 141). Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

Appraisals inherently require significant estimates and assumptions, including but not limited to, determining the timing and estimated costs to complete the in-process R&D projects, projecting regulatory approvals, estimating future cash flows, and developing appropriate discount rates. We believe the estimated fair values assigned to the Acuity and OTI assets acquired and liabilities assumed are based on reasonable assumptions. However, the fair value estimates for the purchase price allocation may change during the allowable allocation period under SFAS No. 141, which is up to one year from the acquisition date, if additional information becomes available that would require changes to our estimates.

*Allowance for Doubtful Accounts and Revenue Recognition*. Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Certain of our products are sold directly to end-users and require that we deliver, install and train the staff at the end-users' facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred. Return policies in certain international markets for our medical device products provide for stringent guidelines in accordance with the terms of contractual agreements with customers. Our estimates for sales returns are based upon the historical patterns of products returned matched against the sales from which they originated, and management's evaluation of specific factors that may increase the risk of product returns. The allowance for doubtful accounts recognized in our consolidated balance sheets at December 31, 2007 was $0.5 million. The allowance for doubtful accounts at December 31, 2007 was due to the acquired OTI medical device products.

***New Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation Number 48, Accounting for Uncertainty in Income Taxes, or FIN 48. FIN 48 applies to all tax positions within the scope of SFAS 109, applies a "more likely than not" threshold for tax benefit recognition, identifies a defined methodology for measuring benefits, and increases the disclosure requirements for companies. FIN 48 is mandatory for years beginning after December 15, 2006; accordingly, we adopted FIN 48 effective January 1, 2007. As a result of our full valuation allowance on our net deferred income tax assets, there was no impact of adoption.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This Statement applies to other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We will adopt SFAS 157 beginning in the first quarter of our 2008 fiscal year and do not expect the impact to be material to our financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, or SFAS 159, which gives companies the option to measure eligible financial assets, financial liabilities, and firm commitments at fair value (i.e., the fair value option), on an instrument-by-instrument basis, that are otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability or upon entering into a firm commitment. Subsequent changes in fair value must be recorded in earnings. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will adopt SFAS 159 beginning in the first quarter of our 2008 fiscal year and do not expect the impact to be material to our financial position or results of operations.

In June 2007, the EITF issued EITF Issue 07-03, Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development, or EITF 07-03. EITF 07-03 addresses the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We plan to adopt EITF 07-03 beginning in the first quarter of our 2008 fiscal year and do not expect the impact to be material to our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations. SFAS 141R will require, among other things, the expensing of direct transaction costs, including deal costs and restructuring costs as incurred, acquired IPR&D assets to be capitalized, certain contingent assets and liabilities to be recognized at fair value and earn-our arrangements, including contingent consideration, may be required to be measured at fair value until settled, with changes in fair value recognized each period into earnings. In addition, material adjustments made to the initial acquisition purchase accounting will be required to be recorded back to the acquisition date. This will cause companies to revise previously reported results when reporting comparative financial information in subsequent filings. SFAS No. 141R is effective for the Company on a prospective basis for transactions occurring in 2009 and earlier adoption is not permitted. SFAS No. 141R may have a material impact on the Company’s consolidated financial position, results of operations and cash flows if we enter into material business combinations after the standard’s effective date.

**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. 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.

Our exposure to market risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds and qualified purchaser funds. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment. At December 31, 2007, we had cash and cash equivalents of $23.4 million. The weighted average interest rate related to our cash and cash equivalents for the year ended December 31, 2007 was 4.9%. As of December 31, 2007, the principal value of our term loan and credit line was $14.6 million, which bear a weighted average interest rate of 10.7%.

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**


| | Page |
|---|---|
| Report of Independent Registered Public Accounting Firm | 51 |
| Consolidated Balance Sheets | 52 |
| Consolidated Statements of Operations | 53 |
| Consolidated Statement of Shareholders' Equity | 54 |
| Consolidated Statements of Cash Flows | 55 |
| Notes to Consolidated Financial Statements | 56 - 72 |

**Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying consolidated balance sheets of OPKO Health, Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2007 and for the period from inception (June 23, 2006) to December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of OPKO Health, Inc. and subsidiaries at December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for the year ended December 31, 2007 and for the period from inception (June 23, 2006) to December 31, 2006, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida
March 28, 2008

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

| | December 31, 2007 | December 31, 2006 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | $ 23,373 | $ 116 |
| Accounts receivable, net | 1,689 | - |
| Inventory | 2,214 | - |
| Prepaid expenses and other current assets | 1,936 | - |
| Total current assets | 29,212 | 116 |
| Property and equipment, net | 410 | - |
| Intangible assets, net | 9,931 | - |
| Other assets | 15 | - |
| Total assets | $ 39,568 | $ 116 |
| | | |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accrued expenses | $ 3,858 | $ 95 |
| Accounts payable | 3,319 | - |
| Current portion of notes payable, net unamortized discount of $8 and capital lease obligations | 2,546 | - |
| Total current liabilities | 9,723 | 95 |
| Long-term liabilities and capital lease obligations | 1,372 | - |
| Line of credit with related party, net unamortized discount of $311 | 11,689 | - |
| Total liabilities | 22,784 | 95 |
| Commitments and contingencies | | |
| Shareholders' equity | | |
| Series A Preferred stock - $0.01 par value, 4,000,000 shares authorized; 954,799 and 0 shares issued and outstanding (liquidation value of $2,387 and $0) December 31, 2007 and 2006, respectively | 10 | - |
| Series C Preferred Stock - $0.01 par value, 500,000 shares authorized; no shares issued or outstanding | - | - |
| Common Stock - $0.01 par value, 500,000,000 shares authorized; 178,344,608 and 61,775,002 shares issued and outstanding at December 31, 2007 and 2006, respectively | 1,783 | 618 |
| Additional paid-in-capital | 284,273 | 280 |
| Accumulated deficit | (269,282) | (877) |
| Total shareholders' equity | 16,784 | 21 |
| Total liabilities and shareholders' equity | $ 39,568 | $ 116 |

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

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

| | For the year ended December 31, 2007 | For the period from inception (June 23, 2006) to December 31, 2006 |
|---|---|---|
| Revenue | $ 847 | $ - |
| Cost of goods sold | 808 | - |
| Gross margin | 39 | - |
| | | |
| Operating expenses | | |
| Selling, general and administrative | 12,466 | 375 |
| Research and development | 10,850 | 508 |
| Write-off of acquired in-process research and development | 243,761 | - |
| Other operating expenses, principally amortization of intangible assets | 150 | - |
| Total operating expenses | 267,227 | 883 |
| Operating loss | (267,188) | (883) |
| Other (expense) income, net | (671) | 6 |
| Loss before income taxes and investment loss from OTI | (267,859) | (877) |
| Income taxes | 83 | - |
| Loss before investment loss from OTI | (267,776) | (877) |
| Loss from investment in OTI | (629) | - |
| Net loss | (268,405) | (877) |
| Preferred stock dividend | (217) | - |
| Net loss attributable to common shareholders | $ (268,622) | $ (877) |
| | | |
| Loss per share, basic and diluted | $ (2.09) | $ (0.01) |
| | | |
| Weighted average number of shares outstanding, basic and diluted | 128,772,080 | 58,733,556 |

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

**OPKO Health, Inc.**
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**
(in thousands except share data)
For the period from inception (June 23, 2006) to December 31, 2007

| | Series A Preferred Stock | | Series C Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Dollars | Shares | Dollars | Shares | Dollars | Capital | Deficit | Total |
| Issuance of capital stock to founders of Froptix, $0.01 per share | - | $ - | - | $ - | 61,775,002 | $ 618 | $ 20 | $ - | $ 638 |
| Equity-based compensation expense | - | - | - | - | - | - | 260 | - | 260 |
| Net loss for the period from inception (June 23, 2006) to December 31, 2006 | - | - | - | - | - | - | - | (877) | (877) |
| Balance at December 31, 2006 | - | - | - | - | 61,775,002 | 618 | 280 | (877) | 21 |
| Equity-based compensation expense | - | - | - | - | - | - | 7,373 | - | 7,373 |
| Issuance of equity securities for net monetary assets at $0.43 per share | 1,081,750 | 11 | - | - | 36,607,023 | 366 | 15,626 | - | 16,003 |
| Issuance of equity securities to acquire Acuity Pharmaceuticals, Inc. at $2.65 per share | - | - | 457,603 | 5 | 14,778,556 | 148 | 234,470 | - | 234,623 |
| Issuance of equity securities to acquire Ophthalmic Technologies, Inc. at $2.57 per share | - | - | - | - | 2,682,928 | 27 | 6,905 | - | 6,932 |
| Issuance of equity securities to acquire software at $3.79 per share | - | - | - | - | 30,000 | - | 114 | - | 114 |
| Issuance of common stock in private placement to related party at $1.84 per share | - | - | - | - | 10,869,565 | 109 | 19,891 | - | 20,000 |
| | - | - | (457,603) | (5) | 45,760,300 | 457 | (452) | - | - |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Issuance of common stock upon automatic conversion of Series C preferred stock | | | | | | | | | |
| Conversion of Series A preferred stock | (213,751) | (2) | - | - | 213,751 | 2 | - | - | - |
| Exercise of common stock options | - | - | - | - | 641,972 | 6 | 117 | - | 123 |
| Exercise of common warrants | - | - | - | - | 4,985,511 | 50 | (50) | - | - |
| Preferred stock dividend | 86,800 | 1 | - | - | - | - | (1) | - | - |
| Net loss for the year ended December 31, 2007 | - | - | - | - | - | - | - | (268,405) | (268,405) |
| Balance at December 31, 2007 | 954,799 | $ 10 | - | $ - | 178,344,608 | $ 1,783 | $ 284,273 | $ (269,282) | $ 16,784 |

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

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

| | For the year ended December 31, 2007 | For the period from inception (June 23, 2006) to December 31, 2006 |
|---|---|---|
| Cash flows from operating activities | | |
| Net loss | $ (268,405) | $ (877) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 184 | - |
| Write-off of acquired in-process research and development | 243,761 | - |
| Accretion of debt discount related to notes payable | 279 | - |
| Loss from investment in OTI | 629 | - |
| Equity based compensation - employees and non-employees | 7,373 | 260 |
| Changes in: | | |
| Accounts receivable | (554) | - |
| Inventory | (317) | - |
| Prepaid expenses and other current assets | (789) | - |
| Accounts payable | (607) | 95 |
| Accrued expenses | 1,497 | - |
| Net cash used in operating activities | (16,949) | (522) |
| Cash flows from investing activities | | |
| Investment in 33% of Ophthalmic Technologies, Inc. | (5,000) | - |
| Acquisition of businesses, net of cash | 2,751 | - |
| Capital expenditures | (489) | - |
| Net cash used in investing activities | (2,738) | - |
| Cash flows from financing activities: | | |
| Issuance of common stock for cash to related party | 20,000 | 638 |
| Issuance of common stock | 16,284 | - |
| Borrowings under line of credit with related party | 8,000 | - |
| Insurance financing | 152 | - |
| Proceeds from the exercise of stock options | 123 | - |
| Repayments of notes payable and capital lease obligations | (1,615) | - |
| Net cash provided by financing activities | 42,944 | 638 |
| Net change in cash and cash equivalents | 23,257 | 116 |
| Cash and cash equivalents at beginning of period | 116 | - |
| Cash and cash equivalents at end of period | $ 23,373 | $ 116 |

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

**OPKO Health, Inc.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 Business and Organization**

OPKO Health, Inc. ("we" or the "Company") is a specialty healthcare company focused on the discovery, development, and commercialization of proprietary pharmaceuticals, diagnostic and imaging systems and instrumentation products for the treatment, diagnosis and management of ophthalmic diseases. We continue to seek to expand our current operations by acquiring additional ophthalmic businesses and pharmaceutical and instrumentation technologies, as well as exploring opportunities in other medical markets that have operational characteristics similar to ophthalmology, such as dermatology. We are a Delaware corporation, headquartered in Miami, Florida, with instrumentation operations in Toronto, Ontario and our clinical operations in Morristown, New Jersey.

On June 8, 2007, we changed our name to OPKO Health, Inc. from eXegenics, Inc. Through March 26, 2007, eXegenics was a public shell company whose assets consisted of cash and nominal other assets. On February 9, 2007, eXegenics, completed the sale of 19,440,491 shares of its common stock for $8.0 million, constituting 51% of its issued and outstanding shares of capital stock on a fully diluted basis, to a small group of investors led by The Frost Group, LLC, or the Frost Group, a related party. The Frost Group members include a trust controlled by Dr. Phillip Frost, who is the Company’s Chief Executive Officer and Chairman of the board of directors, Dr. Jane H. Hsiao, who is the Company's Vice Chairman of the board of directors and Chief Technical Officer, Steven D. Rubin who is the Company's Executive Vice President - Administration and a director, and Rao Uppaluri who is the Company's Chief Financial Officer. On March 27, 2007, pursuant to the terms of a Merger Agreement and Plan of Reorganization, Froptix Corporation, or Froptix, a development stage research and development company, controlled by the Frost Group, and Acuity Pharmaceuticals, Inc., or Acuity, a development stage research and development company, and eXegenics were part of a three-way merger. Per that agreement, eXegenics issued new capital stock to acquire all of the issued and outstanding capital stock of Froptix and Acuity. Per that agreement, eXegenics issued new capital stock to acquire all of the issued and outstanding capital stock of Froptix and Acuity. Froptix was the accounting acquirer in the three-way merger which was accounted for as:

- a reverse merger between Froptix and eXegenics (a public shell company). For accounting purposes Froptix has been treated as the continuing registrant. As a result, all post merger comparative historical financials statements filed by us will be those of Froptix. Froptix was incorporated on June 23, 2006. Further, Froptix’ historical shareholders’ equity prior to the merger has been retroactively restated (recapitalized) for the equivalent number of shares received in the reverse merger. Earnings and loss per share calculations have also been retroactively restated to give effect to the recapitalization for all periods presented. Lastly, the merger between Froptix and eXegenics has been accounted for as a capital transaction equivalent to the issuance of capital stock by Froptix for the net monetary assets of eXegenics.

- an asset acquisition of Acuity by Froptix. Refer to Note 2

As a result, at the closing of the Mergers, we issued (a) an aggregate of 61,775,002 shares of our common stock to the former holders of Froptix common stock, (b) an aggregate of 14,778,556 shares of our common stock to the former holders of Acuity common stock and Acuity Series A preferred stock, and (c) an aggregate 45,760,300 shares of our common stock, to the former holders of Acuity Series B preferred stock which had converted into 457,603 shares of our Series C preferred stock prior to the Series C preferred stock converting into our common stock on June 23, 2007. We also granted 28,358,857 warrants to purchase shares of our common stock to former shareholders of Froptix and Acuity and 15,810,115 options to purchase our common stock to former option holders of Froptix and Acuity and 1,686,600 warrants to purchase our common stock, which had been warrants to purchase our Series C preferred stock prior to our Series C preferred stock converting to common stock on June 23, 2007. As consideration for an increase in our credit line with the Frost Group, we granted to the Frost Group an additional 4,000,000 warrants to purchase our common stock in connection with the Mergers.

On November 28, 2007, we completed the acquisition of Ophthalmic Technologies, Inc., or OTI and as a result we are no longer a development-stage company. Refer to Note 2.

**Note 2 Acquisitions**

On March 27, 2007, we acquired Acuity in a stock for stock transaction. Refer to Note 1. We valued our common stock issued to Acuity shareholders at the average closing price of the common stock on the date of acquisition and the two days prior to the transaction. Acuity's primary focus prior to our acquisition had been on the development of its lead compound, bevasiranib, for the treatment of Wet Age-Related Macular Degeneration, or Wet AMD. We believe the acquisition of Acuity was complementary to our platform of compounds for ophthalmic diseases and that Acuity had an advanced clinical product.

On April 13, 2007, we invested $5 million in exchange for common shares of Ophthalmic Technologies, Inc., or OTI, equaling one-third of the outstanding equity of OTI. On November 28, 2007, we acquired the remaining outstanding shares of OTI and issued approximately 2.7 million shares of our common stock based upon a purchase price of $10,000,000 and a value of $3.55 per share. OTI provides diagnostic and imaging systems to eye care professionals worldwide through its distributor network which covers over 60 countries. We believe our acquisition of OTI will provide a complementary product line to our pharmaceutical business that will improve physician treatment decisions and enhance outcomes for a variety of ocular disorders. The minority interest results in OTI from April 13, 2007 through our acquisition of OTI on November 28, 2007 have been included in our financial statements.

The following table summarizes the estimated fair value of the net assets acquired and liabilities assumed in the acquisition of Acuity and OTI at the dates of acquisition:

| (in thousands) | | |
|---|---|---|
| Current assets (including cash of $ 2,751) | $ | 6,032 |
| Property and equipment | | 85 |
| In-process research and development | | 243,761 |
| Intangible assets | | 8,087 |
| Other assets | | 602 |
| Goodwill | | 1,732 |
| Accounts payable and accrued expenses | | (6,528) |
| Line of credit and term loan | | (7,419) |
| Total purchase price | $ | 246,352 |

The portion of the purchase price allocated to in-process research and development of $243.8 million relates to the acquisition of Acuity and was immediately expensed. The purchase price of Acuity includes $1.5 million of costs incurred by us to acquire Acuity, including $1.3 million of costs associated with the issuance of warrants to the Frost Group as a result of the increase of the credit line with Acuity. Refer to Note 5. The purchase consideration issued and the purchase price allocation are preliminary pending completion of related valuation procedures and as a result, the amounts are subject to change.

The following table summarizes that fair value assigned to our major intangible assets classes:

| (in thousands) | Fair value assigned | Weighted average amortization period |
|---|---|---|
| Technology | $ 4,597 | 10 years |
| Customer relationships | 2,978 | 3 years |
| Covenants not to compete | 317 | 3 years |
| Tradename | 195 | 3 years |
| Total amortizing intangible assets | 8,087 | |
| Goodwill | 1,732 | Indefinite |
| Total intangible assets acquired | $ 9,819 | |

All of the intangible assets acquired and goodwill acquired relate to our acquisition of OTI.

The following table includes the pro forma results for the year ended December 31, 2007 and the period from inception (June 23, 2006) to December 31, 2006 of the combined companies as though the acquisitions of Acuity and OTI had been completed as of the beginning of each period, respectively.

| (in thousands, except per share amounts) | For the year ended December 31, 2007 | Period from inception (June 23, 2006) |
|---|---|---|

| | | | | through December 31, 2006 |
|---|---|---|---|---|
| Revenue | $ | 12,148 | $ | 5,570 |
| Net loss | $ | (278,097) | $ | (7,577) |
| Basic and diluted loss per share | $ | (2.06) | $ | (0.10) |

57

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

**Note 3 Summary of Significant Accounting Policies**

*Basis of Presentation*. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-K and of Regulation S-X.

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

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

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

*Property and Equipment*. Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, generally five to ten years and includes amortization expense for assets capitalized under capital leases. Expenditures for repairs and maintenance are charged to expense as incurred, while betterments are capitalized. Depreciation expense for the year ended December 31, 2007 was $35 thousand. We did not have any property or equipment for the period from inception (June 23, 2006) to December 31, 2006 and as a result did not incur depreciation expense for that period.

*Goodwill and Other Intangible Assets*. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired when accounted for by the purchase method of accounting and arises from our acquisition of OTI. Refer to Note 2. In accordance with SFAS 142, “Goodwill and Intangible Assets,” we do not amortize goodwill. Also in accordance with FAS 142, we will perform an annual impairment test of goodwill. We test for impairment annually during the fourth quarter. We will continue to evaluate our goodwill for impairment annually and whenever events and changes in circumstances suggest that the carrying amount may not be recoverable.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 10 years, and review for impairment at least annually, or sooner when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Amortization expense for the year ended December 31, 2007 was $0.2 million. We did not have any intangible assets for the period from inception to December 31, 2006 and as a result did not incur amortization expense for that period. Amortization expense for the years ended December 31, 2008, 2009, 2010, 2010 and 2011 is expected to be $1.6 million, $1.6 million, $1.5 million, $0.5 million and $0.5 million, respectively.

*Impairment of Long-Lived Assets*. In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for Impairment or Disposal of Long-Lived Assets, long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized by the amount by

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

*Research and Development*. Research and development costs are charged to expense as incurred. We record expense for in-process research and development projects acquired which have not reached technological feasibility and which have no alternative future use.

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

*Loss Per Common Share*. Basic and diluted earnings or loss per common share is based on the net loss increased by dividends on preferred stock divided by the weighted average number of common shares outstanding during the period. In the periods in which their effect would be anti-dilutive, no effect has been given to outstanding options, warrants or convertible preferred stock in the diluted computation. As of December 31, 2007, we have 178,344,608 common shares outstanding, in addition, we have options, warrants and convertible preferred stock outstanding at December 31, 2007 that, if converted or exercised would result in the issuance of an additional 45,934,615 shares of common stock, resulting in 224,279,223 potential common shares outstanding. The diluted loss per share does not include the weighted average impact of the outstanding options and warrants of 30,508,179 for the year ended December 31, 2007 because their inclusion would have been anti-dilutive.

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

Estimated allowances for sales returns are based upon our history of product returns. The amount of allowance for doubtful accounts at December 31, 2007 was $0.5 million.

*Equity-Based Compensation*. We follow the provisions of Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("Statement") No. 123 (revised 2004), Share-Based Payment ("SFAS 123R"), which requires that a company measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the statement of operations over the period during which an employee is required to provide service in exchange for the award. SFAS 123R also requires that excess tax benefits, as defined, realized from the exercise of stock options be reported as a financing cash inflow rather than as a reduction of taxes paid in cash flow from operations. Refer to Note 8. Equity-based compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123R and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," which requires that these equity instruments be recorded at their fair value on the measurement date. The measurement of equity-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

*Comprehensive income or loss*. Our comprehensive loss has no components other than net loss for all periods presented.

*Segment reporting.* Our chief operating decision-maker (or "CODM") is comprised of our executive management with the oversight of our board of directors. Our CODM review our operating results and operating plans and make resource allocation decisions on a company-wide or aggregate basis. Accordingly, we operate as one segment. Our products are being used by and developed for retina specialists, ophthalmologists, and optometrists. During 2007, all

of our instrumentation products were sold internationally.

*New accounting pronouncements*: In July 2006, the FASB issued Interpretation Number 48, Accounting for Uncertainty in Income Taxes, or FIN 48. FIN 48 applies to all tax positions within the scope of SFAS 109, applies a "more likely than not" threshold for tax benefit recognition, identifies a defined methodology for measuring benefits, and increases the disclosure requirements for companies. FIN 48 is mandatory for years beginning after December 15, 2006; accordingly, we adopted FIN 48 effective January 1, 2007. Refer to Note 9.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This Statement applies to other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We will adopt SFAS 157 beginning in the first quarter of our 2008 fiscal year and do not expect the impact to be material to our financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, or SFAS 159, which gives companies the option to measure eligible financial assets, financial liabilities, and firm commitments at fair value (i.e., the fair value option), on an instrument-by-instrument basis, that are otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability or upon entering into a firm commitment. Subsequent changes in fair value must be recorded in earnings. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will adopt SFAS 159 beginning in the first quarter of our 2008 fiscal year and do not expect the impact to be material to our financial position or results of operations.

In June 2007, the EITF issued EITF Issue 07-03, Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development, or EITF 07-03. EITF 07-03 addresses the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We plan to adopt EITF 07-03 beginning in the first quarter of our 2008 fiscal year and do not expect the impact to be material to our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations. SFAS 141R will require, among other things, the expensing of direct transaction costs, including deal costs and restructuring costs as incurred, acquired IPR&D assets to be capitalized, certain contingent assets and liabilities to be recognized at fair value and earn-our arrangements, including contingent consideration, may be required to be measured at fair value until settled, with changes in fair value recognized each period into earnings. In addition, material adjustments made to the initial acquisition purchase accounting will be required to be recorded back to the acquisition date. This will cause companies to revise previously reported results when reporting comparative financial information in subsequent filings. SFAS No. 141R is effective for the Company on a prospective basis for transactions occurring in 2009 and earlier adoption is not permitted. SFAS No. 141R may have a material impact on the Company's consolidated financial position, results of operations and cash flows if we enter into material business combinations after the standard's effective date.

**Note 4 Composition of Certain Financial Statement Captions**

| (in thousands) | December 31, 2007 | 2006 |
|---|---|---|
| Accounts receivable, net | | |
| Accounts receivable | $ 2,154 | $ - |
| Less allowance for doubtful accounts | (465) | - |
| | $ 1,689 | $ - |
| Inventories | | |
| Raw materials (components) | $ 1,913 | - |
| Finished products | 301 | - |
| Less provision for inventory reserve | - | - |
| | $ 2,214 | $ - |
| Prepaid expenses and other current assets | | |
| Prepaid clinical trial expenses | $ 511 | $ - |
| Prepaid insurance | 426 | - |
| Prepaid supplies | 456 | - |
| Canadian tax credit recoverable | 225 | - |
| Other | 318 | - |
| | $ 1,936 | $ - |
| Property and equipment, net | | |
| Machinery and equipment | $ 153 | $ - |
| Furniture and fixtures | 207 | - |
| Software | 117 | - |
| Leasehold improvements | 27 | - |
| Less accumulated depreciation | (94) | - |
| | $ 410 | $ - |
| Intangible assets | | |
| Technology | $ 4,597 | $ - |
| Customer relationships | 2,978 | - |
| Covenants not to compete | 317 | - |
| Tradename | 195 | - |
| Other | 262 | - |
| Less amortization | (150) | - |
| Goodwill | 1,732 | - |
| | $ 9,931 | $ - |
| Accrued expenses | | |
| Accrued royalties | $ 313 | $ - |
| Accrued distributor commissions | 187 | - |
| Product warranties - medical device products | 221 | - |
| Clinical trials | 1,495 | - |
| Customer deposits | 511 | - |
| Other | 1,131 | 95 |
| | $ 3,858 | $ 95 |

**Note 5 Debt**

On January 11, 2007, Acuity entered into an agreement with the Frost Group whereby the Frost Group provided a subordinated secured line of credit of up to $7.0 million to Acuity. In exchange for entering into this agreement, Acuity agreed to grant to the Frost Group a warrant to purchase Acuity Series B Preferred Stock which after the

Merger became warrants to acquire up to 647,800 shares of our common stock at an exercise price of approximately $0.3854 per share and warrants to acquire Acuity common stock which after the Merger become warrants to acquire 81,085 shares of our common stock at an exercise price of $0.0019 per share.

In connection with the acquisition of Acuity, we assumed the rights and obligations of Acuity under this line of credit. We also amended and restated this line of credit to increase the borrowing capacity to $12.0 million and assume Acuity's existing obligation to repay $4.0 million outstanding under the prior line of credit. During 2007, we drew down the remaining available funds of $8.0 million for a total of $12.0 million borrowed. We are obligated to pay interest upon maturity, compounded quarterly on borrowings under the line of credit at a 10% annual rate, which is due on July 11, 2009. The line of credit is collateralized by all of our personal property, except intellectual property. In connection with the assumption and amendment of the line of credit, we granted warrants to purchase 4,000,000 shares of our common stock to the Frost Group. The fair value of the warrants was determined to be $12.4 million using the Black-Scholes option valuation model. Because the issuance of the warrants and the increase in the line of credit were conditioned upon the completion of the Mergers, the value of the warrants has been allocated on a relative fair value basis to the cost of the Acuity acquisition ($1.3 million), the cost of the reverse merger between Froptix and eXegenics ($11.0 million) and debt commitment fee ($0.1 million).

We also assumed the rights and obligations of Acuity's $4.0 million term loan ($2.4 million outstanding of December 31, 2007) with Horizon Financial, Inc., in connection with the Mergers. The term loan bears interest at 12.23%, which is payable monthly. The principal is payable in 12 equal monthly installments which began August 2007. On January 11, 2008, we repaid in full all outstanding amounts and terminated all of our commitments under the term loan with Horizon.

**Note 6 Equity Offering**

On December 5, 2007, in exchange for a $20 million cash investment in the Company, we issued 10,869,565 shares of our common stock, par value $.01, to members of the Frost Group. The shares were issued at a price of $1.84 per share, representing an approximately 40% discount to the average trading price of our stock on the American Stock Exchange for the five trading days immediately preceding the date the board of directors and stockholders approved the issuance of the shares. The shares issued in the private placement are restricted securities, subject to a two year lockup, and no registration rights have been granted. Refer to Note 11.

**Note 7 Stockholders' Equity**

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

***Common Stock***

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

In addition to our equity-based compensation plans, we have warrants to purchase our common stock. Refer to Note 8 for additional information on our share-based compensation plans. The table below provides additional information for warrants outstanding as of December 31, 2007. In connection with the Mergers, we issued a total of:

| Warrants | Number of warrants | Weighted average exercise price | Expiration date |
|---|---|---|---|
| Outstanding at December 31, 2006 | - | - | - |
| Issued to former Acuity warrant holders' | 6,472,652 | $ 0.02 | Various 2015-2016 |
| Issued to Acuity shareholders' | 6,253,236 | $ 0.86 | March 27, 2017 |
| Issued to Acuity Series B warrant holders | 1,686,000 | $ 0.39 | Various 2015-2017 |
| Issued to Froptix shareholders' | 15,632,969 | $ 0.86 | March 27, 2017 |
| Issued in conjunction with debt commitment | 4,000,000 | $ 0.50 | March 27, 2017 |
| Issued to eXegenics warrant holders | 290,000 | $ 0.75 | August 13, 2007 through March 5, 2008 |
| Exercised | (5,537,475) | | |
| Expired | (125,000) | | |
| Outstanding at December 31, 2007 | 28,672,382 | | |
| Exercisable at December 31, 2007 | 28,672,382 | | |

Of the 5,537,475 warrants exercised to purchase common stock, 551,964 shares were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements.

***Preferred Stock***

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

***Series A Preferred Stock***

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

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

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

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

***Series C Preferred Stock***

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

**Note 8 Equity-Based Compensation**

We maintain equity-based incentive compensation plans that provide for grants of stock options to our directors, officers, key employees and certain outside consultants. Our 2007 Equity Incentive Plan includes all options assumed from the companies combined in the Merger discussed in Note 1. Options granted under the 1996 Stock Option Plan, 2000 Stock Option Plan and the plans assumed from Froptix and Acuity are exercisable for a period of up to 10 years from date of grant. Options granted under the 2007 Equity Incentive Plan are exercisable for a period up to 7 years. Vesting periods range from immediate to 4 years.

***Adoption of New Accounting Guidance and Transition***

Upon our incorporation in June 2006, we adopted the fair value recognition provisions of SFAS No. 123R, which is a revision of SFAS No. 123, using the prospective transition method.

SFAS No. 123R requires that we classify the cash flows resulting from the tax benefit that arises when the tax deductions exceed the compensation cost recognized for those options (excess tax benefits) as financing cash flows. There were no excess tax benefits for the year ended December 31, 2007 or the period from inception (June 23, 2006) to December 31, 2006.

Equity-based compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123R and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,” which requires that these equity instruments are recorded at their fair value on the measurement date. The measurement of equity-based compensation is subject to periodic adjustment over the waiting time of the equity instruments.

***Valuation and Expense Information***

We recorded equity based compensation expense of $7.4 million and $0.3 million, for the year ended December 31, 2007 and the period from inception (June 23, 2006) to December 31, 2006, respectively, all of which were reflected as operating expense. Of the $7.4 million of expense recorded during the year ended December 31, 2007, $4.4 million was included as selling, general and administration expense and $3.0 million was recorded as research and development expense. During the third quarter of 2007, a reversal of equity-based compensation expense of $8.1 million was recorded as a result of the termination of a consulting agreement prior to the vesting of any of the equity based awards issued under a consulting agreement. Originally, we accrued $0.3 million for this expense during 2006 and $7.8 million during the first six months of 2007. During the 2006 period, all of the equity-based compensation was recorded as selling, general and administration expense. As of December 31, 2007, there was $16.0 million of total unrecognized compensation cost related to non-vested stock options, which will be expensed over a weighted-average period of 3.0 years. We did not recognize a tax benefit for equity-based compensation arrangements during the year ended December 31, 2007.

As required by SFAS No. 123R, we estimate forfeitures of stock options and recognize compensation cost only for those awards expected to vest. Forfeiture rates are determined for all employees and non-employee directors based on historical experience and our estimate of future vesting. Estimated forfeiture rates are adjusted from time to time based on actual forfeiture experience.

***Stock Options***

In accordance with SFAS No. 123R, we estimate the fair value of each stock option on the date of grant using a Black-Scholes option-pricing formula, applying the following assumptions, and amortized the fair value to expense over the option’s vesting period using the straight-line attribution approach for employees and non-employee directors,

and the amortization method allowed by Financial Accounting Standards Board Interpretation 28, “Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an interpretation of APB Opinions No. 15 and 25”, for awards issued to non-employees which allows for recognizing compensation expense on a graded basis, with most of the compensation expense being recorded during the initial period of vesting:

| | Year Ended | |
|---|---|---|
| | December 31, 2007 | December 31, 2006 |
| Expected term (in years) | 3.5 - 9.7 | 9.5 |
| Risk-free interest rate | 3.2% - 5.2% | 4.5% |
| Expected volatility | 73% - 76% | 35% |
| Expected dividend yield | 0% | 0% |

Expected Term: The expected term of the stock options to employees and non-employee directors was calculated using the shortcut method allowed by the provisions of SFAS No. 123R and interpreted by Staff Accounting Bulletin No. 110 (SAB 110). We believe this method is appropriate as our equity shares have been publicly trade for a limited period of time and as such we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The expected term of stock options issued to non-employee consultants is the remaining contractual life of the options issued.

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

Expected Volatility: The expected volatility was based on a peer group of publicly-traded stocks' historical trading which we believe will be representative of the volatility over the expected term of the options. We believe the peer group's historical volatility is appropriate as our equity shares have been publicly traded for a limited period of time. The expected volatility for the 2006 period utilized a different peer group than the year ended December 31, 2007 and as a result had a lower volatility.

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

We maintain incentive stock plans that provide for the grants of stock options to our directors, officers, employees and outside consultants. For the year ended, December 31, 2007, there were 18,038,329 shares of common stock reserved for issuance under our 2007 Incentive Plan. We intend to issue new shares upon the exercise of options. Stock options granted under these plans have been granted at an option price equal to the closing market value of the stock on the date of the grant. Options granted under these plans to employees typically become exercisable over four years in equal annual installments after the date of grant, and to non-employee directors become exercisable in full after one-year after the grant date, subject to, in each case, continuous service with the Company during the applicable vesting period. The Company assumed options to grant common stock as part of the Merger, which reflected various vesting schedules, including monthly vesting to employees and contractors.

A summary of option activity under our stock plans as of December 31, 2007 and the changes during the year is presented below:

| Options | Number of options | Weighted average exercise price | Weighted average remaining contractual term (years) | Aggregate intrinsic value (in thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2006 | 4,436,878 | $ 0.01 | | |
| Assumed from Acuity Pharmaceuticals | 11,373,237 | 0.14 | | |
| Assumed from eXegenics | 305,000 | 0.59 | | |
| Granted | 5,220,000 | 4.45 | | |
| Conversion of Series C Stock Options to Common Stock Options | 731,700 | 0.32 | | |
| Exercised | (654,220) | 0.26 | | |
| Forfeited | (5,103,216) | 0.04 | | |
| Expired | (1,945) | 0.04 | | |
| Outstanding at December 31, 2007 | 16,307,434 | $ 1.53 | 6.2 | $ 29,979 |

| | | | | | |
|---|---|---|---|---|---|
| Vested and expected to vest at December 31, 2007 | 15,172,394 | $ | 1.45 | 6.1 | $ 28,826 |
| Exercisable at December 31, 2007 | 8,529,411 | $ | 0.20 | 5.2 | $ 22,571 |

The amount of compensation costs recorded in 2007 related to stock options awards is $7.4 million and $0.3 million was recorded during 2006. As of December 31, 2007, there was $15.9 million of unrecognized compensation cost related to the stock options granted under our stock plans. That cost is expected to be recognized over a weighted-average period of 3 years. The per share weighted-average fair value of stock options granted during 2007 was $2.73. The total intrinsic value of stock options exercised was $2.3 million during 2007. There were no stock option exercises during 2006, our year of inception.

Of the 654,220 stock options exercised, 12,248 shares were surrendered in lieu of a cash payment via the net exercise feature of the option agreements.

**Note 9 Income Taxes**

Income before income taxes was taxed in the U.S. and Canada.

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

| (in thousands) | For the Year Ended December 31, 2007 | For the period from inception (June 23, 2006) through December 31, 2006 |
|---|---|---|
| Current | | |
| Federal | $ - | $ - |
| State | - | - |
| Foreign | (83) | - |
| | (83) | - |
| Deferred | | |
| Federal | (5,274) | (199) |
| State | (333) | (30) |
| Foreign | (106) | - |
| | (5,714) | (229) |
| Total | (5,797) | (229) |
| Change in valuation allowance | 5,714 | 229 |
| Total, net | $ (83) | $ - |

Deferred income tax assets and liabilities as of December 31, 2007 and December 31, 2006 are comprised of the following:

| (in thousands) | December 31, 2007 | December 31, 2006 |
|---|---|---|
| Deferred income tax assets | | |
| Federal net operating loss | | |