Valera Pharmaceuticals Inc
Form 10-K
March 20, 2006

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

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2005**
**Commission File Number 000-51768**

**VALERA PHARMACEUTICALS, INC.**
*(Exact Name of Registrant as Specified in Its Charter)*

| **Delaware** | **13-4119931** |
|---|---|
| *(State or Other Jurisdiction of Incorporation or Organization)* | *(I.R.S. Employer Identification No.)* |

**7 Clarke Drive**
**Cranbury, New Jersey 08512**
*(Address of Principal Executive Offices) (Zip Code)*
**Registrant s Telephone Number, Including Area Code: (609) 235-3000**
**Securities registered pursuant to Section 12(b) of the Act: None**
**Securities registered pursuant to Section 12(g) of the Act: common stock $0.001 par value**
*(Title of class)*

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

| Large accelerated filer o | Accelerated filer o | Non-accelerated filer þ |
|---|---|---|

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

As of March 1, 2006, the aggregate market value of the common stock of registrant held by non-affiliates of registrant was approximately $50.0 million. The common stock of the registrant did not trade on a public market as of June 30, 2005.

As of March 1, 2006, there were 14,885,546 shares of registrant s common stock, $0.001 par value, outstanding.

Documents Incorporated by Reference: None

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## Part I

### Forward-Looking Statements

We have included, and from time to time may make in our public filings, press releases or other public statements, certain statements, including (without limitation) those under Management s Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 ( MD&A ), and Quantitative and Qualitative Disclosures about Market Risk in Part II, Item 7A, that may constitute forward-looking statements. In addition, our management may make forward-looking statements to analysts, investors, representatives of the media and others. These forward-looking statements are not historical facts and represent only Valera Pharmaceuticals beliefs regarding future events, many of which, by their nature, are inherently uncertain and beyond our control.

The nature of Valera Pharmaceuticals business makes predicting the future trends of our revenues, expenses and net income difficult. The risks and uncertainties involved in our businesses could affect the matters referred to in such statements and it is possible that our actual results may differ from the anticipated results indicated in these forward looking statements. Important factors that could cause actual results to differ from those in the forward-looking statements include (without limitation):

- changes in reimbursement rates for Vantas and any future products;
- the actions and initiatives of current and potential competitors;
- the impact of current, pending and future legislation, regulation and legal actions in the U.S. and worldwide affecting the pharmaceutical and healthcare industries;
- our ability to manufacture our Vantas product;
- our ability to develop products, receive regulatory approvals, and market our products; and
- other risks and uncertainties detailed under Risk Factors in Part I, Item 1A, Competition and Regulation in Part I, Item 1 and elsewhere throughout this report.

Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made. Valera Pharmaceuticals undertakes no obligation to update publicly or revise any forward-looking statements to reflect the impact of circumstances or events that arise after the dates they are made, whether as a result of new information, future events or otherwise except as required by applicable law. You should, however, consult further disclosures Valera Pharmaceuticals may make in future filings of its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and any amendments thereto.

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## Item 1. *Business*

### Overview

Valera Pharmaceuticals is a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize our proprietary technology. Our first product, Vantas, was approved by the FDA in October 2004. Vantas is a 12-month implant indicated for the palliative treatment of advanced prostate cancer. Vantas slows prostate tumor growth by delivering histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist. We began marketing Vantas in November 2004 utilizing our sales force that is currently calling on urologists in the U.S. that account for the majority of LHRH agonist product sales. In addition to Vantas, we are developing a pipeline of product candidates for indications that include central precocious puberty, acromegaly, opioid addiction, interstitial cystitis, nocturnal enuresis and bladder cancer.

Total U.S. sales of LHRH agonist products for the palliative treatment of prostate cancer were approximately $900 million in 2005 based on our estimates and IMS Health Incorporated data, with the leading products being three- and four-month injection formulations. We believe that total U.S. sales of LHRH agonist products declined by approximately 10% in 2005, primarily as a result of lower prices due to changes in Medicare reimbursement rates. We believe that Vantas has a competitive advantage over other products because it delivers an even, controlled dose of LHRH agonist over a 12-month period, and is the only product indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, the most potent LHRH agonist available on the market.

Vantas is a hydrogel implant based on our patented Hydron Technology, which is a drug delivery system that allows us to control the amount and timing of the release of drugs into the body for up to 12 months. Several of our product candidates utilize our Hydron Technology delivery system. We intend to leverage our specialized sales force to market certain of our product candidates, if approved, since the indications of these product candidates are treated by many of the same physicians we are calling on for Vantas.

### Our Competitive Strengths

We believe that our key competitive strengths that distinguish us from our competitors include:

*Technology.* We believe that Hydron Technology offers significant advantages over existing drug delivery systems. Implants using Hydron Technology can be adapted to deliver many kinds of drugs over an extended period of time. Currently, we only have regulatory approvals for Vantas. We will have to obtain approval for each product we develop, including products using Hydron Technology. In addition, our implants are soft and flexible, enhancing patient comfort. Further, because we own the manufacturing know-how to develop products utilizing Hydron Technology, we are able to control and maximize the potential commercial uses of this technology.

*Development Capability.* As demonstrated by Vantas, we have succeeded in developing a product, successfully taking it through the regulatory process to market in the U.S. in less than a year from the submission of a new drug application without utilizing an accelerated approval process. However, we may not be able to obtain FDA approval for our product candidates as quickly as we did for Vantas. Over the past three years, we have advanced two other product candidates into late-stage clinical development. We expect to continue to utilize this capability to efficiently develop future products.

*Manufacturing Ability.* We manufacture Vantas and our product candidates utilizing Hydron Technology using a patented process. In addition, we have developed proprietary equipment and scalable manufacturing methods to achieve cost-effective commercial production. Further, because we control the manufacture of Vantas and our product candidates that use Hydron Technology, we can ensure high quality and fully realize any manufacturing cost efficiencies.

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*Sales and Marketing.* We are currently calling on urologists that account for the majority of LHRH agonist product sales in the U.S. By adjusting our current sales force structure slightly, we will be able to call on physicians in additional specialty areas, such as endocrinology. These therapeutic areas are attractive because a small, focused sales force can effectively target them. We also believe that the direct physician distribution channel of Vantas may present a barrier to the future entry of competition from generic products because generic drug companies do not typically have field sales forces. Outside the U.S., we intend to partner with companies with a local presence and proven distribution channels in the urology market for distribution of Vantas.

**Product Development**

The following table summarizes certain information regarding Vantas and our product candidates:

| Product | Indication | Therapeutic Area | Delivery Method | Status | Next Anticipated Milestone |
|---|---|---|---|---|---|
| Vantas | Prostate Cancer | Urology | Implant | U.S. Commercial Sales | Commence Mutual Recognition Process in Europe in Second Quarter of 2006 |
| Supprelin®-LA | Central Precocious Puberty (early onset of puberty) | Endocrinology | Implant | Phase III | New Drug Application Filing in Second Quarter of 2006 |
| VP003 (Octreotide) | Acromegaly (giantism) | Endocrinology | Implant | Phase I/II | Phase IIb Clinical Trial in First Half of 2006 |
| VP004 (Naltrexone) | Addiction Disorders | Central Nervous System | Implant | Pre-clinical | Phase I/II Clinical Trial in First Half of 2006 |
| VP005 (Anti-inflammatory) | Interstitial Cystitis (bladder inflammation) | Urology | Bladder Instillation | Pre-clinical | Phase I/II Clinical Trial in Second Half of 2006 |
| VP006 (Peptide) | Nocturnal Enuresis (bed-wetting) | Urology | Oral Tablet | Phase I | Clinical Trials in First Half of 2006 |
| Valrubicin | Bladder Cancer | Urology | Bladder Instillation | Acquisition Pending | Closing of Asset Purchase in First Quarter of 2006 |

***Vantas***

Vantas is a soft and flexible implant utilizing Hydron Technology to deliver histrelin over a 12-month period for the palliative treatment of advanced prostate cancer. The total number of patients with advanced prostate cancer in the

U.S. was 666,300 in 2004, and we estimate that approximately 50% of these patients are receiving treatment with LHRH therapy. We estimate the patient population to be similar in Europe. We received regulatory approval to commercialize Vantas in Denmark in November 2005, and we expect to commence the mutual recognition process for regulatory approval in other European countries in the second quarter of 2006. We received regulatory approval in Canada in March 2006. In addition, one of our marketing partners has applied for regulatory approval in Thailand, Singapore, Malaysia, and Taiwan.

The current standard of care for the palliative treatment of prostate cancer is LHRH agonist therapy. An agonist is a chemical substance capable of activating a receptor to induce a full or partial pharmacological response. LHRH agonist therapies for advanced prostate cancer are designed to suppress the production of testosterone because testosterone promotes and accelerates the growth of tumors

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associated with prostate cancer. Histrelin, a powerful inhibitor of testosterone production, is the most potent LHRH agonist available.

Total U.S. sales of LHRH agonist products for the palliative treatment of prostate cancer were approximately $900 million in 2005 based on our estimates and IMS Health market data. We believe that amount represents a decline of approximately 10% from 2004, primarily as a result of lower prices due to changes in Medicare reimbursement rates. The most common dosage forms for the administration of LHRH agonists for this indication involve three- and four-month injection formulations such as Lupron and Eligard, which deliver leuprolide, Trelstar, which delivers triptorelin, and Zoladex, a biodegradable rod, which delivers goserelin. Another product is Viadur, a rigid metal implant that releases leuprolide over a 12-month period. We believe that Vantas is a more comfortable and convenient alternative to competing products because it eliminates the requirement of multiple physician visits and repeated injections and is smaller, softer and more flexible than other implants. Implantation, however, may be less well-received by some patients than injection therapy. In addition, in our Phase III clinical trial for Vantas, 100% of the evaluable patients achieved chemical castration at week four and testosterone suppression was maintained throughout the 52-week study period for 99% of the patients. Based on these data, we believe Vantas is a highly effective product for the palliative treatment of advanced prostate cancer. During the Phase III clinical trial, side effects included hot flashes, fatigue and implant site reactions, such as swelling and redness.

Prostate cancer is the most common cancer for men and the second leading cause of cancer death in men. According to the American Cancer Society, every year approximately 200,000 men are diagnosed with prostate cancer and 30,000 die from this disease. The National Cancer Institute s SEER Program and the National Oncology Database each project that this patient group will grow at an annual rate of 2% to 3% per year through 2008 and beyond.

Our sales force is currently selling and marketing Vantas to the urologists that account for the majority of LHRH agonist product sales in the U.S. Our product specialists utilize various promotional materials when making clinical presentations, including instructional videos on proper implantation technique. In remote areas where our product specialists cannot make personal visits, we conduct direct mail programs to selected physicians. We also supply physicians, health plan administrators and specialty pharmacies with a pharmaco-economic model to demonstrate the cost effectiveness of Vantas compared to other LHRH agonist products due to decreased utilization of staff time for repeated injections and a single reimbursement claim per year as opposed to three or four. Additionally, we support our sales efforts by employing a wide range of marketing programs to promote Vantas, including journal advertising, industry publications, medical educational conferences and internet initiatives.

***Supprelin-LA***

Supprelin-LA is an implant utilizing Hydron Technology to deliver histrelin over a 12-month period for the treatment of central precocious puberty, or CPP. The prevalence of this condition is estimated to be between one in 5,000 to 10,000 children. This yields a potential population of up to 11,700 children with this condition who are 14 or younger in the U.S. CPP is the early onset of puberty in young children, resulting in the development of secondary sexual characteristics and short stature, if left untreated. The development of these secondary sexual characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. The standard of care of CPP involves the use of LHRH agonists to suppress the secretion of sex hormones in order to delay the onset of puberty.

One therapy currently marketed to treat CPP is Lupron Depot-PED, which is manufactured and marketed by TAP Pharmaceutical Products, Inc. According to IMS Health market data, sales of Lupron Depot-PED generated revenues in excess of $76 million in the U.S. in 2005. The monthly cost of Lupron Depot-PED is in excess of $1,000 per month. CPP treatment using Lupron Depot-PED consists of intramuscular injections of leuprolide every four weeks to hormonally suppress these children. Our research indicates that, in many cases, hormonal suppression may not be achieved by a four-week injection schedule, and leuprolide needs to be administered more frequently. Supprelin-LA delivers histrelin, which

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has ten times the relative potency of leuprolide, and which has been previously approved for this condition as a daily injection for children. Supprelin-LA is formulated to release a higher daily dose of histrelin than Vantas because children with CPP need higher doses of LHRH agonist to achieve hormonal suppression. If approved, Supprelin-LA would provide hormonal suppression over a 12-month period. We believe Supprelin-LA would have a competitive advantage over Lupron Depot-PED because it eliminates the monthly injections given to these children and offers increased convenience and reduced costs by eliminating the need for monthly physician visits. Depending on the age of diagnosis, typical therapy may last three to five years.

In a survey conducted by D2 Market Research on our behalf at the 2004 Pediatric Academic Society conference, over 50% of the pediatric endocrinologists who completed a self-administered questionnaire indicated they would be likely to use a one-year implant like Supprelin-LA. There are approximately 700 pediatric endocrinologists in the U.S., and most of them are located in the same major metropolitan areas as the urologists we are calling on for Vantas. We intend to market Supprelin-LA, if approved, by leveraging our existing sales force and hiring only a small number of additional product specialists.

Results from our Phase II clinical trial of Supprelin-LA showed that all patients achieved clinically relevant levels of hormonal suppression, which is less than 4 mlU/ml, for the entire 12-month period. As demonstrated by blood tests, the primary efficacy endpoints of our Phase II clinical trial were the suppression of testosterone in boys and estradiol in girls. During the Phase II clinical trial, side effects included implant site reactions. Based on the successful outcome of our Phase II clinical trial, we are currently conducting a single Phase III clinical trial with 36 patients and plan on filing a new drug application with the FDA in the second quarter of 2006. Because the patient population for CPP is small, clinical studies with smaller sample sizes are permitted by the FDA. The endpoints of this clinical trial, as agreed with the FDA, will be the suppression of luteinizing hormone upon a gonadotropin releasing hormone challenge. All patients in the Phase III clinical trial have met their first efficacy endpoint, which is hormone suppression below pubertal levels. This was true for both patient groups; those who were being treated with a competitive therapy as well as those who had not started therapy prior to the clinical trial. There were no serious side effects for any patients and no patient discontinuations from the clinical trial. Monthly assessments of efficacy and safety will be gathered until the end of the study, which is scheduled for April 2006. In November 2005, we received notification from the FDA that Supprelin-LA was granted orphan drug designation for the treatment of central precocious puberty. Orphan drug designation provides us with certain economic benefits and tax credits, and exclusivity in the marketplace for a period of seven years.

***VP003 (Octreotide)***

VP003 is an implant utilizing Hydron Technology to deliver octreotide over a six-month period for the treatment of acromegaly, or giantism. We believe there are approximately 1,000 new acromegalic patients per year and 16,000 total patients in the U.S. Acromegaly is a chronic hormonal disorder that occurs when a pituitary tumor produces excess growth hormone, or GH. It most commonly affects middle-aged adults, and if untreated, causes enlargement of certain bones, cartilage, muscles, organs and other tissue, leading to serious illness and potential premature death.

Octreotide is a treatment used to substantially reduce GH levels and insulin-like growth factor levels, or IGF-1 levels, in patients with acromegaly. Octreotide is also approved to treat the symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors. Octreotide is currently being marketed by Novartis as Sandostatin injections in several strengths in both daily and monthly formulations.

Worldwide sales of Sandostatin generated revenues of $896 million in 2005 according to Scrip World Pharmaceuticals News. We estimate the U.S. acromegalic market to be approximately $200 million annually, consisting mostly of monthly injections of octreotide. We believe there is a market for a longer-acting octreotide formulation such as VP003 in order to reduce the number of physician visits for injections of octreotide. In addition, since there are a limited number of endocrinologists dispensing

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octreotide and patients are dispersed throughout the country, we believe patient compliance would also be significantly improved by longer-acting treatment with VP003.

Research conducted by Verispan Market Research on our behalf shows that a longer-acting octreotide product would be favorably received in the endocrinology market. The endocrinologists interviewed by Verispan cited the poor compliance of acromegalics who are required to visit a doctor every month to get injections for a disease in which patients rarely notice the changes being caused by the condition. Another reason cited for poor compliance was the long distances many patients have to travel for treatment because of the limited number of physicians willing to administer the monthly formulation of Sandostatin due to the complexity of the technique involved.

There are about 4,400 endocrinologists practicing in the U.S., and most of them are located in the same metropolitan areas where we are marketing Vantas to urologists. We intend to market VP003 by leveraging our existing sales force and hiring only a small number of additional product specialists. Furthermore, we may already have a presence with endocrinologists to market VP003, if approved, as a result of the potential marketing of Supprelin-LA, our histrelin implant to treat CPP.

In 2004, we initiated and completed a Phase I/ II pharmacokinetic clinical trial with 11 acromegalic patients to evaluate the release characteristics of VP003 and examine safety and efficacy parameters. The endpoints achieved in this clinical trial were the reductions in GH and IGF-1 levels in the blood in these patients. During the Phase I/II clinical trial, side effects included diarrhea, low blood sugar and implant site reactions. We plan to initiate a Phase IIb clinical trial in the first half of 2006 to evaluate the efficacy of VP003 as compared to the monthly formulation of Sandostatin. This study will be conducted in both the U.S. and Brazil and the goal is to enroll 45 patients for at least six months. The endpoints of our Phase IIb clinical trial will be the reductions in GH and IGF-1 levels in the blood in these patients, which were the endpoints in the Phase III clinical trial of Sandostatin.

***VP004 (Naltrexone)***

VP004 is an implant utilizing Hydron Technology to deliver naltrexone for the treatment of opioid addiction over a six-month period. The National Institute for Drug Addiction estimates that there are approximately one million heroin addicts in the U.S. of which only 25% seek treatment. Naltrexone is an opiate antagonist currently approved as an oral daily formulation in the U.S. for the treatment of opiate dependence. Naltrexone competitively binds at the opiate receptor sites in the brain, thereby blocking the euphoric effects of opiates such as heroin.

Although naltrexone is effective, the addict population is typically non-compliant. We believe that this creates an attractive opportunity for VP004 because it provides controlled release of naltrexone over a six-month period. There are over 200 registered addiction medicine specialists practicing in the U.S. Further, a significant number of primary care providers treat opioid addicts. In addition to opioid addiction, naltrexone is also currently approved in the U.S. for the treatment of alcoholism.

VP004 has completed animal testing for evaluation of safety and pharmacokinetics. We intend to file an investigational new drug application and initiate a pilot Phase I/ II clinical trial among an opioid addict population in the first half of 2006. The purpose of the study is to evaluate the extent of opiate blockade following a morphine challenge. While we are currently developing VP004 for the treatment of opioid addiction, we may decide in the future to pursue an indication for the treatment of alcoholism as well. We plan to license the rights to use VP004 to an addiction specialty firm prior to conducting Phase III clinical trials.

***VP005 (Anti-inflammatory)***

VP005 is a proprietary polymer solution instillation for the treatment of symptoms associated with interstitial cystitis, a chronic inflammatory condition of the bladder. Interstitial cystitis, or IC, affects approximately one million people in the U.S. IC is characterized by frequent urination and pain above the

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pubic region. The cause of IC is unknown but is believed to involve inflammation of the lining of the bladder.

We believe that IC is a disease that has been poorly served by the pharmaceutical industry. Elmiron is the only product currently approved for the relief of bladder pain or discomfort associated with IC. Elmiron is marketed by Bayer HealthCare LLC and is an oral formulation containing 100 milligrams of pentosan polysulfate sodium, a semi-synthetic molecule that is taken three times a day. According to IMS Health market data, sales of Elmiron generated revenues in excess of $100 million in the U.S. in 2004. Our discussions with urologists indicate that Elmiron is only occasionally effective and that many patients require instillation therapy, a more invasive form of treatment utilizing a catheter to fill up the bladder with various solutions. Instillation therapy has been shown to abate the symptoms of IC in some patients. VP005 is an instillation therapy that forms a temporary coating on the internal lining of the bladder and facilitates the slow, controlled release of the drug in VP005 into the bladder. We intend to license the drug delivery technology used in VP005 and intend to apply for patent protection for this application of that technology.

VP005 has been successful in animal models in treating what we believe to be the major contributing factor in producing the painful symptoms of IC. We have drafted a Phase I/II protocol to evaluate VP005 in humans. In March 2005, we met with a panel of IC experts from the U.S. to help refine the protocol. We expect to file an investigational new drug application with the FDA and initiate a Phase I/II clinical trial in the second half of 2006.

***VP006 (rapid dissolve desmopressin)***

VP006 is a proprietary modified release oral formulation of desmopressin for the treatment of nocturnal enuresis, commonly referred to as bed-wetting. Nocturnal enuresis affects approximately five to seven million children in the U.S.

We believe that nocturnal enuresis has been poorly served by the pharmaceutical industry. DDAVP, Tofranil and several generics are the products currently approved for the management of nocturnal enuresis. The most common pharmaceutical treatment is DDAVP, which is manufactured and marketed by Sanofi-Aventis.

According to IMS, sales of DDAVP for 2004 were approximately $220 million. It is available as an oral tablet or a nasal spray containing 0.1-0.2 milligrams of desmopressin acetate, an antidiuretic hormone affecting renal water conservation. We believe that the rapidly dissolving formulation of desmopressin would be preferred by children and their parents because young children can have difficulty swallowing solid tablets.

VP006 is currently in Phase I clinical trials. Depending on the results of these studies and the regulatory pathway, we anticipate entering further clinical trials in the first half of 2006, followed by a regulatory filing in the second half of 2006.

***Valrubicin***

We have entered into an agreement to acquire certain assets from Anthra Pharmaceuticals, Inc. associated with Anthra s valrubicin business in the U.S. and Canada. The valrubicin product, formerly marketed in the U.S. under the trademark Valstar, is a bladder instillation approved to treat bladder cancer that is no longer responsive to conventional treatment such as surgery and/or topical drug application. This product was previously administered and billed as an office procedure, and predominantly covered under Medicare reimbursement. We believe that it will continue to be administered and billed as an office procedure and that the Medicare reimbursement per course of treatment will be approximately $8,500. The product is not covered by any patents and its orphan drug status has expired. If the transaction closes as planned, we will make: (i) installment payments totaling $600,000; (ii) additional payments of up to 13.5% of net sales depending upon the product s formulation, indication and market share; and (iii) certain milestone payments based upon achieving certain sales levels.

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According to the National Institutes of Health data, bladder cancer has an incidence of 499,000 patients in the U.S. Market research conducted by Verispan on our behalf and performed at the May 2002 American Urology Association meeting found that approximately 31% of bladder cancer patients are treated with BCG (Bacillus Calmette-Guerin), the most common form of topical treatment. The research further shows that about 17% of the BCG patients become unresponsive, or refractory, to treatment each year and must now either have a cystectomy, the medical term for bladder removal, or stand the chance of disease progression. Urologists surveyed in the study further stated that 69% of these refractory patients go on to have their bladder removed, resulting in a patient population of approximately 8,200 with this type of cancer who could be candidates for valrubicin.

Anthra s product was withdrawn from the market in 2002 due to a manufacturing problem and a lack of resources to address the problem. We believe that we have identified the cause of the manufacturing problem and that we will be able to correct it. We initiated discussions with the FDA in the fourth quarter of 2005 regarding our plan to reintroduce the product in the U.S. market, and in January 2006, the FDA agreed to our plan. Our acquisition of the product and related assets is expected to close during the first quarter of 2006, subject to various conditions. Subject to closing occurring in the first quarter of 2006 and our successful implementation of the reintroduction plan, we anticipate being able to re-launch the product in the U.S. in the fourth quarter of 2006. We expect to address reintroduction of the product in Canada following reintroduction in the U.S. and expect distribution to be handled by Paladin Labs, the existing Canadian distributor.

***Research and Development Expenditures***

Research and development expense for the years ended December 31, 2005, 2004 and 2003 was $5.9 million, $6.4 million and $5.2 million, respectively.

**Our Drug Delivery System**

Human implantable drug delivery is a relatively new therapeutic drug delivery approach in which drugs are administered directly into the circulatory system through a biocompatible, non-toxic device. We believe this type of drug delivery is suitable for certain drugs that are not amenable to oral delivery, such as therapeutic peptides that are destroyed in the gastrointestinal tract, or GI tract, or drugs poorly absorbed by the GI tract or destroyed in the liver. In such cases, increasing the dosage of these drugs to increase absorption may result in harmful side effects. As a result, we believe that implantable drug delivery systems may provide safer and more effective administration of therapy by delivering the drug directly to the bloodstream at even, controlled rates.

Hydron Technology, our proprietary drug delivery technology, is the basis of our patented hydrogel implant, which is inserted under a patient s skin. This technology, which evolved from similar technology used in soft contact lenses, is flexible and can be adapted to deliver many types of drugs. Currently, we only have FDA approval for Vantas. We will need to obtain approval for each product we develop, including products using Hydron Technology. Our implant is designed to allow release of drugs continuously, at even, controlled rates for up to a 12-month period. We believe that such predictable release over a period of 12 months has not been achieved by most other drug delivery systems, including sustained release injections, bioerodible implants and transdermal devices. In addition, implants utilizing Hydron Technology are smaller, softer and more flexible than other implants and eliminate the requirement of multiple physician visits and repeated injections.

Utilizing Hydron Technology, we are able to manufacture implants to the exact chemical and physical specifications required by the particular drugs to be released. By modifying the geometric characteristics (wall thickness, diameter and length) and the polymer make-up of the implants, we can vary the release rates of a broad spectrum of drugs according to the therapeutic levels required for a particular indication. Once filled with an active ingredient, sealed and sterilized, the implant is inserted into a patient in a minor outpatient procedure generally performed in a physician s office. The procedure to insert the implant takes approximately 7 to 10 minutes. First, the insertion site is swabbed with an antiseptic. Next, the physician

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injects an anesthetic immediately under the skin in the upper arm along the path where the implant is to be inserted. Then the physician makes a small incision and inserts the implant using an insertion tool. The tool is then retracted, leaving the implant under the skin. The incision is then closed with adhesive tape and a bandage is applied for one day. Lastly, the patient is given home care instructions and sent home. If necessary, the physician can easily remove the implant from the body in a similar procedure.

We believe that advantages of our Hydron Technology include:

*Increased Patient Compliance.* Hydron Technology releases drugs for up to a 12-month period. As a result, the need for multiple physician visits and the inconvenience associated with frequent injections are eliminated, reducing the risk that a patient will miss a treatment.

*Adaptability.* Hydron Technology can be adapted to deliver many types of drugs. In addition, it provides a controlled and even drug release over a period of time that can result in increased efficacy and safety. Currently, we only have FDA approval for Vantas. We will need to obtain approval for each additional product we develop including products using our Hydron Technology.

*Decreased Cost.* As a result of the reduced number of patient visits to doctors offices, the overall costs associated with such visits, including scheduling, office visit and reimbursement claim costs, are significantly lowered. In addition, use of Hydron Technology lessens the administrative burden on private insurance and Medicare by reducing the number of reimbursement claims processed per year.

Finally, since Vantas is based on Hydron Technology, we believe that the regulatory approval of Vantas may be helpful in obtaining approval of our product candidates that utilize this technology.

Hydron Technology is limited by the amount of drug which can be loaded into an implant due to its small size, the inability of the technology to deliver drugs that are water insoluble, the inability to deliver molecules with a large molecular weight and the need for a minor surgical procedure to insert and remove the implant.

**Our Business Strategy**

In addition to increasing sales of our approved product, Vantas, our goal is to develop, acquire and commercialize products for the treatment of urological and endocrine conditions, diseases and disorders. To achieve this goal, our strategy includes the following key elements:

*Continue to Focus on Urological and Endocrine Conditions, Diseases and Disorders.* We intend to continue to focus on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders. Our aim is to build our urological and endocrine product portfolio and opportunistically acquire or in-license later-stage urological and endocrine products that are currently on the market or require minimal development expenditures, or have some patent protection or potential for market exclusivity or product differentiation. We intend to collaborate with major and specialty pharmaceutical companies to develop and commercialize products that are outside of our core urology and endocrinology focus.

*Develop Proprietary Pharmaceutical Portfolio.* We are building a product portfolio based on Hydron Technology. We have demonstrated the utility of Hydron Technology through Vantas, and we believe that we can utilize this technology to bring additional products to market. We intend to apply Hydron Technology to the delivery of drugs with established safety and efficacy profiles to reduce product development risk and speed time to market.

*Develop or Acquire New Drug Delivery Technologies.* In addition to our Hydron Technology, we intend to continue to evaluate other drug delivery technologies as candidates for in-license, acquisition and development, including various implantable technologies and other drug delivery systems. We believe that, by devoting our resources to continued development of new drug delivery technologies, we can develop a broader base that will enable us to deliver a greater variety of drugs than would be possible using a single drug delivery technology.

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*Leverage Sales and Marketing Expertise.* We will continue to expand our commercialization efforts by leveraging our existing sales and marketing expertise to market new products as they are approved. We intend to expand our commercial organization, which consisted of approximately 41 employees as of January 1, 2006, incrementally in a cost-effective manner and expand or realign territories as products emerge from our development pipeline or are acquired.

*Partner Outside the U.S. to Reach New Geographic Markets.* To reach markets outside the U.S., we are pursuing primarily a licensing strategy, whereby we partner with companies with a local presence and proven distribution channels in the urology and endocrinology markets for distribution of our products. We may retain full or co-marketing rights, however, on a select territory-by-territory basis to further leverage our sales and marketing expertise.

**Sales, Marketing and Distribution**

As of January 1, 2006, our commercial organization consisted of approximately 41 employees, and we expect to hire approximately ten additional employees in this area. As of January 1, 2006, we had 31 product specialists. Our product specialists have an average of seven years of pharmaceutical sales experience and the majority of our sales force have sold other LHRH agonist products prior to joining us. Each product specialist is responsible for marketing Vantas to physicians in an assigned geographic territory. At present, we are calling on the urologists that account for the majority of LHRH agonist products in the U.S. As revenue increases and resources become available, we intend to scale up our sales force to market new products which emerge from our pipeline. We continue to analyze physician prescribing habits so that we can direct our product specialists to physicians who maintain the largest prostate cancer practices. We will also evaluate the need to hire additional product specialists as we get closer to acquiring a new product or launching Supprelin-LA, our histrelin implant for CPP. By adjusting our current sales force structure slightly, we will be able to call on our current physician base and on physicians in additional specialty areas, such as endocrinology. Further, we believe that the direct physician distribution channel of Vantas may present a barrier to the future entry of competition from generic products because generic drug companies do not typically have a field sales force.

Our product specialists utilize various promotional materials when making clinical presentations, including, instructional videos on proper implantation technique. In remote areas where our product specialists cannot productively make personal visits, we conduct direct mail programs. We also supply physicians, health plan administrators and specialty pharmacies with a pharmaco-economic model to demonstrate the cost effectiveness of Vantas compared to other LHRH agonist products due to decreased utilization of staff time for repeated injections and one reimbursement claim per patient per year as opposed to three or four.

Additionally, we support our sales efforts by employing a wide range of marketing programs to promote Vantas, including journal advertising, industry publications, medical educational conferences and internet initiatives. We hold meetings in major cities where a Vantas clinical investigator presents data about Vantas, relates his own impressions and demonstrates proper implantation technique. In addition, our product specialists utilize local thought leaders as peer influence speakers in their specific markets.

As part of our marketing strategy, we entered into two group purchasing agreements with International Urology Networks, LLC, or IUN, a subsidiary of AmerisourceBergen Corporation. IUN was founded in 2001 as a group purchasing organization for over 40% of practicing urologists in the U.S. This network designs and supports practice management, business planning and accredited continuing medical education for all of its members. Our agreements with IUN provided for access to their physician members, support from their strategic account managers and services from two other AmerisourceBergen subsidiaries: US Bioservices Corporation, a specialty pharmacy, and Besse Medical, a wholesale distributor for many GPOs, including IUN. Under the agreements, physician practices and clients who are members of IUN or US Bioservices were eligible to purchase Vantas from Besse Medical. In addition, US Bioservices could dispense Vantas purchased under the agreements to patients of member physicians upon request by healthcare providers, patients, or third party payors, as well as provide drug management and

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patient care support services. Our agreements with IUN and Besse expired on November 30, 2005. However, we have extended the term of the distribution services of Besse Medical and are currently discussing potential new arrangements with IUN.

Outside the U.S., we are primarily pursuing a licensing strategy, whereby we partner with companies with a local presence and proven distribution channels in the urology or other market for distribution of Vantas or other products we may offer. We may retain co-marketing rights, however, on a select territory-by-territory, basis. For example, we have executed an agreement with Paladin Labs, Inc., a Canadian company, under which it will distribute Vantas and file all required regulatory applications in Canada, and have signed similar agreements with each of Key Oncologics (Pty) Ltd., a South African company, BioPro Pharmaceutical, Inc., an organization specializing in marketing oncology drugs in the pan Asian region, and Teva-Tuteur, an organization specializing in marketing oncology drugs in Argentina. We are actively seeking relationships or distribution arrangements with additional GPOs, specialty pharmacies and local companies abroad.

**Reimbursement**

Advanced prostate cancer is generally treated by urologists in their offices. LHRH agonist products are sold directly from the pharmaceutical manufacturer to the physician and are administered in the office through injections or a 12-month implant. Once a physician acquires and administers the LHRH agonist product, he files a claim with Medicare or the patient s private insurance for reimbursement.

Approximately 70% of patients diagnosed with prostate cancer and receiving LHRH agonist therapy are over the age of 65 and therefore covered by Medicare. In light of this, we have retained a group of Medicare experts to monitor pricing of LHRH agonist products and the Medicare reimbursement environment.

Medicare reimbursement for LHRH agonist therapy is comprised of two parts. The first part of the reimbursement is based on reimbursement for the LHRH agonist product. In some states, the reimbursement rate is based on the manufacturers average sales price, or ASP. This ASP method was introduced in 2005 for all products covered by Medicare. Under the ASP method, each LHRH agonist product manufacturer must calculate a quarterly average unit sales price for its product and report it to the Centers for Medicare and Medicaid Services, or CMS. CMS will then post the ASP for that product on its web page for the physicians to reference. A physician will be reimbursed by Medicare at 106% of the ASP for that product. In most states, however, the reimbursement rates for Vantas are even lower because the Medicare carriers in those states now apply the Least Costly Alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent . The reimbursement rate for Vantas, as determined by the Medicare carriers, is lower in LCA states than the reimbursement rate in non-LCA states, resulting in a lower sales price in LCA states.

The second part of the reimbursement is derived from the actual procedure the physician completes to administer the LHRH agonist product. A physician can expect to receive approximately $125 for an implant procedure, such as implanting Vantas, as compared to approximately $28 per injection procedure. In fact, a physician can expect to receive approximately $240 when explanting a Vantas implant and implanting a new Vantas implant.

Reimbursement is often confusing and requires exacting procedures in order to be honored by Medicare or private insurance carriers. As a result, we have set up a toll-free phone number for physicians to call for help in resolving any billing issues concerning reimbursement for Vantas. In addition, effective January 1, 2006, Vantas has an assigned J-code from CMS which will further facilitate the physician s reimbursement by Medicare.

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**Intellectual Property**

Our success will depend in large part on our ability to maintain a proprietary position in our products and product candidates through patents, trade secrets and FDA exclusivity. We rely upon patents, trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We plan to aggressively protect and defend our proprietary position.

As of December 2005, we own three issued U.S. patents and 24 issued foreign patents relating to our Hydron Technology. We own three pending foreign patent applications relating to our Hydron Technology. Our patents and patent applications cover a variety of novel pharmaceutical formulations, methods of use, and processes to manufacture hydrogel polymers and implants incorporating active agents. Within the Hydron Technology patent portfolio, we own two issued U.S. patents and 23 issued foreign patents relating to Vantas.

The following table sets forth information related to U.S. and foreign patents and patent applications owned by us:

| Technology Family | Brief Description of Coverage | No. of Patents | No. of Pending Applications | Date of Grant/ Expiration |
|---|---|---|---|---|
| Water-Swellable Hydrophilic Articles | Method of preparing a hydrophilic plastic cartridge | 15 | 0 | 1994/2011 |
| Homogenous Hydrogel Copolymers | Method of preparing homogeneous copolymers having a predetermined equilibrium water content value | 10 | 0 | 1993/2010 |
| Hydrogel Composition | Method of preparing homogenous porous hydrogel | 2 | 3 | 2002/2020 |
| Implanting Device | Device for inserting implantable objects under the skin | 0 | 16 | Not Applicable/ 2023 |
| Implanting Device Design | Design for an implanting device | 4 | 1 | 2004/2017 |
| Compositions and Treatments for Central Precocious Puberty | Controlled delivery of gonadotropin-release hormone agonists for the treatment of central precocious puberty | 0 | 2 | Not Applicable/ 2025 |
| Polyurethane Implant Formulations | Polyurethane implant formulations and methods of preparing | 0 | 3 | Not Applicable/ 2024 |
| Total | | 31 | 25 | |

We have filed a U.S. and a foreign patent application covering pharmaceutical formulations, processes and methods of use relating to Supprelin-LA. In addition, as of December 2005, we also own four other issued patents and

have approximately 18 other patent applications pending worldwide relating to other areas, including implanting devices and designs thereof.

Our commercial success will depend in part on obtaining this patent protection. Other intellectual property and know-how, including the Hydron Technology, that we have produced and own, are safeguarded through copyrights, trademarks, trade secret protections and contractual safeguards such as confidentiality and proprietary information agreements. The development of our technology and many of our processes are dependent upon the knowledge, experience and skills of key scientific and technical personnel. To protect our rights to this proprietary information and technology, which are not patentable,

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we require all employees, consultants and advisors to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside our company. As a matter of company policy, all scientific employees are hired to invent and all have executed agreements that recognize this policy and generally require disclosure and assignment to us of ideas, developments, discoveries and inventions made by employees. However, these agreements may not effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information if there is unauthorized use or disclosure.

**Material Agreements**

We are a party to certain material agreements including:

***GP Strategies Corporation***

In June 2000, we entered into a contribution agreement with GP Strategies Corporation, our former parent. Under this contribution agreement, GP Strategies contributed, assigned, transferred and conveyed to us the assets of GP Strategies drug delivery business, including all intellectual property and certain agreements with Hydron Technologies, Inc., formerly known as Dento-Med Industries, Inc., The Population Council, Inc., and Shire US, Inc., successor to Roberts Laboratories Inc.

We assumed all assets, liabilities and obligations of GP Strategies relating or arising from the operation of the drug delivery business and the assets.

***Hydron Technologies, Inc.***

In November 1989, National Patent Development Corporation entered into an agreement with Dento-Med Industries, Inc., now known as Hydron Technologies. Under the contribution agreement in June 2000 between us and GP Strategies, GP Strategies transferred its rights and obligations under the agreement with Hydron Technologies to us.

Under the agreement, Hydron Technologies was granted an exclusive, worldwide license, with the right to grant sublicenses, in and to presently owned or subsequently issued patents and the Hydron trademark, to manufacture, market or use products composed of the Hydron polymer or produced with the use of the Hydron polymer in certain consumer and oral health fields, excluding prescription and non-prescription drugs. The agreement purports to continue indefinitely, unless terminated earlier by the parties. We have the exclusive right to manufacture, sell or distribute any prescription drug or medical device as defined under the Federal Food, Drug and Cosmetic Act made with the Hydron polymer, however, we will not have the right to sell or distribute any Hydron polymer product in the oral health field, except for prescription drug products for lip sores and oral ulcers. We also have the exclusive right to manufacture, sell or distribute certain other excepted Hydron products from Hydron Technologies license. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the Hydron polymer, subject to certain exceptions, for limited exclusivity periods.

In the event we withdraw from the business of manufacturing the Hydron polymer, we shall assign all of our right and interest in the Hydron trademark to Hydron Technologies. Upon request from Hydron Technologies, we may provide certain research services, including limited use of our facilities, for Hydron Technologies research activities, for which we will be reimbursed a specified amount. In addition, subject to certain conditions and exceptions, Hydron Technologies has the right to purchase from us and we are obligated to supply to Hydron Technologies certain types of Hydron polymers.

Subject to certain exceptions (including Vantas), each party will pay to the other a 5% royalty on net sales for Hydron polymer products marketed by us or Hydron Technology, as applicable, or a third party. Subject to certain excepted Hydron polymer products, in the event either party sells any non-prescription Hydron polymer drug products itself, such party will pay a 5% royalty fee on net sales, including research payments, to the other party. Subject to certain Hydron polymer excepted products, if either party sells

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non-prescription drug products to a third party and receives up-front license fees, royalties or similar payments, such party will pay a 25% royalty on such payments to the other.

***The Population Council***

In September 1990, National Patent Development Corporation entered into a joint development agreement with The Population Council regarding the development of hydrogel implants containing LHRH. Under the contribution agreement entered into in June 2000 between us and GP Strategies, GP Strategies transferred its rights and obligations under the agreement with The Population Council to us.

By amendment to the agreement dated October 1, 1997, the Joint Development Agreement was terminated in its entirety and superseded by the terms and conditions of the amendment. Under the amendment, The Population Council concluded all ongoing prostate cancer clinical studies and provided us with all data and records relating to those trials to enable us to advance the clinical trials and seek regulatory approval to commercially develop and market any polymer implant containing any LHRH analog or any polymer implant containing any other active agent, other than an LHRH analog. We can enter into licensing and marketing agreements for the commercial development of those implants without the consent of The Population Council. The term of the agreement is the shorter of twenty-five years from the date of the amendment or until the date on which The Population Council receives approximately $40 million in payments from us. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings or if, after receiving written notice the other party is in default of a material term and such default has not been cured within thirty days of the notice.

By a further amendment to the agreement dated August 2004, The Population Council is entitled to 30% of certain revenues received by us from the licensing of Vantas or any other polymer implant containing an LHRH analog and 5% of certain revenues received by us from the licensing of any other polymer implant to the extent those revenues are related to the use or sale of implants in all areas other than the European Union and certain Southeast Asian countries. We are required to pay to The Population Council 3% of our net sales of Vantas and any polymer implant containing an LHRH analog and 0.5% of our net sales of any other polymer implant. The Population Council is also entitled to 4% of any licensee s net sales of Vantas and any other polymer implant containing an LHRH analog within the European Union and certain Southeast Asian countries and 0.667% of any licensee s net sales for any other polymer implant within the European Union and certain Southeast Asian countries. In addition, we are required to establish a patient assistance program within one year after the first commercial sale of Vantas in the U.S. and maintain the program for a period ending on the earlier of ten years after establishment of the program or the cessation of the marketing of Vantas.

***Shire Pharmaceuticals Group plc***

In March 1998, GP Strategies entered into a license agreement and a related manufacturing and supply agreement with Roberts Laboratories Inc. under which Roberts was responsible for conducting Phase III clinical trials, managing the regulatory approval process and marketing the product now known as Vantas. When Roberts was acquired by Shire Pharmaceuticals Group in December 1999, Shire took over the development of Vantas. In December 2001, we entered into a termination, license back and option agreement with Shire US, a subsidiary of Shire Pharmaceuticals Group, which terminated and released all claims of the parties under the previous license and manufacturing agreements. Under this agreement, Shire transferred to us all on-going activities under the development program for Vantas, including all data, know-how and other information with respect to Vantas generated in connection with the development program, and granted us an exclusive license to such data, know-how and information for the development, manufacture, use, supply and sale of Vantas in the designated territory, including, but not limited to, the U.S., Canada, and various European and other countries.

The term of the license continues for ten years from the date of the first commercial sale of Vantas. Thereafter, we will have a fully paid up license in the designated territory with respect to all data, know-

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how and other information related to Vantas generated under Shire s previous development program for Vantas.

We are required to pay Shire 2% of net sales of Vantas in the designated territory. However, for the purposes of this agreement, net sales are reduced by the amount of any royalty payments we make to The Population Council with respect to sales of Vantas. If we sublicense Vantas to another entity in the designated territory, we will pay Shire fees of 20% of royalty income and 20% of any milestone payments we receive, up to a maximum of $5 million, relating to any sublicensing of Vantas. Royalty income does not include amounts paid to The Population Council with respect to sales of Vantas by a sublicensee. However, the $5 million cap on our royalties payments with respect to milestone payments is only applicable if we are entitled to receive at least 10% of net sales under the sublicense agreement.

We also granted Shire an exclusive, irrevocable option, on a country-by-country basis in the designated territory, to exclusively market and distribute Vantas in each country of the designated territory, other than in the U.S. This option, with respect to each country, will expire on the earlier of the date we enter into a sublicense agreement for that particular country or 180 days following the date of regulatory approval in that particular country for Vantas. We may market Vantas in any country at the expiration of the option with respect to that country. Upon exercise of the option, with respect to a particular county, Shire is obligated to pay us milestone payments of $0.2 million in respect of the European Union and $500,000 in respect of any other countries within the designated territory. This amount will be reduced by $250,000 if we enter into a sublicense agreement within the European Union. These milestone payments are payable with respect to a particular country when Vantas is approved for marketing in the applicable country. If Shire exercises the option with respect to a particular country, we will supply Vantas at the cost of manufacture. Shire will pay us 13.5% of its net sales within the option territory. Each marketing and distribution arrangement requested by Shire under its option will have a term of 10 years. Either party may terminate if either party becomes insolvent or there is a material breach of the agreement.

***Paladin Labs, Inc.***

In October 2002, we entered into a license and distribution agreement with Paladin Labs under which we granted Paladin Labs an exclusive, royalty bearing license under our intellectual property, including our patents, trademarks and know-how, to seek regulatory approval for the marketing, distribution and sale in Canada and its territories of (i) Vantas for the treatment of prostate cancer and (ii) any other Hydron histrelin implant, which is, or may be, developed by us for other indications, such as our histrelin implant for CPP. Paladin Labs is obligated to use commercially reasonable efforts to apply for and maintain regulatory approval for Vantas and any other Hydron histrelin implant and to sell, market and distribute those implants in Canada and its territories. The initial term of the agreement is for fifteen years from March 2006 the date on which regulatory approval for Vantas in Canada was obtained for the treatment of advanced prostate cancer and will automatically renew for subsequent three year terms, unless terminated earlier. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings, or if, after receiving written notice the other party commits a material breach that has not been cured within thirty days of the notice or the other party is unable to fully perform its obligations as a result of a force majeure event. We also granted Paladin Labs an exclusive license to use the trademarks owned by us, including all trademarks and trade names approved by us, in connection with the marketing, distribution and sale of Vantas or any other Hydron histrelin implant in the designated territory. We have given Paladin Labs the exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas for the treatment of prostate cancer in the designated territory. If Paladin Labs does not conduct such trials within one year of our request to do so, we will have the right to conduct such Phase IV clinical trials on our own.

We have the sole right and responsibility for the manufacturing, assembling, packaging and labeling of Vantas or any other Hydron histrelin implant in such quantities required for Paladin Labs demand forecast and we must use all reasonable efforts to supply those products. In addition, Paladin granted us a non-exclusive license to use its trademarks on labeling of Vantas or any other Hydron histrelin implant. We have agreed not to supply Vantas or any other Hydron histrelin implant for distribution or sale in

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Canada and its territories for use in any indication to any other party except Paladin Labs. Paladin Labs will pay us a flat transfer fee of $190 per unit and a royalty of 8% of its net sales of Vantas or any other Hydron histrelin implant.

We are obligated to use commercially reasonable efforts to complete all necessary pre-clinical and clinical trials that are required by the Therapeutic Products Directorate of Health Canada, Canada s federal regulatory authority for pharmaceutical drugs, for use of Vantas in the treatment of prostate cancer in Canada. However, we are not required to undertake any pre-clinical or clinical trials beyond those activities conducted in the U.S. and Canada.

Under the terms of the agreement, we and Paladin have agreed not to develop, market, distribute or sell in Canada or its territories any products that contain the same active ingredient as that which is contained in Vantas, or any products similar to or competitive with Vantas or any other Hydron histrelin implant approved in Canada during the term of the agreement and for a period of three years following the expiration or termination of the agreement; provided that we are permitted to make, market, distribute and sell Vantas in the designated territory for all indications following the expiration or termination of the agreement.

***Key Oncologics (Pty) Ltd.***

In September 2003, we entered into a license and distribution agreement with Key Oncologics, under which we appointed Key Oncologics as the exclusive agent to apply for regulatory approval for and distribute Vantas in South Africa and its territories for use in the treatment of prostate cancer. The initial term of the agreement is for five years after the date on which regulatory approval for Vantas for the treatment of prostate cancer is obtained in South Africa, subject to automatic one-year renewal periods unless terminated earlier. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings, or if, after receiving written notice, the other party commits a material breach that has not been cured within thirty days of the notice or the other party is unable to fully perform its obligations as a result of a force majeure event. Key Oncologics may terminate the agreement if regulatory approval of Vantas for the treatment of prostate cancer is finally denied by South Africa s regulatory authority. Terminations with respect to one or more, but not all forms or dosages, will only apply to the affected forms or dosages. Key Oncologics is obligated to use commercially reasonable efforts to apply for and maintain regulatory approval in South Africa for Vantas for use in the treatment of prostate cancer. Key Oncologics is required to use its best efforts to market, distribute and sell Vantas in South Africa.

We have agreed to supply Vantas, as well as containers for and components of Vantas, to Key Oncologics exclusively in South Africa. We are obligated to supply Key Oncologics with all data and information in our possession or control as is necessary for the purpose of obtaining regulatory approval of Vantas for use in the treatment of prostate cancer in South Africa. We have given Key Oncologics the exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas for the treatment of prostate cancer in the designated territory. If Key Oncologics does not conduct such trials within one year of our request to do so, we will have the right to conduct such Phase IV clinical trials on our own. We will receive a perpetual, fully-paid, royalty-free license to use any data developed by Key Oncologics in the Phase IV trials.

Under the terms of the agreement, Key Oncologics has agreed not to develop, market, distribute or sell in South Africa any products that contain the same active ingredient contained in Vantas, or any products similar to or competitive with Vantas that are used to treat prostate cancer during the term of the agreement and for a period of three years following the expiration or termination of the agreement, except that Key Oncologics may market, distribute and sell a certain product under a previous third party license agreement.

We have granted Key Oncologics an exclusive license to use our trademarks owned by us, including all trademarks and trade names approved by us, in connection with the marketing, distribution and sale of Vantas in South Africa in connection with the treatment of prostate cancer. Key Oncologics has granted

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us a non-exclusive license to use Key Oncologics trademarks on labeling of Vantas. We have the sole right and responsibility for manufacturing, assembling, packaging and labeling Vantas and we are required to supply Vantas in sufficient quantities to meet Key Oncologics demand forecast. We have agreed not to supply Vantas for distribution or sale in any of the designated countries for use in the treatment of prostate cancer to any other party except Key Oncologics. For a period of twelve months following the receipt of regulatory approval, Key Oncologics will pay us a flat transfer fee of $250 per unit of Vantas, plus 10% of the net sales collected by Key Oncologics. After the end of the first twelve-month period, we will have the right to adjust the price per unit once per year, subject to certain exceptions.

***International Urology Network***

To supplement our own marketing and distribution efforts, we entered into two group purchasing agreements in November 2004 with the group purchasing organization, IUN. These agreements made Vantas available for purchase to IUN members with respect to facilities located in the U.S. The agreements were amended in March and July of 2005 and expired on November 30, 2005. We are currently discussing potential new arrangements with IUN.

Under the agreements, physician practices and clients who are members of IUN or US Bioservices, Inc. a specialty pharmacy, were eligible to purchase Vantas from Besse Medical, IUN s wholesale distributor. In addition, US Bioservices could dispense Vantas purchased under the agreements to patients of member physicians upon request by healthcare providers, patients, or third party payors, as well as provide drug management and patient care support services.

***Besse Medical***

In connection with the amended IUN agreements described above, we entered into a separate letter agreement with Besse Medical in March 2005, with respect to Besse Medical s distribution of Vantas. Under this agreement, we designated Besse Medical as an authorized specialty distributor of Vantas to those purchasers eligible to buy Vantas under the IUN agreements. Besse Medical was responsible for services customarily provided by a wholesale distributor under the agreement, including the stocking, packing and shipment of our products, and was paid a distribution services fee based on the purchases of Vantas through Besse Medical. The agreement with Besse Medical expired on November 30, 2005, together with the amended IUN agreements. Since November 30, 2005, and notwithstanding the termination of the written agreement with Besse Medical, we have continued to use the distribution services of Besse Medical and expect to continue use of such services through March 2006. We are currently considering both the need for, as well as our options with respect to, wholesale distribution of Vantas for the period after March 2006.

***BioPro Pharmaceutical, Inc.***

In January 2005, we entered into an exclusive license and distribution agreement with BioPro. The initial term of the agreement is for ten years after the date on which the first regulatory approval allowing sales of Vantas to proceed in any country of the designated territory is issued, unless terminated earlier and automatically renews for additional periods of one year unless notice of termination is given. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings, or if, after receiving written notice, the other party commits a material breach that has not been cured within thirty days of the notice or the other party is unable to fully perform its obligations as a result of a force majeure event. Either party may terminate the agreement on a country-by-country basis if regulatory approval of Vantas for the treatment of prostate cancer is finally denied by the regulatory authority within that country. Terminations with respect to one or more, but not all, forms, dosages, countries or indications will apply to the affected forms, dosages, countries or indications. Additionally, we may terminate the agreement if BioPro fails to achieve minimum net sales and then fails to make minimum required payments to us, or we may terminate the agreement on a country-by-country basis and on an indications-by-indications basis if BioPro fails to file necessary marketing approval applications.

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Under the agreement, BioPro will be the exclusive distributor of Vantas in the designated territory consisting of Brunei, Cambodia, China (including Hong Kong), Laos, India, Indonesia, Malaysia, the Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam. BioPro is required to use commercially reasonable efforts to apply for and maintain regulatory approval for Vantas for the treatment of prostate cancer in the designated territory. In connection with obtaining regulatory approval for Vantas, we are required to supply BioPro with all data and information in our possession or control as is necessary for that purpose. We also granted BioPro an exclusive license to use the trademarks owned by us, including all trademarks and trade names approved by us, in connection with the marketing, distribution and sale of Vantas in the designated territory. We have given BioPro the non-exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas for the palliative treatment of prostate cancer in each country of the designated territory. BioPro has applied for regulatory approval for the commercialization of Vantas in Thailand, Singapore, Malaysia, and Taiwan.

BioPro granted us the right to use BioPro s trademarks on labeling of Vantas. We have the sole right and responsibility to manufacture, assemble, package and label Vantas and are required to supply Vantas in quantities sufficient to meet BioPro s demand forecast. We have agreed not to supply Vantas for distribution or sale in any of the countries in the designated territory for use in any indication to any other party except BioPro. BioPro shall pay us a flat transfer fee of $250 per unit and a royalty of 25% of net sales of Vantas, in addition to various milestone payments. BioPro must pay us a minimum amount if it fails to achieve certain minimum net sales. In addition, BioPro is obligated to pay a royalty of 2% of net sales of Vantas directly to The Population Council or a minimum payment if certain minimum net sales are not achieved. Twelve months following the first commercial sales of Vantas in the designated territory, we will have the right, subject to certain exceptions, to adjust the price per unit once per year.

Affiliates of Sanders Morris Harris, Inc., of which James Gale, the Chairman of our Board of Directors, is a managing director, own approximately 40% of BioPro. Affiliates of Sanders Morris Harris, Inc. own approximately 37% of our Company.

***Alpex Pharma S.A.***

In April 2005, we entered into a collaboration and development agreement with Alpex Pharma to research and develop a rapid dissolve desmopressin product. Under the agreement, we have an exclusive, royalty-bearing license, based in part on Alpex s intellectual property, including the right to sublicense, to make, use, sell, and otherwise commercialize the rapid dissolve desmopressin product in the United States, Canada, and Mexico. The agreement continues in effect until the expiration of all Alpex patents related to Alpex s platform technology that cover the rapid dissolve desmopressin product. Upon expiration of all Alpex patents related to Alpex s platform technology that cover the rapid dissolve desmopressin product, we will have a fully paid-up, royalty-free, non-exclusive, irrevocable license, including the right to sublicense, to make, use, sell, and otherwise commercialize the product in the United States, Canada and Mexico.

Under the agreement, Alpex is obligated to use commercially reasonable efforts to diligently perform its obligations under the agreement, including developing the rapid dissolve desmopressin product. We are obligated to use commercially reasonable efforts to perform our obligations under the agreement, including to obtain and maintain all regulatory approval for the rapid dissolve desmopressin product in the United States, Canada, and Mexico. If we do not file for regulatory approval in the United States within six months after satisfaction of certain product success criteria, as agreed upon by us and Alpex, Alpex may elect to transform our license into a non-exclusive, royalty-free license. Alpex is required to make all intellectual property and technical information available to us as may reasonably be necessary for regulatory approval. Alpex owns all intellectual property related to the platform technology, and will own any intellectual property developed pursuant to the collaboration that relates to the platform technology. We will own all intellectual property related to the rapid dissolve desmopressin product in the United States, Canada and Mexico. Alpex will own all intellectual property related to the rapid dissolve desmopressin product outside of the United States, Canada and Mexico.

We are obligated to use our commercially reasonable efforts to market, distribute and sell the rapid dissolve desmopressin product in the United States, Canada and Mexico. Alpex has agreed not to, directly

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or indirectly develop, market, distribute or sell a product that contains desmopressin in the United States, Canada or Mexico. Alpex shall manufacture and supply sufficient quantities of the rapid dissolve desmopressin product for clinical trials and commercial sale to meet our needs. Both parties must use best efforts to enter into such a manufacturing and supply agreement prior to the first commercial shipment of the rapid dissolve desmopressin product.

We may terminate the agreement and obligations of the parties if we determine, in our sole discretion, that the development and/or commercialization of the rapid dissolve desmopressin product has been impaired due to (i) difficulties in development or formulation; (ii) unfavorable action by the FDA; (iii) likelihood of failure to obtain regulatory approval; (iv) concerns of possible third party infringement; and (v) unfavorable market conditions for the rapid dissolve desmopressin product. In the event we discontinue the development and/or commercialization of the product, Alpex may continue or resume the development and/or commercialization of the rapid dissolve desmopressin product, provided that it reimburses us for at least a portion of our development costs, including any license or milestone payments.

We are required to pay Alpex one-time milestone payments related to the development of the rapid dissolve desmopressin product and lump-sum payments upon regulatory filing in the United States and upon approval in the United States. We are also required to pay Alpex a range of royalty payments based on net sales of the rapid dissolve desmopressin product and a percentage of all sublicensing income. Our royalty payment obligations will expire twenty years from the date of the first commercial shipment of the rapid dissolve desmopressin product, and the license will become a royalty-free, non-exclusive, perpetual, worldwide license to make, have made, use, import, export, sell, offer to sell and otherwise commercialize the rapid dissolve desmopressin product in the U.S., Canada and Mexico.

James Gale, the Chairman of our Board of Directors, is also on the Board of Directors of Alpex. Affiliates of Sanders Morris Harris, Inc. of which Mr. Gale is a managing director, own approximately 37% of our Company and more than 90% of Alpex.

***Valrubicin***

In September 2005, we entered into an agreement with Anthra Pharmaceuticals, Inc. to acquire certain assets of Anthra associated with its valrubicin business in the U.S. and Canada. Anthra s valrubicin business involved the manufacture and sale of valrubicin for use in the treatment of bladder cancer. The product was distributed in the U.S. and Canada by third party partners of Anthra. In the U.S., the product was distributed under the trademark Valstar. The product is not covered by any patents and its orphan drug status has expired.

Anthra s valrubicin product was taken off the market in 2002 due to a manufacturing problem and a lack of resources to address the problem. We have analyzed the manufacturing issues and believe that we have determined the cause of, and a solution to, the problem. As such, we have agreed to acquire certain assets of Anthra required for the manufacture, marketing and sale of valrubicin in the U.S. and Canada including the NDA filed with the FDA, the drug master file, the Canadian regulatory submission and all data produced by or on behalf of Anthra in support of the NDA and other governmental approvals, or in any other scientific experiment or clinical trial relating to valrubicin. The acquisition is expected to close during the first quarter of 2006, subject to various conditions. We initiated discussions with the FDA in the fourth quarter of 2005 regarding our plan to reintroduce the product into the U.S. market, and in January 2006, the FDA agreed to our plan.

The purchase price payable for the product consists of guaranteed payments, totalling $600,000, revenue sharing payments of up to 13.5% of our sales and receipt of license fees and additional payments based on our sales performance. Subject to certain exceptions, Anthra s indemnification obligations survive for two years after closing and are funded by setoff against the purchase price payable to Anthra under the agreement.

***Teva-Tuteur***

In December 2005, we entered into an exclusive distribution agreement with Teva-Tuteur for distribution of Vantas in Argentina. The initial term of the agreement ends on the date that is ten years

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after the date on which the first regulatory approval allowing sales of Vantas to proceed in Argentina, is granted, unless terminated earlier. The agreement automatically renews for additional periods of one year each unless notice of termination is given. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings or if the other party fails to cure a material breach within a specified time period after receipt of notice or the other party is unable to fully perform its obligations for one hundred-fifty days as a result of a force majeure event. Either party may terminate the agreement on an indication-by-indication basis if regulatory approval of Vantas for such indication is finally denied by the regulatory authority within Argentina. Terminations with respect to one or more, but not all, forms, dosages or indications will apply to the affected forms, dosages or indications. Additionally, we may terminate the agreement if Teva-Tuteur fails to purchase a specified number of units of Vantas in a calendar year. We may also terminate the agreement on an indications-by-indications basis if Teva-Tuteur fails to file necessary marketing approval applications within the required time.

Under the agreement, Teva-Tuteur will be the exclusive distributor of Vantas in Argentina. Teva-Tuteur is required to use commercially reasonable efforts to apply for and maintain regulatory approval for Vantas in Argentina for each indication for which we own or hold a regulatory approval anywhere in the world. In connection with obtaining regulatory approval for Vantas, we are required to supply Teva-Tuteur with all data and information in our possession or control as is necessary for that purpose. We also granted Teva-Tuteur an exclusive license to use the trademarks owned and approved by us, in connection with the marketing, distribution and sale of Vantas. We have given Teva-Tuteur the non-exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas in each approved indication in Argentina.

Teva-Tuteur granted us the right to use Teva-Tuteur s trademarks on labeling of Vantas. We have the sole right and responsibility to manufacture, assemble, package and label Vantas; provided that Teva-Tuteur is responsible for any and all Argentinean-specific labeling. We have agreed not to supply Vantas for distribution or sale for use in any indications to any other party except Teva-Tuteur. Teva-Tuteur shall pay us a flat transfer fee per unit, which fee is subject to an index-based adjustment. Beginning in the first calendar year after the first commercial sale of Vantas in Argentina, Teva-Tuteur must make certain minimum purchases during each calendar year unless it provides written notice one hundred and twenty (120) days prior to the end of any such calendar year, in which case Teva-Tuteur is relieved of the minimum purchase requirement for such calendar year. If Teva-Tuteur provides such notice, we have the option to (i) convert the exclusive right granted to Teva-Tuteur into a non-exclusive right effective as early as the date of the receipt of such written notice from Teva-Tuteur or (ii) terminate the agreement effective as early as the date of the receipt of such written notice from Teva-Tuteur.

**Competition**

The biotechnology and pharmaceutical industries are very competitive. In particular, competition for the development and marketing of urological and endocrine pharmaceutical products is intense and is expected to increase. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approval of products and manufacturing and marketing products. We compete against all pharmaceutical companies that manufacture or market LHRH agonist products. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of urological and endocrine products, technologies and processes that are, or in the future may be, the basis for competitive commercial products.

In particular, we compete against the following LHRH agonist products for the palliative treatment of advanced prostate cancer: TAP Pharmaceutical Products Lupron and Sanofi-Aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar that delivers triptorelin; AstraZeneca s Zoladex, a biodegradable rod that delivers goserelin for up to three months; and Bayer Pharmaceuticals Viadur, a rigid metal implant that releases leuprolide over a 12-month period. With respect to our endocrine pharmaceuticals in late-stage development for the treatment of CPP and acromegaly, our competitors currently include TAP Pharmaceutical Products Lupron Depot-PED and

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Novartis Sandostatin injections and Sandostatin LAR Depots and Pfizer s Somavert. We believe that Vantas represents a more comfortable and convenient alternative to competing products because it eliminates the requirement of multiple physician visits and repeated injections, and is smaller, softer and more flexible than other implants.

**Regulatory Matters**

***General***

The production, distribution and marketing of products employing our technology, and our research and development activities, are subject to extensive governmental regulation in the U.S. and in other countries. In the U.S., our product candidates are regulated as drugs, and are subject to the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and the regulations promulgated under these statutes, as well as to other federal, state and local statutes and regulations. These laws govern the clinical and non-clinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, import, export, storage, record keeping, reporting, advertising and promotion of our products. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violation of regulatory requirements at any stage may result in various adverse consequences, including FDA s delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and civil or criminal penalties.

***Research, Development and Product Approval Process***

The research, development and approval process in the U.S. is intensive and rigorous, and generally takes many years. The typical process required by the FDA before a therapeutic drug may be marketed in the U.S. includes:

pre-clinical laboratory and animal tests and analysis;

submission to the FDA of an application for an investigational new drug application, which must become effective before human clinical trials may commence;

preliminary human clinical studies to evaluate the drug and its manner of use;

adequate and well-controlled human clinical trials to establish whether the drug is safe and effective for its intended uses;

FDA review of whether the facility in which the drug is manufactured, processed, packed or held meets standards designed to assure the product s continued quality; and

submission and approval of an appropriate product application to the FDA, and approval of the application by the FDA.

During pre-clinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An investigational new drug application must be submitted to the FDA and become effective before studies in humans may commence.

In the U.S., clinical trial programs in humans generally follow a three-phase process:

Phase I studies are typically conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease, to determine the metabolic and pharmacological action of the product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

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Phase II studies are generally conducted in larger groups of patients having the target disease or condition in order to validate the clinical endpoint and to obtain preliminary data on both the effectiveness of the product candidate and optimal dosage. This phase also helps determine further the safety profile of the product candidate.

Phase III large-scale clinical trials are generally conducted in hundreds of patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate.

In the case of products for cancer and certain other life-threatening diseases, however, the initial Phase I testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will provide results traditionally obtained in Phase II studies. These studies are often referred to as Phase I/II studies. Even if patients are used in initial human testing in a Phase I/II study, the sponsor is still responsible for obtaining all the data usually obtained in both Phase I and Phase II studies.

U.S. law requires that studies conducted to support approval for product marketing be adequate and well controlled. In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with the FDA s good clinical practice regulations.

The clinical trial process can take up to ten years or more to complete, and the data may not be collected in compliance with good clinical practice regulations, demonstrate that the product is safe or effective, or be sufficient to support FDA approval of the product candidate. The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product s use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing authorization, can result in liability claims against us.

During the course of, and following the completion of clinical trials, the data are analyzed to determine whether the trials successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the U.S., if the product is regulated as a drug, a new drug application must be submitted and approved before commercial marketing may begin. The FDA Center for Drug Evaluation and Research, known as CDER, has responsibility for the review and approval of drugs. The new drug application must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability and proposed product labeling.

Each domestic and foreign biopharmaceutical manufacturing establishment, including any contract manufacturers we may decide to use must be listed in the new drug application and must be registered with the FDA. The application will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug product and determines that the facility is in compliance with the FDA s current good manufacturing practice requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products.

Under the Prescription Drug User Fee Act, the FDA receives fees for reviewing a new drug application and supplements thereto, as well as annual fees for both commercial manufacturing establishments and approved products. These fees can be significant. The new drug application review fee alone can exceed $0.6 million, although certain deferrals, waivers and reductions may be available.

Under applicable laws and FDA regulations, each new drug application submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will file the new drug application, thereby

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triggering substantive review of the application. The FDA can refuse to file any new drug application that it deems incomplete or not properly reviewable. If the FDA refuses to file an application, the FDA will retain 25% percent of the user fee as a penalty. The FDA has established performance goals for the review of new drug applications six months for priority applications and ten months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an action letter that describes additional work that must be done before the application can be approved. The FDA s review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval or otherwise limit the scope of any approval.

Significant legal and regulatory requirements also apply after FDA approval to market under a new drug application. These include, among other things, requirements related to adverse events and other reporting, product advertising and promotion and ongoing adherence to current good manufacturing practices, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

Overall research, development and approval times depend on a number of factors, including the period of review at the FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA questions, the severity of life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials and the risks and benefits demonstrated in the clinical trials.

***Drugs for Serious or Life-threatening Illnesses***

The Federal Food, Drug and Cosmetic Act and FDA regulations provide certain mechanisms for the accelerated Fast Track approval of products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. The procedures permit early consultation and commitment from the FDA regarding the pre-clinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, new drug applications to be approved on the basis of valid surrogate markers of product effectiveness, thus accelerating the normal approval process. We have not applied for fast track status for any of our current product candidates. However, certain product candidates employing our Hydron Technology might qualify for this accelerated regulatory procedure. However, the FDA may not agree, and even if the FDA agrees that these products qualify for accelerated approval procedures, the FDA may deny approval of our drugs or may require that additional studies be required before approval. The FDA may also require us to perform post-approval, or Phase IV, studies as a condition of such early approval. In addition, the FDA may impose restrictions on distribution and promotion in connection with any accelerated approval and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product candidates.

***Other U.S. Regulatory Requirements***

In the U.S., the research, manufacturing, distribution, sale and promotion of drugs may also be subject to regulation by various federal, state and local authorities including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), the U.S. Department of Health and Human Services and state and local governments. For example, sales, marketing and scientific and educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, and False Claims Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to

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authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Moreover, we are now, and may become, subject to additional federal state and local laws, regulations and policies relating to safe working conditions, laboratory practices, and experimental use of animals, and the use, storage, handling, transportation and disposal of human tissue, waste and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

***European Union Regulatory Requirements***

Our ability to market our products outside the U.S. will be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above. We received regulatory approval to commercialize Vantas in Denmark in November 2005. We expect to commence the mutual recognition process for regulatory approval in other European countries in the second quarter of 2006.

Under the European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Agency, known as the EMEA, leads to an approval granted by the European Commission which permits the marketing of the product throughout the European Union. We assume that the centralized procedure will apply to our products that are developed by means of a biotechnology process. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for product that do not qualify under the centralized procedure. Under the decentralized procedure, the holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states, which will then be requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. The recognition process should take no longer than 90 days, but if one member state made an objection, which under the legislation can only be based on a possible risk to human health, we have the option to withdraw the application from that country or take the application to arbitration by the Committee for Proprietary Medicinal Products, known as CPMP, of the EMEA. If a referral for arbitration is made, the procedure is suspended, and in the intervening time, the only European Union country in which the product can be marketed will be the country where the original authorization has been granted, even if all the other designated countries are ready to recognize the product. The opinion of the CPMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all European Union countries concerned. Arbitration can be avoided if the application is withdrawn in the objecting country, but once the application has been referred to arbitration, it cannot be withdrawn. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval, we may not be able to secure regulatory approvals in certain European countries in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufacturers, marketing or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

There has recently been introduced in Europe new legislation designed to harmonize the regulation of clinical trials across the European Union, and that legislation is currently being implemented on a country-by-country basis. In addition, new proposals are under advanced consideration which, if brought into law, will effect substantial and material changes in the regulation of medicinal products in Europe. Accordingly,

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in seeking approval for our products in Europe we face a marked degree of chance and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations.

***Other Foreign Regulatory Requirements***

We and our collaborative partners are subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been obtained, we must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are significant restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

**Employees**

As of January 1, 2006, we had 100 full-time employees, consisting of 13 individuals in management and administration, 41 individuals in sales and marketing, 12 individuals in research and development, 19 individuals in manufacturing and distribution and 15 individuals in quality assurance and quality control. We expect to hire approximately ten additional employees in sales and marketing. From time to time, we also employ independent contractors or consultants to support our clinical and regulatory efforts. None of our employees are represented by a collective bargaining unit and we have never experienced a work stoppage. We believe that our relations with our employees are good.

**Available Information**

Valera Pharmaceuticals files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the SEC ). You may read and copy any document we file with the SEC at the SEC s public reference room at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for information on the public reference room. The SEC maintains an internet site that contains annual, quarterly and current reports, proxy and information statements and other information that issuers (including Valera Pharmaceuticals) file electronically with the SEC. Valera Pharmaceuticals electronic SEC filings are available to the public at the SEC s internet site,*www.sec.gov*.

Valera Pharmaceuticals internet site is *www.valerapharma.com*. You can access Valera Pharmaceuticals Investor Relations webpage through our internet site, *www.valerapharma.com*, by clicking on the Corporate Information link to the heading Investors. You can also access our Investor Relations webpage directly at *www.valerapharma.com/investors.asp*. Valera Pharmaceuticals makes available free of charge, on or through our Investor Relations webpage, its proxy statements, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to the Securities Exchange Act of 1934, as amended (the Exchange Act ), as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Valera Pharmaceuticals also makes available, through our Investor Relations webpage, via a link to the SEC s internet site, statements of beneficial ownership of Valera Pharmaceuticals equity securities filed by its directors, officers, 10% or greater shareholders and others under Section 16 of the Exchange Act.

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Valera Pharmaceuticals has a webpage with its Corporate Code of Business Conduct and Ethics and certain Corporate Governance information. You can access this information on Valera Pharmaceuticals webpage through our internet site, *www.valerapharma.com,* by clicking on the Corporate Information link to the heading Investors. You can also access our Investor Relations webpage directly at *www.valerapharma.com/investors.asp*. We will post any amendments to the Code of Business Conduct and Ethics, and any waivers that are required to be disclosed by the rules of either the SEC or The NASDAQ National Market, on our internet site.

You can request a copy of these documents, excluding exhibits, at no cost, by contacting Investor Relations, 7 Clarke Drive, Cranbury, NJ 08512 or (609-235-3000). The information on Valera Pharmaceuticals internet site is not incorporated by reference into this report.

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**Item 1A.** ***Risk Factors***

*You should carefully consider the risk factors described below and all other information contained in this Form 10-K, including our historical financial statements and related notes and schedule, before you decide to invest in our common stock. If any of the following risk factors actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose part or all of your investment.*

**Risks Related to Our Business**

***We are largely dependent on the success of Vantas, our first product to be approved for commercial sale by the FDA, and we cannot be certain that we will be able to successfully expand the commercialization of Vantas.***

We have invested and will invest a significant portion of our time and resources in the commercialization of Vantas, which was approved for commercial use by the FDA in October 2004. The commercial success of Vantas is dependent on many factors, including building and maintaining a focused sales force, generating commercial sales, gaining acceptance of Vantas by patients and the medical community, and obtaining reimbursement from third party payors. All of our net product sales to date have been generated solely from sales of Vantas. Until our product candidates are approved for commercial use, our only source of revenue will be sales of Vantas. If we are unable to successfully expand the commercialization of Vantas, we may be required to cease or reduce our operations.

***We have a history of operating losses and may not achieve or sustain profitability.***

The extent of our future operating losses or profits is highly uncertain, and we may not achieve or sustain profitability. Our product development and clinical activities will require significant continuing expenditures. Vantas is our only product that has been approved for commercial use by the FDA and that may generate any significant revenues. From our inception through December 31, 2005 we have incurred annual operating losses, and as of December 31, 2005, we had an accumulated deficit of approximately $39.7 million. The majority of the deficit is attributable to research and development expenditures of $25.6 million, primarily for Vantas. We may incur additional operating losses, and we anticipate that our expenses will increase in the foreseeable future as we make expenditures to expand our sales of Vantas, continue our product development and clinical research, acquire or in-license other pharmaceutical products and expand our infrastructure. Although we expect our net product sales, together with borrowings under our line of credit and the proceeds from our initial public offering, to fund these expenses, we may not generate sufficient revenue from sales of Vantas to meet all of our expenses.

***We are dependent on single suppliers for certain services and raw materials, including histrelin, that are necessary for the manufacture of our Hydron implants. If any of these suppliers fail or are unable to perform in a timely and satisfactory manner, we may be unable to manufacture Vantas or some of our product candidates, which could delay sales of Vantas and hinder research and development of our product candidates that use Hydron Technology.***

We currently rely on single suppliers for histrelin, the active ingredient in Vantas, for our implantation devices and for sterilization services for our implants, including Vantas. We currently have no written agreements with any of these suppliers. Although we have identified alternate sources of these raw materials and services, these raw materials and services may not be immediately available to us. Further, even if these alternative raw materials are immediately available, they must first meet our internal specifications. Consequently, if any of our suppliers are unable or unwilling to supply us with these raw materials in sufficient quantities with the correct specifications, or provide services on commercially acceptable terms, we may not be able to manufacture Vantas or our product candidates in a timely manner or at all, which could delay the production or sale of Vantas and hinder the research and development of some of our product candidates. Our inability to obtain these raw materials and services for the manufacture of our implants may force us to cease or reduce operations.

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***We have previously experienced disruptions in our manufacturing of Vantas due to issues caused by our supply of histrelin, the active ingredient in Vantas, including a manufacturing disruption during the second and third quarters of 2005 that caused a material decrease in our sales for the third quarter of 2005 and may have an adverse impact on our sales of Vantas in the future. Further interruptions in our manufacturing process for Vantas or our product candidates may have an adverse impact on our sales of Vantas and the development of our product candidates in the future.***

We have experienced two separate disruptions in our manufacturing of Vantas due to issues caused by our supply of histrelin, the active ingredient in Vantas. In the fourth quarter of 2004, we experienced difficulties processing histrelin in its raw, powder form. These difficulties delayed the manufacturing of Vantas for several weeks as our supplier reformulated the histrelin. In the second and third quarters of 2005, we experienced an issue with the histrelin used to produce five lots of Vantas. This issue, which was caused by the method by which our supplier formulated the histrelin, ultimately resulted in these five lots not meeting certain quality control specifications and caused a delay in production of approximately six weeks. We have resolved each of these issues and have developed additional specifications with our supplier of histrelin in an effort to ensure a more consistent supply of histrelin that meets our needs. However, the disruption we experienced in the second and third quarters of 2005 directly impacted our supply of Vantas in the third quarter of 2005 by limiting the amount of finished product available for sale in the quarter to three lots, or approximately 2,400 units. Our third quarter sales were 1,747 units, which was less than our sales in the first and second quarters of 2005, in which we sold 2,925 units and 3,974 units, respectively. As a result of this decrease in sales, we had a net loss in the third quarter of 2005.

The interruption in our supply of Vantas in the second and third quarters of 2005 may have an adverse effect on our ability to sell Vantas in the future. The lack of supply during that period may have an adverse impact on our future sales because physicians may have elected to use alternative treatments during this time frame or may, as a result of this interruption, permanently switch to another product. Additionally, in the future, we may experience other disruptions in our manufacturing process for Vantas or our product candidates. Any disruptions we may experience may adversely impact sales of Vantas or the development of our product candidates.

***The successful commercialization of Vantas and any other products we develop will depend on obtaining reimbursement at adequate levels from private health insurers and Medicare/Medicaid for patient use of these products. We expect the reimbursement levels for Vantas to decline, which will have an adverse effect on our net product sales.***

Sales of pharmaceutical products largely depend on the reimbursement of patients medical expenses by government healthcare programs, such as Medicare and Medicaid, and private health insurers. These third party payors control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services and altering reimbursement levels. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for Vantas and other products we may develop could affect the extent to which we are able to commercialize these products.

Vantas is currently eligible for insurance reimbursement coverage. Sales of Vantas in the first half of 2005 were supported, in part, by favorable reimbursement rates, which decreased at the beginning of the third quarter of 2005. The favorable reimbursement rates we experienced in the first half of 2005 were due to the fact that Vantas was a new product that did not yet have an established average selling price, or ASP. As a result, Vantas was reimbursed at wholesale acquisition cost, which is typically higher than ASP. Vantas received an established ASP effective July 2005, which resulted in a lower reimbursement rate for Vantas.

We expect the reimbursement levels for Vantas to continue to decline, which will have an adverse effect on our net product sales. In some states, where the reimbursement rate for Vantas is based on ASP, the reimbursement levels will continue to decline because the ASP for Vantas will decline as we sell Vantas at prices below the reimbursement rate. In most states, however, the reimbursement rates for Vantas are even

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lower because the Medicare carriers in those states now apply the Least Costly Alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent . The reimbursement rate for Vantas, as determined by the Medicare carriers, is lower in LCA states than the reimbursement rate in non-LCA states, resulting in a lower sales price in LCA states.

Significant uncertainty generally exists as to the reimbursement status of newly approved healthcare products. Our ability to achieve acceptable levels of reimbursement for product candidates will affect our ability to successfully commercialize, and attract collaborative partners to invest in the development of, our product candidates. Reimbursement may not be available for Vantas or any other products that we develop and reimbursement or coverage levels may reduce the demand for, or the price of, Vantas or any other products that we may develop. If we cannot maintain coverage for Vantas and obtain adequate reimbursement for other products we develop, the market for those products may be limited.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to profitably sell Vantas and any other products that we develop. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has been enacted by Congress and signed by the President. Additionally, Medicare regulations implementing the prescription drug benefit became effective as of January 1, 2006. These and other regulatory and legislative changes or proposals may affect our ability to raise capital, obtain additional collaborators and market Vantas and any other products that we may develop. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, our ability to sell Vantas and other products we develop in commercially acceptable quantities at profitable prices may be harmed.

***As a manufacturer of our products, we are subject to regulatory requirements. If we do not comply with such requirements, the development and sales of our products and our financial performance may be materially harmed.***

Pharmaceutical products are required to be manufactured under regulations known as current good manufacturing practice, or cGMP. Before commercializing a new product, manufacturers must demonstrate compliance with the applicable cGMP regulations, which include quality control and quality assurance requirements, as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of their technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and civil or criminal sanctions.

We may also encounter problems with the following:

- production yields;
- raw materials;
- shortages of qualified personnel;
- compliance with FDA regulations, including the demonstration of purity and potency;

changes in FDA requirements;

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controlling production costs; and

development of advanced manufacturing techniques and process controls.

In addition, we are required to register our manufacturing facilities with the FDA and other regulatory authorities. The facilities are subject to inspections confirming compliance with cGMP or other regulations. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, or revocation of pre-existing approval for a product, such as Vantas, which would eliminate our sole source of revenue.

***We may not be able to complete our acquisition of the assets associated with the valrubicin product or realize a return on our investment in this product candidate.***

We have entered into an agreement with Anthra Pharmaceuticals, Inc. to acquire certain assets associated with its valrubicin product for the treatment of bladder cancer, including the right to sell the product in the U.S. and Canada. This product was withdrawn from the market in 2002 due to a manufacturing problem. We may not be able to complete our acquisition of these assets or realize a return on our investment in such assets due to risks related to the lack of intellectual property protection and potential manufacturing difficulties. Our acquisition of the assets is expected to close during the first quarter of 2006, subject to various conditions. Even though the FDA has agreed to our reintroduction plan, there is no assurance that we will be able to successfully implement the plan. Further, we will not have exclusive rights with respect to the sale of the valrubicin product, because the product is not covered by any patents or orphan drug exclusivity. As a result, competitors may compete with us by, among other things, introducing a generic version of the product or a similar product that contains the active ingredient, valrubicin.

Although we believe that we have identified the cause of the previous manufacturing problem and that we will be able to correct it, there can be no assurance that we will be able to correct the problem or that there will not be manufacturing problems in the future. We plan to contract with third-parties to manufacture the valrubicin as well as the finished product. Even if we establish an acceptable manufacturing protocol, our third-party manufacturers may be unable to manufacture the product in sufficient quantities with the correct specifications or in compliance with cGMP or other applicable regulatory requirements. As a result of these risks, we may be unable to complete our acquisition of this product or realize a return on our investment in this product.

***We have limited sales, marketing and distribution experience and may be unable to successfully commercialize our products.***

We have limited experience in marketing, selling, and distributing our products in the U.S. and abroad. To achieve commercial success, we must build on our current marketing and sales force or contract with other parties, including collaborators, to perform these services for us. We may not be able to negotiate favorable distribution or marketing arrangements. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties which may not be successful and are only partially within our control. We will be competing with companies that have experienced and well-funded marketing and sales operations. The failure to adequately sell and distribute Vantas or our product candidates, if approved, could impair our net product sales, cash flows from operations and our cash position.

***We may not be able to obtain additional capital that may be necessary for growth and market penetration or to continue our operations.***

We believe that the net proceeds we received from our initial public offering, together with our existing cash, cash generated from future sales of Vantas, and our line of credit will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may need to raise additional funds through public or private debt or equity financings in order to acquire new products or product candidates, significantly expand our sales and marketing capabilities, expand our manufacturing capacity, develop product candidates, obtain FDA approval of our product candidates and continue our commercial growth. Any additional equity financings may be on terms that are dilutive or potentially

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dilutive to our stockholders. Any debt financing we enter into may involve incurring significant interest expense and include covenants that restrict our operations. If we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. We may not be able to obtain financing on terms acceptable to us or at all. If financing is insufficient or unavailable, we will have to modify our growth and marketing strategies and scale back operations by delaying, reducing the scope of, or eliminating one or more of our planned development, commercialization or expansion activities. This may negatively affect our ability to expand our commercialization of Vantas and develop and bring new products to market, which could have a material adverse effect on our business, financial condition and results of operations.

Our future capital requirements may be significantly greater than we expect and depend on many factors, including:

- costs associated with conducting pre-clinical and clinical testing;
- costs associated with commercializing Vantas and other products we may develop, including expanding sales and marketing functions; for example, in connection with Supprelin-LA, we expect to increase our sales force;
- costs of establishing arrangements for manufacturing;
- costs of acquiring new pharmaceutical products and drug delivery systems;
- payments required under our current and any future license agreements and collaborations; for example, we are required to make certain royalty payments, which are tied to sales of Vantas;
- costs, timing and outcome of regulatory reviews;
- costs of obtaining, maintaining and defending patents on proprietary technology; and
- costs of increased general and administrative expenses.

As of December 31, 2005, the cumulative amount of royalty expense incurred by us as a result of sales of Vantas was $1.6 million.

***If products utilizing our technology fail to gain market acceptance, we may be unable to generate significant revenue.***

Even if clinical trials demonstrate the safety and efficacy of products developed utilizing our technology and all regulatory approvals are obtained, such products may not gain market acceptance among physicians, patients, third party payors or the medical community. The current method of administration for our product candidates in late-stage development is implantation, which may be less well received by some patients than injection therapy. The degree of market acceptance of any product employing our technology will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness;
- adequate reimbursement by third parties;
- relative convenience and ease of administration;
- timing of market introduction of competitive products;

alternative treatment methods, for example, injections and oral formulations; and

marketing and distribution support.

If our products do not achieve significant market acceptance, we may be unable to generate significant revenue, which could have a material adverse effect on our business, cash flows and results of operations.

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***Our failure to recruit, retain, and motivate qualified management and scientific personnel could adversely affect us.***

Our success depends, in part, on our continued ability to attract, retain and motivate highly qualified management, scientific and clinical and sales and marketing personnel. We are substantially dependent on our senior management and key scientific and technical personnel, particularly David S. Tierney, M.D., Matthew L. Rue, III, Pete J. Perron and Petr F. Kužma, each of whose services are critical to the successful implementation of our development, regulatory and commercialization strategies. We will need to expand our employee base as we continue to commercialize Vantas and develop our product candidates. The loss of the services of any member of our senior management, scientific or technical staff may significantly delay or prevent the achievement of drug development and other business objectives, and could have a material adverse effect on our business, financial condition and results of operations. We may not be able to recruit and retain qualified personnel in the future due to intense competition for personnel among pharmaceutical businesses, and our failure to do so could delay or curtail our product development efforts, impair our ability to execute our business strategy and adversely affect us. We have entered into an employment agreement with Dr. Tierney. Following July 1, 2006, unless this employment agreement is renewed, Dr. Tierney will become an at-will employee. In addition, we have entered into change of control agreements with each of our other executive officers. We have not purchased any key man life insurance for any of our employees.

We also utilize consultants and advisors to assist us with research and development. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us, which could have a material adverse effect on our business, financial condition and results of operations.

***We face substantial competition and our competitors may discover, develop or commercialize products similar to ours before or more successfully than we do.***

The biotechnology and pharmaceutical industries are very competitive. We compete against all pharmaceutical companies that manufacture or market LHRH agonist products. We also compete against biotechnology companies, universities, government agencies, and other research institutions in the development of urological and endocrine products, technologies and processes that are, or in the future may be, the basis for competitive commercial products.

In particular, we compete against the following LHRH agonist products for the palliative treatment of advanced prostate cancer: TAP Pharmaceutical Products Lupron and Sanofi-Aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar, a multiple injection formulation that delivers triptorelin; AstraZeneca s Zoladex, a biodegradable rod that delivers goserelin for up to three months; and Bayer Pharmaceuticals Viadur, a rigid metal implant that releases leuprolide over a 12-month period. With respect to our endocrine pharmaceuticals in late-stage development for the treatment of central precocious puberty and acromegaly, our competitors currently include TAP Pharmaceutical Products Lupron Depot-PED, Novartis Sandostatin injections and Sandostatin LAR Depots and Pfizer s Somavert.

Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approvals and manufacturing and marketing products. Consequently, competition for the development and marketing of urological and endocrine pharmaceutical products is intense and is expected to increase. For example, in the past we have received communications from Bayer Pharmaceuticals regarding our sales and marketing techniques for Vantas. Our practice has been to review these communications with counsel to determine whether any remedial or corrective action needs to be made. These communications have not resulted in any notice of violations or other action by any government authority or agency.

Our competitors may discover, develop or commercialize products similar to ours before or more successfully than we do and may compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our

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programs or advantageous to our business. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates. If any of them are successfully developed and approved, they could compete directly with our product candidates. This could result in reduced sales and pricing pressure on any similar products that we develop, which in turn would reduce our ability to generate revenue and could have a material adverse effect on our net product sales, gross margin and cash flows from operations.

***Our sales of Vantas and any other products we may develop could suffer from competition by generic products.***

Although we have proprietary protection for Vantas and other products we are developing, we could face competition from generic substitutes of these products if generics are developed by other companies and approved by the FDA. Because generic manufacturers are not exposed to development risks for such generic substitutes, these manufacturers can capture market share by selling generic products at lower prices, which can reduce the market share held by the original product. Competition from the sale of generic products may cause a decrease in our selling price or units sold, and could have a material adverse effect on our net product sales, gross margin and cash flows from operations.

***We may encounter difficulties managing our growth, which could adversely affect our results of operations.***

In connection with our commercial launch of Vantas, we may experience rapid and significant growth in the number of our employees and the scope of our operations. As of January 1, 2006, we had approximately 41 employees devoted to sales and marketing, and we expect to hire approximately ten additional employees in this area. Our future financial performance and our ability to commercialize Vantas and any other products that we develop and to compete effectively will depend, in part, on our ability to manage any future growth effectively. This growth and expansion is expected to place a significant demand on our financial, managerial and operational resources.

Our success in managing our growth will also depend on the ability of our executive officers and senior management to continue to implement and improve our operational, management, information and financial control systems and to expand, train and manage our employee base. Our inability to manage growth effectively could cause our operating costs to grow at a faster pace than is currently anticipated and could have a material adverse effect on our business, financial condition and results of operations.

***We face a risk of product liability claims and may not be able to obtain adequate insurance.***

Our business exposes us to potential liability risks that may arise from the clinical testing of our product candidates and the manufacture and sale of Vantas and other products that we may develop. Plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Such liability claims may be expensive to defend and may result in large judgments against us. Although we have liability insurance with a coverage limit of $10 million, our insurance may not reimburse us, or this coverage may not be sufficient to cover claims that may be made against us. In addition, if we are no longer able to maintain this coverage or have to obtain additional coverage, we may not be able to obtain liability insurance on acceptable terms or at all. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in:

- significant awards against us;
- substantial litigation costs;
- recall of the product;
- injury to our reputation; and
- withdrawal of clinical trial participants;

all of which could have a material adverse effect on our business, financial condition and results of operations.

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***The approved drugs used in Vantas and our product candidates, as well as the implant itself, may cause side effects and we may not be able to achieve an acceptable level of side effect risks, compared to the potential therapeutic benefits, for our product candidates.***

The active compound in Vantas and each of our product candidates has been approved by the FDA for the treatment of the conditions, diseases and disorders that we are seeking to treat. Each of these compounds, as well as the implant itself, is associated with certain side effects. Although we have not experienced any difficulties with the side effects profile of Vantas, the implant or our product candidates to date, the side effects of the approved drugs in our product candidates may be acceptable when a drug is used in its approved dosage to achieve a therapeutic benefit for its currently approved indications, but the side effect risk compared to the therapeutic benefit may not be acceptable when used for the intended indications for the product candidate. Side effects of the approved drugs, the implant or the combination of these elements, could prevent successful development and commercialization of some or all of our product candidates.

Further, the development of a product candidate could be adversely affected by safety or efficacy issues that subsequently arise regarding use of the approved drug, similar drugs or the implant. We could be forced to abandon a product candidate or an approved product, such as Vantas, due to adverse side effects from long-term or other use of the implant or the active pharmaceutical ingredients in the product candidate or product.

***Because we operated as a private company prior to our initial public offering in February 2006, we have no experience attempting to comply with public company obligations, including recently enacted changes in securities laws and regulations; attempting to comply with these requirements will increase our costs and require additional management resources and we still may fail to comply.***

We are a small company with limited resources. We operated as a private company prior to our initial public offering in February 2006, not subject to many of the requirements applicable to public companies. The number and qualifications of our finance and accounting staff are consistent with those of a private company. While we have plans to expand our staff, we may encounter substantial difficulty attracting qualified staff with requisite experience due to the high level of competition for experienced financial professionals.

As a public reporting company, we will need to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded periodic reports, disclosures and accelerated reporting requirements and more complex accounting rules.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company s internal control over financial reporting in their annual reports on Form 10-K. In addition, the independent registered public accounting firm auditing the company s financial statements must attest to and report on management s assessment of the effectiveness of the company s internal control over financial reporting. This requirement will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2007. If we are unable to conclude that we have effective internal control over financial reporting or, if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2007 and future year ends as required by Section 404 of the Sarbanes-Oxley Act of 2002, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

**Risks Related to Clinical Trials and Other Regulatory Matters**

***If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, we may not be able to commercialize our product candidates.***

We must provide the FDA and similar foreign regulatory authorities with pre-clinical and clinical data to demonstrate that our product candidates are safe and effective for each indication before they can be approved for commercialization. The pre-clinical testing and clinical trials of any product candidates that we develop must comply with the regulations of numerous federal, state and local government authorities

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in the U.S., principally the FDA, and by similar agencies in other countries. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials.

We have one product candidate currently in Phase I clinical trials and expect to have two product candidates in Phase I/II clinical trials in 2006 and one product candidate in a Phase IIb clinical trial in the first half of 2006. We expect to file a new drug application for Supprelin-LA in the second quarter of 2006. It may take several years to complete the testing of a product candidate, and failure can occur at any stage of development, for many reasons, including:

- interim results of pre-clinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies;
- product candidates that appear promising at early stages of development may ultimately fail because the products may be ineffective, may be less effective than competitors products or may cause harmful side effects;
- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a product candidate or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any product candidates or result in marketable products;
- the FDA may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a product candidate to market; and
- a product candidate may not be approved for all the indications which we request.

***The development and approval process may take many years, require substantial resources and may never lead to the approval of a product. With the exception of Vantas, we do not have, and may never obtain, the regulatory approvals we need to market our product candidates. Our failure to obtain, or delays in obtaining, regulatory approvals would have a material adverse effect on our business, financial condition and results of operations.***

Product candidates are subject to extensive and rigorous government regulation by the FDA, other regulatory agencies, and their respective foreign equivalents. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products. Any of our products marketed abroad will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a

given product and its uses.

Government regulation substantially increases the cost of researching, developing, manufacturing and selling pharmaceutical products. The regulatory review and approval process, which includes pre-clinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. We must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product s safety, efficacy, potency and purity for each

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intended use. Moreover, approval policies or regulations may change. We will not be able to commercialize our product candidates until we obtain FDA approval in the U.S. or approval by comparable authorities in other countries. The development and approval process takes many years, requires substantial resources and may never lead to the approval of a product. In October 2004, we received FDA approval for the commercial sale of Vantas in the United States. In November 2005, we received approval to market Vantas in Denmark. In March 2006, we received approval to market Vantas in Canada. Approval of any of our product candidates is not anticipated until 2007 and thereafter. Failure to obtain, or delays in obtaining, regulatory approvals may:

adversely affect the commercialization of any products that we develop;

impose additional costs on us;

diminish any competitive advantages that we may attain; and

adversely affect our receipt of revenues or royalties.

***Even if we receive regulatory approval for our product candidates, our approval may be limited and, we will be subject to significant ongoing regulatory obligations and oversight.***

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated uses for the product, may otherwise limit our sales practices and our ability to promote, sell and distribute the product, may require that we conduct costly post-marketing surveillance and may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. If we or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in:

refusals or delays in the approval of applications or supplements to approved applications;

refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;

warning letters;

fines;

import or export restrictions;

product recalls or seizures;

injunctions;

total or partial suspension of clinical trials or production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

recommendations by the FDA or other regulatory authorities against entering into governmental contracts with us; or

criminal prosecutions.

***The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.***

We intend to also market our products outside of the U.S. For example, we have executed agreements to license Vantas in Canada, South Africa, Asia and Argentina. To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval

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set forth above, and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

***We rely on third parties to conduct certain of the clinical trials for our product candidates, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We design the clinical trials for our product candidates, but we rely on academic institutions, corporate partners, contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. We are currently conducting the clinical trials for Supprelin-LA for CPP, however, the data management will be contracted to an outside data management firm. We are also conducting certain clinical trials for VP003 (octreotide) in Brazil, however, we have employed a local contract research organization to monitor the trials for us, and we will contract with a third party to handle the data management. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements, and we may fail to obtain regulatory approval for our product candidates, if these requirements are not met.

**Risks Related to Intellectual Property**

***Our success depends on the protection of our intellectual property rights, and our failure to secure these rights would materially harm our business.***

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We may not be able to obtain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties. Moreover, patents issued or that may be issued or licensed may not be enforceable or valid or may expire prior to the commercialization of our product candidates. The patent position of a pharmaceutical company involves complex legal and factual questions and, therefore, enforceability or validity cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against our competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S.

***If we are unable to protect the confidentiality of our proprietary information and know-how, our competitive position would be impaired and our business could be adversely affected.***

In addition to patent protection, we also rely on the protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we have entered into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements 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

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agreements with employees also provide that 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 the terms of these agreements. In the event of unauthorized use or disclosure of their trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection for our trade secrets or other confidential information. Further, to the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for us, disputes may arise 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 could harm our business.

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

Others may obtain patents that could limit our ability to use, import, manufacture, market or sell products or impair our competitive position. No patent can protect its holder from a claim of infringement of another patent. Therefore, our patent position cannot and does not provide any assurance that the commercialization of our products would not infringe the patent rights of another. In the event our technologies infringe or violate the proprietary rights of third parties, we may be prevented from pursuing the development, manufacturing or commercialization of our products that utilize such technologies. While we know of no actual or threatened claim of infringement that would be material to us, there can be no assurance that such a claim will not be asserted. If such a claim is asserted, the resolution of the claim may not permit us to continue marketing the relevant product, such as Vantas, on commercially reasonable terms, if at all.

***Protecting our intellectual property is expensive and time consuming and could harm our business.***

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expenses and the diversion of financial resources and technical and management personnel. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, we may be required to pay substantial financial damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights. In addition, an adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry of generic substitutes for our products.

**Risks Related to Our Common Stock**

***The trading price of the shares of our common stock could be highly volatile.***

The trading price of the shares could be highly volatile in response to various factors, many of which are beyond our control, including:

developments concerning Vantas or any of our product candidates;

announcements of technological innovations by us or our competitors;

new products introduced or announced by us or our competitors;

changes in reimbursement levels;

changes in financial estimates by securities analysts;

actual or anticipated variations in operating results;

expiration or termination of licenses, research contracts or other collaboration agreements;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

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intellectual property, product liability or other litigation against us;

changes in the market valuations of similar companies; and

sales of shares of our common stock, particularly sales by our officers, directors and significant stockholders.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the U.S., Europe or globally, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or results. These broad market and industry factors may materially affect the market price of the shares, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

***The ownership interests of our officers, directors and largest stockholders could conflict with the interests of our other stockholders.***

Our directors, executive officers and holders of 5% or more of our outstanding common stock beneficially own approximately 61% of our common stock as of March 1, 2006. As a result, these stockholders, acting together, are able to significantly influence all matters requiring approval by our stockholders, including the election of directors and approval of mergers or other significant corporate transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

***Our use of our initial public offering proceeds may not yield a favorable return on your investment.***

We will use the net proceeds from our initial public offering to expand our sales and marketing capabilities, fund our research and development activities, expand our manufacturing capabilities, and for general corporate purposes, including the potential acquisition or in-license of additional urological and endocrine products. We used a portion of the net proceeds from our initial public offering to repay amounts outstanding under our line of credit. In addition, we may use a portion of the net proceeds to acquire businesses, products or technologies that are complementary to our current or future business and product lines. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. We also plan to invest the proceeds from our initial public offering. However, the proceeds may not be invested effectively or in a manner that yields a favorable or any return, and consequently, this could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and/or delay the development of our product candidates.

***Our common stock has been publicly traded for a short time and an active trading market may not be sustained.***

Although we are currently listed for trading on The NASDAQ National Market, an active trading market for our common stock may not be sustained. An inactive market may impair your ability to sell shares at the time you wish to sell them or at a price that you consider reasonable. Furthermore, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, products and technologies by using our shares as consideration.

***Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay and discourage takeover attempts that stockholders may consider favorable.***

Certain provisions of our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, and applicable provisions of Delaware corporate

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law may make it more difficult for or prevent a third party from acquiring control of us or changing our board of directors and management. These provisions include:

- the ability of our board of directors to issue preferred stock with voting or other rights or preferences;
- limitations on the ability of stockholders to amend our charter documents, including stockholder supermajority voting requirements;
- the inability of stockholders to act by written consent or to call special meetings;
- a classified board of directors with staggered three-year terms;
- requirements that special meetings of our stockholders may only be called by the chairman of our board of directors, our president, or upon a resolution adopted by, or an affirmative vote of, a majority of our board of directors; and
- advance notice procedures our stockholders must comply with in order to nominate candidates for election to our board of directors or to place stockholders proposals on the agenda for consideration at meetings of stockholders.

We will also be afforded the protections of Section 203 of the Delaware General Corporation Law, which will prevent us from engaging in a business combination with a person who acquires at least 15% of our common stock for a period of three years from the date such person acquired such common stock, unless board or stockholder approval were obtained.

Any delay or prevention of a change of control transaction or changes in our board of directors or management could deter potential acquirors or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares.

***Future sales of our common stock may depress our stock price.***

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of approximately 11,022,380 shares of our common stock as of March 1, 2006, will have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

The holders of approximately 11,034,380 shares of our outstanding common stock as of March 1, 2006 have agreed with the underwriters of our initial public offering to be bound by a 180-day lock-up agreement that generally prohibits these holders from selling or transferring their stock until August 1, 2006, the end of the 180-day period, subject to specified exceptions. If we issue an earnings release or material news or if a material event relating to us occurs during the 15 calendar days plus 3 business days before the last day of the lock-up period, or if prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16 days following the last day of the lock-up period, the restrictions provided in the lock-up agreements will continue to apply until 18 days after the issuance of the earnings release or the occurrence of material news or a material event. At any time and without public notice our underwriters, UBS Securities LLC and Banc of America Securities LLC, may in their sole discretion release all or some of the securities from these lock-up agreements. If the restrictions of the lock-up agreements are waived, shares of our common stock will be available for sale into the market, subject only to applicable securities rules and regulations, which may cause our stock price to decline.

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***Our quarterly financial results are likely to fluctuate significantly because our sales prospects are uncertain and, as a result, our stock price may decline.***

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. For example, as described above, less favorable reimbursement rates of Vantas became effective at the beginning of the third quarter of 2005, as the basis for determining reimbursement rates switched from wholesale acquisition cost to the typically lower ASP. In addition, as described above, we anticipate that the number of states that provide reimbursement for Vantas under the Medicare program using the LCA methodology will increase in future quarters, leading to a decline in our sales price for Vantas. The level of our revenues and results of operations at any given time will be based primarily on the following factors:

success of the commercialization of Vantas and any other product candidates that may be approved;

changes in our ability to obtain FDA approval for our product candidates;

results of our clinical trials;

timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;

regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;

our ability to establish, grow and maintain a productive sales force;

demand and pricing of Vantas and other products we may offer;

physician and patient acceptance of Vantas and other products we may offer;

levels of third-party reimbursement for Vantas and other products we may offer;

interruption in the manufacturing or distribution of Vantas and other products we may offer; and

the effect of competing technological and market developments.

It will be difficult for us to forecast demand for Vantas and our product candidates that may be approved with any degree of certainty, and therefore, our sales prospects are uncertain. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

**Item 1B.** ***Unresolved Staff Comments***

Not applicable

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**Item 2.** ***Properties***

We maintain our headquarters and manufacturing facility in Cranbury, New Jersey in two leased facilities consisting of a total of 51,046 square feet. The following table sets forth more information regarding our facilities.

| Address | Square Feet | Function | Lease Expiration |
|---|---|---|---|
| 7 Clarke Drive<br>Cranbury, NJ | 21,274 | Research and Development; Administration | 2015 |
| 8 Clarke Drive<br>Cranbury, NJ | 29,772 | Manufacturing | 2015 |

Our manufacturing facility is subject to periodic inspections by the FDA and other federal and state regulatory agencies and is subject to cGMP regulations. Despite the relative complexity and length of our manufacturing process, we believe that our existing manufacturing facilities are capable of producing commercial quantities of our implants. In order to achieve cost-effective production, we have developed proprietary equipment and scalable commercial manufacturing methods that we use in our production line.

In May 2005, we began a construction project at our headquarters to increase the size of our manufacturing facility. We believe that our current manufacturing facilities, as supplemented by the space under construction, will provide sufficient capacity to meet our current needs and support the introduction of new products over the next several years, and that suitable additional space will be available in the future on commercially reasonable terms as needed.

**Item 3.** ***Legal Proceedings***

We are not subject to any pending or, to our knowledge, threatened litigation.

**Item 4.** ***Submission of Matters to a Vote of Security Holders***

There were no matters submitted to a vote of our security holders in the fourth quarter of 2005.

**PART II**

**Item 5.** ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Our common stock is quoted on The NASDAQ National Market under the symbol VLRX. We began trading on The NASDAQ National Market on February 2, 2006. As such, our common stock was not traded during the period covered by this annual report.

As of March 1, 2006, there were approximately 21 holders of record of our common stock. On March 1, 2006, the last reported sale price of our common stock as reported on The NASDAQ National Market was $9.95 per share.

We have not declared or paid any dividends on our stock since our inception and do not anticipate paying any dividends on our common stock in the foreseeable future. We currently intend to retain future earnings, if any, to fund the development and expansion of our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Under our credit agreement with Merrill Lynch Capital, we agreed to not declare or pay any cash dividends. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and other factors our board of directors deems relevant.

**Recent Sales of Unregistered Securities**

Since our inception, we have issued the following securities that were not registered under the Securities Act of 1933, as amended (the Securities Act ) (the option, share and price numbers below

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give effect, where applicable to the one-for-six reverse stock split of our common stock, which was completed prior to the closing of our initial public offering:

Since our inception until our initial public offering, we issued an aggregate of 1,667,082 shares of common stock, par value $0.001 per share, of which 1,666,666 shares were issued to MXL Industries in June 2000 as a result of our spinout from GP Strategies Corporation and 416 shares were issued as a result of the exercise of options in October 2005.

Since our inception, we also issued an aggregate of 40,669,000 shares of preferred stock, par value of $0.001 per share. These shares included 7,000,000 shares of series A convertible preferred stock issued in January 2002 at $1.00 per share for gross proceeds of $7 million, 22,069,000 shares of series B convertible preferred stock issued between May 2003 and June 2004, at a purchase price per share of $0.725, for gross proceeds of $16 million, and 11,600,000 shares of series C convertible preferred stock issued in August 2004 at a purchase price per share of $1.00, for gross proceeds of $11 million. In connection with our IPO, all shares of preferred stock were converted into common stock at pre-determined rates and were subject to the one-for-six reverse split.

No underwriters were involved in the foregoing sales of securities. The securities described in this Item 5 were issued to United States investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Rule 506 of Regulation D promulgated thereunder relative to sales by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of our convertible preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration.

**Use of Proceeds from Sales of Registered Securities**

On February 7, 2006, we closed the sale of 3,862,500 shares of our common stock in our initial public offering. The Registration Statement on Form S-1 (Reg. No. 333-123288) (the Registration Statement ) we filed to register our common stock in the initial public offering was declared effective by the Securities and Exchange Commission on February 1, 2006. The initial public offering commenced as of February 1, 2006 and did not terminate before any securities were sold. The initial public offering was completed and all shares were sold at an initial price per share of $9.00. The aggregate purchase price of the common stock registered in the initial public offering was $34.8 million.

The managing underwriters for the initial public offering were UBS Investment Bank, Banc of America Securities LLC, First Albany Capital and Fortis Securities LLC. We incurred expenses in connection with the initial public offering of approximately $4.5 million, which consisted of direct payments of: (i) $1.9 million in legal, accounting and printing fees; (ii) $2.4 million in underwriters discounts, fees and commissions; and (iii) $0.2 million in miscellaneous expenses.

After deducting expenses of the initial public offering, we received net offering proceeds of approximately $30.3 million. We used $1.6 million of the proceeds to repay borrowings we had under our line of credit. We intend to use these remaining proceeds to advance our product candidates through preclinical and clinical trials, for commercialization of our products, for general corporate purposes including acquisition or in-licensing of products or product candidates, and for working capital. We regularly assess the specific uses and allocations for these funds.

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**Equity Compensation Plan Information as of December 31, 2005**

The following table sets forth information as of the end of the Company s 2005 fiscal year with respect to compensation plans under which the Company is authorized to issue shares.

| Plan Category | Number of Shares to be Issued Upon Exercise of Outstanding Options | Weighted-Average Exercise Price of Outstanding Options ($) | Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities in 1st Column) |
|---|---|---|---|
| Equity compensation plan approved by security holders(1) | 1,265,849 | $ 4.25 | 567,484 |
| Equity compensation plans not approved by security holders(2) | | | |
| Total | 1,265,849 | $ 4.25 | 567,484 |

(1) 2003 Equity Incentive Plan.

(2) The Company does not maintain any equity compensation plans that have not been approved by its stockholders.

In September 2002, we adopted our Equity Incentive Plan, which was approved by our stockholders in May 2003. Our Equity Plan provides for the award of:

restricted shares of our common stock;

incentive stock options;

non-qualified stock options; or

any combination of the foregoing.

Grants of restricted shares and non-qualified stock options can be made to our employees, directors, consultants, and other individuals who perform services for us. Grants of incentive stock options may only be made to our employees. The principal features of our Equity Incentive Plan are summarized below, but the summary is qualified in its entirety by reference to our Equity Incentive Plan, which was filed as exhibit 10.14 to the Registration Statement in connection with our initial public offering.

***Number of shares of our common stock available under our Equity Plan***

We have reserved a total of 1,833,333 shares of our common stock for issuance pursuant to our Equity Plan. Shares subject to forfeited, cancelled, or expired awards and shares received in satisfaction of the exercise price of an option become available for grant again under our Equity Plan. In addition, shares withheld in payment of any

exercise price or in satisfaction of any withholding obligation arising in connection with an award granted under our Equity Plan become available for grant again under our Equity Plan. In connection with recapitalizations, stock splits, combinations, stock dividends, and other events affecting our common stock, the compensation committee of our board of directors (the Compensation Committee ) may make adjustments or equitable substitutions it deems appropriate in its sole discretion to the maximum number, type and issuer of the securities reserved for issuance under the Equity Plan, to the maximum number, type and issuer of shares of our common stock subject to outstanding options, to the exercise price of the options and to the number, type and issuer of restricted shares.

***Administration of our Equity Plan***

The Compensation Committee administers our Equity Plan under authority granted to it by our board of directors in accordance with the terms of our Equity Plan. To administer our Equity Plan, the Compensation Committee must consist of at least two members of our board of directors, each of whom is a non-employee director for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, or the Exchange Act and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, an outside director for the purposes of

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Section 162(m). The Compensation Committee, among other things, interprets our Equity Plan, selects award recipients, determines the type of awards to be granted to such recipients and determines the number of shares subject to each award and the terms and conditions thereof. The Compensation Committee may also determine if or when the exercise price of an option may be paid in the form of shares of our common stock and the extent to which shares or other amounts payable with respect to an award can be deferred by the participant. Our board of directors may amend or modify our Equity Plan at any time. In addition, our board of directors is also authorized to adopt, alter and repeal any rules relating to the administration of our Equity Plan and to rescind the authority of the Compensation Committee and thereafter directly administer our Equity Plan. However, subject to certain exceptions, no amendment or modification will impair the rights and obligations of a participant with respect to an award unless the participant consents to that amendment or modification.

Our Equity Plan will continue in effect until terminated by us in accordance with its terms, although incentive stock options may not be granted more than 10 years after the adoption of our Equity Plan.

**Transfer Agent and Registrar**

Our transfer agent and registrar is Computershare Trust Company, N.A. Their address is 250 Royall Street, Canton, MA 02021 and their telephone number is (781) 575-2000.

***Stockholder action by written consent***

Our certificate of incorporation provides that our stockholders may not act by written consent without a meeting.

***Stockholder meetings***

Our certificate of incorporation and bylaws provide that, except as otherwise required by law and subject to the rights of holders of any series of preferred stock, special meetings of stockholders may be called at any time, but only by the chairman of our board of directors, our president, or upon a resolution adopted by, or affirmative vote of, a majority of our board of directors, and not by the stockholders.

***Requirements for advance notification of stockholder nominations and proposals***

Our bylaws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors other than nominations made by or at the direction of our board of directors or a committee of our board of directors.

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**Item 6.** ***Selected Financial Data***

The following tables set forth our selected historical financial data as of December 31, 2005 and 2004 and for the years ended December 31, 2005, 2004 and 2003, which have been derived from our audited financial statements, included elsewhere in this Form 10-K. The selected historical financial data as of December 31, 2003, 2002 and 2001 and for the years ended December 31, 2002 and 2001 have been derived from our audited financial statements, which are not included in this Form 10-K. It is important that you read this information together with Management s Discussion and Analysis of Financial Condition and Results of Operations , Risk Factors and our financial statements and related notes and schedule to these financial statements beginning on page 60 of this Form 10-K. The historical results presented below are not necessarily indicative of the results to be expected in any future period.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (in thousands, except per share amounts) | | | | |
| Net product sales | $ 26,798 | $ 5,511 | $ 7 | $ 15 | $ 8 |
| Licensing revenue | 34 | 135 | | | |
| Total net revenue | 26,832 | 5,646 | 7 | 15 | 8 |
| Operating costs and expenses | | | | | |
| Cost of product sales | 5,966 | 608 | | | |
| Research and development | 5,930 | 6,376 | 5,230 | 4,320 | 2,616 |
| Selling and marketing | 10,754 | 5,025 | 509 | 270 | |
| General and administrative | 5,500 | 5,897 | 1,838 | 1,324 | 1,522 |
| Total operating expenses | 28,150 | 17,906 | 7,577 | 5,914 | 4,138 |
| Loss from operations | (1,318) | (12,260) | (7,570) | (5,899) | (4,130) |
| Interest income (expense), net | 49 | (6) | 13 | 16 | (30) |
| Loss before income taxes | (1,269) | (12,266) | (7,557) | (5,883) | (4,160) |
| Provision for (benefit from) income taxes | 75 | (243) | | | |
| Net loss | (1,344) | (12,023) | (7,557) | (5,883) | (4,160) |
| Deemed dividend | | (5,861) | (1,139) | | |
| Net loss attributable to common stockholders | $ (1,344) | $ (17,884) | $ (8,696) | $ (5,883) | $ (4,160) |
| Basic and diluted net loss attributable to common stockholders per share | $ (0.81) | $ (10.73) | $ (5.22) | $ (3.53) | $ (8.06) |
| Weighted average shares outstanding basic and diluted | 1,667 | 1,667 | 1,667 | 1,667 | 516 |

| | As of December 31, |
|---|---|

| | 2005 | 2004 | 2003 | 2002 | 2001 |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 2,340 | $ 5,053 | $ 5,241 | $ 641 | $ 6,621 |
| Working capital | 2,845 | 8,306 | 4,585 | (404) | 5,658 |
| Total assets | 16,532 | 13,667 | 6,665 | 1,296 | 7,172 |
| Long-term liabilities | 300 | 17 | 33 | 67 | 124 |
| Convertible preferred stock | 39,925 | 39,925 | 20,469 | 6,604 | 6,604 |
| Total stockholders deficit | (31,593) | (29,887) | (15,158) | (6,465) | (582) |

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**Item 7.** ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

*The following discussion and analysis should be read in conjunction with our financial statements and the related notes and schedule thereto appearing elsewhere in this Form 10-K. This discussion and analysis may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially as a result of various factors, including those set forth under Risk Factors or elsewhere in this Form 10-K.*

**Overview**

We are a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize our proprietary technology. Our first product, Vantas, was approved by the FDA in October 2004. Vantas is a 12-month implant indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist. We began selling Vantas in November 2004 utilizing our sales force that is currently calling on urologists in the U.S. that account for the majority of LHRH agonist product sales.

Total U.S. sales of LHRH agonist products for the palliative treatment of prostate cancer were approximately $900 million in 2005 based on our estimates and IMS Health Incorporated data, with the leading products being the three- and four-month injection formulations. We believe that total U.S. sales of LHRH agonist products declined by 10% in 2005, primarily as a result of lower prices due to changes in Medicare reimbursement rates. We expect future reimbursement levels to continue to decline, which will have an adverse effect on our net product sales. We believe that Vantas has a competitive advantage over other LHRH agonist products because it delivers an even, controlled dose of LHRH agonist over a 12-month period, and is the only product indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, the most potent LHRH agonist available.

In addition to Vantas, a hydrogel implant based on our patented Hydron Technology, we are developing a pipeline of proprietary product candidates for indications that include central precocious puberty, acromegaly, opioid addiction, interstitial cystitis, nocturnal enuresis and bladder cancer. Several of our product candidates also utilize our Hydron Technology delivery system. We intend to leverage our existing specialized sales force to market certain of our product candidates, if approved, since the indications of these product candidates are treated by many of the same physicians we are calling on for Vantas.

We expect to continue to spend significant amounts, including for clinical trial costs, on the development of our product candidates. We plan to seek marketing approvals for our products in various countries throughout the world, particularly in the United States, Canada and Europe. We expect our costs to increase significantly as we continue to develop and ultimately commercialize our product candidates. While we will be focusing on the clinical development of our later stage product candidates in the near term, we expect to increase our spending on earlier stage clinical candidates as well. We also aim to build our urological and endocrine product portfolio and opportunistically acquire or in-license later-stage urological and endocrine products that are currently on the market or require minimal development expenditures, or have some patent protection or potential for market exclusivity or product differentiation. Further, we intend to collaborate with major and specialty pharmaceutical companies to develop and commercialize products that are outside of our core urology and endocrinology focus. Accordingly, we will need to generate significant revenues to achieve or maintain profitability.

Drug development in the United States and most countries throughout the world is a multi-stage process defined by the FDA and similar regulatory authorities in foreign countries. In the United States, the FDA approval process for a new drug involves completion of pre-clinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an investigational new drug application, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant expenses associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the

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drug development stage. In responding to a new drug application, the FDA may refuse to accept the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In order to commence clinical trials or marketing of a product outside the United States, we must obtain approval of the applicable foreign regulatory authorities. Although governed by the laws and regulations of the applicable country, clinical trials conducted outside the United States typically are administered in a similar three-phase sequential process.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- future clinical trial results;
- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Research and development expenses in the aggregate, represented approximately 21% of our total operating expenses for the year ended December 31, 2005, approximately 36% of our total operating expenses for the year ended December 31, 2004 and approximately 69% of our total operating expenses for the year ended December 31, 2003. Research and development expenses consist primarily of costs incurred for clinical trials and manufacturing development costs related to our clinical product candidates, personnel and related costs related to our research and product development activities and outside professional fees related to clinical development and regulatory matters.

We expect our research and development expenses to continue to decline, when measured as a percentage of total operating expenses, due to the fact we will be selling our products and growing our infrastructure. We do not disclose estimated research and development costs for product candidates that are not yet in Phase III clinical trials. We estimate that we will incur approximately $1.0 million to $1.5 million of expenses, in addition to costs previously incurred, in order to complete Phase III trials for our Supprelin-LA implant and to complete the regulatory process in the U.S. These estimates assume the completion of a single Phase III trial which is currently underway.

**Basis of Presentation**

***Product Sales and Costs***

We generate revenues from sales of Vantas, our lead product. We began commercial sales of Vantas in November 2004. Currently, all sales are in the U.S. We distribute Vantas directly to physicians, or through Besse Medical Distribution Company, or Besse Medical, which is a subsidiary of AmerisourceBergen Corporation. Approximately 9% and 6% of our unit sales went through Besse Medical in 2004 and 2005, respectively. Our business may be affected by physician utilization, pricing pressure and Medicare or third party reimbursement, as well as other factors which may cause variances in our revenue.

We sold 2,925, 3,974, 1,747 and 2,868 units of Vantas during the first, second, third and fourth quarters of 2005, respectively. The third quarter number of units sold was affected by a manufacturing disruption due to issues caused by our supply of histrelin, which issues were resolved in June 2005.

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Our sales of Vantas from launch in November 2004 through June 30, 2005 were supported, in part, by favorable reimbursement rates, which decreased beginning in the third quarter of 2005. Our initial favorable reimbursement rates were due to the fact that Vantas was a new product that did not yet have an established ASP in connection with Medicare reimbursement. As a result, Vantas was reimbursed at wholesale acquisition cost, which is typically higher than ASP. Vantas received an established ASP effective July 2005, which resulted in lower reimbursement rates and a corresponding lower sales price to our customers. Our net average selling price to our customers was $2,604 for the six months ended June 30, 2005, it declined to $2,099 during the three months ended September 30, 2005 and further declined to $1,801 per unit in the fourth quarter of 2005.

We expect future reimbursement levels to continue to decline, which will have an adverse effect on our net product sales. In some states, where the reimbursement rate for Vantas is based on ASP, the reimbursement levels will continue to decline because the ASP for Vantas will decline as we sell Vantas at prices below the reimbursement rate. In most states, however, the reimbursement rates for Vantas are even lower because the Medicare carriers in those states now apply the least costly alternative, or LCA, methodology to Vantas. The reimbursement rate for Vantas, as determined by Medicare carriers, is lower in LCA states than the reimbursement rate in non-LCA states, resulting in a lower sales price in LCA states. We describe the factors affecting reimbursement in more detail in the section entitled Business Reimbursement in this Form 10-K.

In prior years, we received all of our revenue from the sale of certain polymer products. We discontinued manufacturing these polymers in 1996, as they were no longer profitable, so that we could concentrate all of our efforts on developing pharmaceutical products.

Our cost of product sales are all related to the production of Vantas and represent the cost of materials, overhead associated with the manufacture of Vantas, direct labor, distribution charges and royalties. Prior to approval of Vantas in October 2004, we expensed all of our manufacturing costs as research and development. Aggregate royalty costs were $0.3 million or 5.4% of net revenue for the year ended December 31, 2004 and $1.3 million or 4.9% of net revenue for the year ended December 31, 2005. No royalties were due in prior years. For a more complete description of our royalty arrangements, see Business Material Agreements.

***Research and Development Expenses***

Our research and development expenses consist of costs incurred for company-sponsored and collaborative research and development activities. These expenses consist primarily of direct and research-related allocated overhead expenses such as facilities costs, salaries and benefits and material supply costs. We do not track or report our research and development expenses on a project basis as we do not have the internal resources or systems to do so. To date, the vast majority of our research and development resources have been devoted to the development of Vantas.

***Selling and Marketing Expenses***

Selling and marketing expenses consist primarily of sales and marketing personnel compensation, sales force incentive compensation, travel, tradeshows, promotional materials and programs, advertising and healthcare provider education materials and events.

***General and Administrative Expenses***

Our general and administrative expenses consist primarily of personnel expenses for accounting, human resources, outside consulting, information technology and corporate administration functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal and accounting services.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make judgments, estimates and

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assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, the expected course of development, historical experience and other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The list below is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management s judgment in selecting any available alternative would not produce a materially different result. Our audited financial statements and the related notes and schedule thereto included in Item 8 of the Form 10-K contain accounting policies and other disclosures required by GAAP.

***Revenue Recognition***

Our revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, or SAB No. 104, *Revenue Recognition in Financial Statements*, which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the Securities and Exchange Commission. SAB 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on our management s judgments regarding the fixed nature of the fee charged for products delivered and the collectibility of those fees. Should changes in conditions cause our management to determine that these criteria are not met for certain future transactions, revenue recognition for those transactions will be delayed and our revenues could be adversely affected.

Allowances have been recorded for any potential returns or adjustments in accordance with our policies. We historically have recorded allowances based upon a percentage of gross sales. To date, we have not changed our percentage estimates of product returns, and, therefore, have not made any adjustments to date in this allowance. We distribute our product directly to physicians or through our distributor, Besse Medical. The majority of our sales are made directly to physicians by our product specialists. We believe that physicians typically order product on an as needed basis, and, therefore, typically maintain inventory of our product only to cover their immediate and short-term future requirements. In addition, our product specialists routinely confirm product utilization and inventory levels, if any, as part of their normal sales calls with physicians. We continue to monitor our distribution channels in order to assess the adequacy of our allowances. We do not believe that it is reasonably likely that a material change will occur in the allowance as of December 31, 2005.

***Pre-clinical Study and Clinical Trial Expenses***

Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are based on actual and estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates accordingly on a prospective basis.

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***Stock-based Compensation***

In December 2002, Statement of Financial Accounting Standards, or SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an Amendment of FASB Statement No. 123* was issued. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation from the intrinsic value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB No. 25. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123, *Accounting for Stock Based Compensation*. We adopted the disclosure requirements of SFAS No. 148 effective December 31, 2002. As allowed by SFAS No. 123, we have elected to continue to apply the intrinsic value-based method of accounting prescribed in APB No. 25 and, accordingly, do not recognize compensation expense for employee stock option grants made at an exercise price equal to or in excess of the estimated fair value of the stock at the date of grant. To the extent the company granted options with an exercise price below the estimated fair value of the stock on the date of grant, deferred compensation was recognized and amortized over the vesting period of the related options.

In December 2003, the exercise price of all options issued prior to 2003 was amended to $3.00, the fair market value at that time. In accordance with FASB Interpretation ( FIN ) No. 44, the repriced options were accounted for as variable from the date of the modification to the date the options are exercised, forfeited, or expire. Under SFAS 123R, which the Company adopted on January 1, 2006, there will be no additional compensation expense for these repriced options as the vesting is complete and the requisite service period has ended.

We account for options issued to non-employees under SFAS No. 123 and Emerging Issues Task Force, or EITF, Issue 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services*. As such, the value of such options is periodically remeasured and income or expense is recognized during their vesting terms. The amount of stock-based compensation expense to be recorded in future periods may decrease if unvested options, for which stock compensation expense has been recorded, are subsequently canceled.

In addition, please refer to the discussion of SFAS No. 123(R), *Share Based Payment*, in the recent accounting pronouncements section.

**Results of Operations**

***Comparison of the Years Ended December 31, 2005 and 2004***

*Net Product Sales.* Net product sales for the year ended December 31, 2005 were $26.8 million, during which period we sold 11,514 units of Vantas at a net average selling price per unit of $2,327. Net product sales for the year ended December 31, 2004 were $5.5 million during which period we sold 2,187 units of Vantas at a net average selling price per unit of $2,520. The increase in net product sales of $21.3 million, or 386%, was primarily due to the fact we launched Vantas, our only commercialized product, in November 2004 and as a result, we had only two months of sales in 2004.

Our net average selling price to our customers was $2,604 for the six months ended June 30, 2005. The net average selling price declined to $2,099 during the three months ended September 30, 2005 and further declined to $1,801 per unit during the three months ended December 31, 2005. We expect our net average selling price to continue to decline in future periods as a result of an expected decrease in Medicare reimbursement rates for Vantas. The expected decrease in our net average selling price will negatively impact our net product sales, gross margins, and our cash flows from operations. However, we are unable to quantify the extent of such declines beyond the fourth quarter of 2005. Please refer to Basis of Presentation Product Sales and Costs .

In the second and third quarters of 2005, we experienced a disruption in our manufacturing of Vantas due to issues caused by our supply of histrelin as described in Risk Factors Risks Related to Our Business . This manufacturing disruption which occurred in May and June of 2005 limited the amount of finished product available for sale in the third quarter of 2005 to three lots, or approximately 2,400 units. The issue was resolved in June and we released approved finished product in August. Our third quarter sales of 1,747 units were less than our sales in the first and second quarters of 2005, in which we sold

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2,925 units and 3,974 units, respectively. As a result of this decrease in sales, we had a net loss in the third quarter of 2005. Our production of Vantas in the fourth quarter of 2005 was sufficient to meet demand as well as to continue to build quantities of finished goods inventory.

*Licensing Revenue.* During the year ended December 31, 2005, we recorded $34,000 in licensing revenue from Hydron Technologies under a licensing arrangement. In addition, in January 2005 we received $300,000 from BioPro, our distribution partner for certain countries in Asia. The BioPro payment is reflected as deferred revenue on the December 31, 2005 balance sheet. We will recognize this payment ratably over a ten-year period once Vantas is approved in the licensed territory. In 2004, back fees of $135,000 were paid, as an agreement with Hydron Technologies to terminate the cross licensing agreement could not be reached.

*Cost of Product Sales.* Our cost of product sales for the year ended December 31, 2005 was $6.0 million resulting in a gross margin of 78%. In 2004, cost of product sales was $0.6 million and the gross margin percentage was 89% due to higher selling prices and lower costs on a per unit level. The 2004 gross margin percentage includes the benefit of the sale of units that were partially manufactured prior to FDA approval and, as such, were previously partially expensed. As discussed previously, during the second quarter of 2005, due to an issue regarding our supply of histrelin, the active ingredient in Vantas, several lots of Vantas that we produced did not meet our quality control specifications. Specifically, we acquired a supply of histrelin in January 2005 from our single-source supplier and we used that histrelin during February, March and April in the production of Vantas. In May and June of 2005, we discovered that the histrelin had lower than normal solubility. This caused the lots made with that histrelin to fail to meet our quality control specifications and, as a result, those lots were not available for sale. This resulted in the write-off of five lots of Vantas in May and June of 2005 which had an unfavorable impact of approximately $1 million. The issue was resolved in June and we released approved finished product in August. We expect the gross margin percentage to decrease in future periods as we expect our net average selling price of Vantas to decrease as a result of declining reimbursement rates.

The cost of product sales calculation includes royalty expense of $1.3 million and $0.3 million for the years ended December 31, 2005 and 2004, respectively. Freight and distribution expense is also included in the cost of product sales for all periods presented.

*Research and Development Expense.* Research and development expense for the years ended December 31, 2005 and 2004 was $5.9 million and $6.4 million, respectively. Expenses related to clinical trials pursuant to contracts with research institutions and clinical research organizations represented 46% of our total research and development expense for the year ended December 31, 2005 and 23% of our research and development expense for the year ended December 31, 2004. The overall decrease in research and development expense in 2005 was attributable to lower stock compensation expense and lower material costs as all costs associated with producing Vantas are carried in inventory and expensed to cost of product sales as Vantas is sold. We expect to continue to spend significant amounts, including for clinical trial costs, on the development of our product candidates. We plan to seek marketing approvals for our products in various countries throughout the world, particularly in the United States, Canada and Europe. We expect our costs to increase significantly as we continue to develop and ultimately commercialize our product candidates.

*Selling and Marketing Expense.* Selling and marketing expense for the years ended December 31, 2005 and 2004 was $10.8 million and $5.0 million, respectively. The increase in the 2005 period over the 2004 period was predominantly the result of an increase in payroll and the related expenses of adding employees to our sales force as well as increased promotional costs resulting from a full year of Vantas promotions. Our commercial organization consisted of 41 individuals at December 31, 2005. We expect our selling and marketing expense to increase in future periods as we continue to grow our commercial organization and marketing activities in support of our lead product, Vantas.

*General and Administrative Expense.* General and administrative expense was $5.5 million for the year ended December 31, 2005, and $5.9 million for the year ended December 31, 2004. The decrease from 2004 to 2005 was attributable to a decrease in stock-based compensation. For the years ended December 31, 2005 and 2004, general and administrative expense included a stock-based compensation charge of ($0.3) million and $2.3 million, respectively. Without stock-based compensation expense, general and administrative expenses increased by approximately

$2.2 million from 2004 to 2005 because of hiring

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of additional personnel, increased regulatory fees, increased legal fees associated with pursuing and maintaining patent protection for our product candidates and other corporate matters, increased accounting fees relative to the increased size of our business and the scope of the audit, bad debt expense and other professional services required to support the hiring of personnel.

*Stock-Based Compensation.* We recorded non-cash compensation charges of $164,000 and $51,000 for the years ended December 31, 2005 and 2004, respectively, relative to stock options granted to non-employees. In December 2003, the exercise price of all options issued prior to that date were amended to $3.00, the estimated fair market value at that date. In connection with this re-pricing of grants and in accordance with FASB Interpretation ( FIN ) No. 44, the re-priced options will be accounted for as variable from the date of the modification to the date the options are exercised, forfeited, or expire. As a result, we recorded stock-based compensation of ($770,000) and $3.0 million for the years ended December 31, 2005 and 2004, respectively. Under SFAS 123R, which we adopted on January 1, 2006, there will be no additional compensation expense for these re-priced options as the vesting is complete and the requisite service period has ended.

The years ended December 31, 2005 and 2004 stock-based compensation charges also include stock-based compensation of $243,000 and $73,000, respectively, for stock options granted in 2005 and 2004 at prices below the deemed fair value on the option grant dates.

Total stock-based compensation expense (benefit) is included in the following line items in the statement of operations:

| | Year Ended December 31, | |
|---|---|---|
| | 2005 | 2004 |
| | (In thousands) | |
| General and administrative | $ (331) | $ 2,278 |
| Sales and marketing | 1 | 580 |
| Research and development | (37) | 297 |
| Cost of product sales | 4 | |

*Net Interest Income (Expense).* Net interest income (expense) was $49,000 for the year ended December 31, 2005 and ($6,000) for the year ended December 31, 2004. The variance was primarily attributable to slightly greater cash balances, improved cash management and less borrowing under capital leases.

*Income Taxes.* We have incurred net operating losses since inception. However, in 2005 we generated taxable income as a result of certain temporary and permanent differences between book income and taxable income. As a result we recorded an alternative minimum tax provision of $20,000 for federal purposes and $55,000 for state taxes.

Our deferred tax assets primarily consist of net operating loss carryforwards and research and development tax credits. We have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As of December 31, 2005, we had federal net operating loss carryforwards of approximately $19.4 million. These federal loss carryforwards will begin expiring in 2022 for federal purposes. Annual limitations may result in the expiration of net operating loss and credit carryforwards before they are used. Under the provisions of the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income.

***Comparison of Years Ended December 31, 2004 and 2003***

*Net Product Sales.* After receiving FDA approval in October 2004 for our lead product Vantas, we commenced commercial sales in November 2004. Net sales for the year ended December 31, 2004 were $5.5 million. We sold 2,187 units of Vantas at an average net selling price of $2,520. Net sales for the year ended December 31, 2003 were $7,000 and were completely derived from the sale of certain polymer products.

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*Licensing Revenue.* During the year ended December 31, 2003 through September 2004, we did not recognize any licensing revenue, as we were attempting to eliminate the cross licensing arrangement we have with Hydron Technologies. During this time, no licensing fees were paid to us. In 2004, back fees of $135,000 were paid, as an agreement with Hydron Technologies to terminate the cross licensing agreement could not be reached.

*Cost of Product Sales.* Our cost of product sales for the year ended December 31, 2004 was $0.6 million resulting in a gross margin of 89%. Such gross margin included the benefit of the sale of units that were partially manufactured prior to FDA approval and, as such, were previously partially expensed. The cost of product sales calculation includes an accrued royalty expense of $307 thousand for the year ended December 31, 2004. Through October 2004, all manufacturing costs were included in research and developments costs. There were no sales for the year ended December 31, 2003 that were subject to a royalty. For the year ended December 31, 2003, there was no cost of product sales, as the value of the polymer products were written off in prior years.

*Research and Development Expense.* Research and development expense for the years ended December 31, 2004 and 2003 was $6.4 million and $5.2 million, respectively. The 21.9% increase from 2003 to 2004 was primarily attributable to manufacturing costs of Vantas through October 2004, and a stock-based compensation charge of $297,000.

Expenses related to clinical trials pursuant to contracts with research institutions and clinical research organizations represented 24% of our total research and development expenses in 2004 and 55% of our research and development expenses in 2003.

*Selling and Marketing Expense.* Selling and marketing expense for the years ended December 31, 2004 and 2003 was $5.0 million and $0.5 million, respectively. The increase in 2004 over 2003 was primarily the result of expenses related to the launch of our lead product Vantas in November 2004. We hired a national sales force consisting of approximately thirty experienced individuals. In addition, marketing expense was increased due to the promotion of Vantas and a stock-based compensation charge of $580 thousand.

*General and Administrative Expense.* General and administrative expense was $5.9 million for 2004, and $1.8 million for 2003. The increase from 2003 to 2004 was primarily attributable to a stock-based compensation charge of $2.3 million, the hiring of additional personnel, increased legal fees associated with pursuing and maintaining patent protection for our product candidates and other corporate matters, accounting fees relative to our expanding business, and other professional services required to support the hiring of personnel.

*Stock-Based Compensation.* We recorded non-cash compensation charges of $51,000 and $3,000 in 2004 and 2003, respectively, relative to non-employee stock options. In December 2003, the exercise price of all options issued prior to that date were amended to $3.00, the estimated fair market value at that date. In connection with the grant of stock options to employees, we recorded stock-based compensation of $3.0 million in 2004 which was related to a repricing of grants made in 2002. In accordance with FIN No. 44, the re-priced options will be accounted for as variable from the date of the modification to the date the accruals are exercised, forfeited, or expire.

The 2004 stock-based compensation charge also includes stock-based compensation of $73,000 for stock options granted in 2004 at prices below the deemed fair value on the option grant dates. The stock-based compensation is included in the following line items in the statement of operations (in thousands):

| | |
|---|---|
| General and administration | $ 2,278 |
| Sales and marketing | 580 |
| Research and development | 297 |

*Net Interest Income (Expense).* Net interest income was ($6,000) in 2004 and net interest expense was $13,000 in 2003. The variance was primarily attributable to fluctuations in our average cash balances and lower interest rates.

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*Income Taxes.* We have incurred net operating losses since inception and, consequently, have not recorded any federal or state income tax benefit. In 2004, the New Jersey Economic Development Authority approved our application to sell New Jersey State income tax benefits under the New Jersey Technology Tax Transfer Program. During the fourth quarter of 2004, we recognized $0.2 million from the sale of State of New Jersey income tax benefits. The program requires that we maintain certain employment levels in New Jersey and that the proceeds from the sale of the tax benefits be spent in New Jersey.

Our deferred tax assets primarily consist of net operating loss carryforwards and research and development tax credits. We have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain.

**Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through the net proceeds from private and public placements of our equity securities. As of December 31, 2005, we had received net proceeds of approximately $33 million from the issuance of our series A, B, and C convertible preferred stock. In February 2006, we completed our initial public offering of our common stock in which we issued approximately 3.9 million shares and received approximately $34.8 million in gross proceeds. After expenses, we expect the net proceeds from our initial public offering to be approximately $30.3 million.

As of December 31, 2005, cash and cash equivalents were $2.3 million, compared to $5.1 million as of December 31, 2004.

Net cash provided by operating activities was $0.3 million for the year ended December 31, 2005. Operating cash flows in the year ended December 31, 2005 primarily consisted of an increase in accrued expenses, collections of accounts receivable and collections of monies related to deferred revenue, offset by the increase in prepaid expenses, the building of inventory and the reduction in accounts payable.

Net cash used in investing activities was $3.0 million for the year ended December 31, 2005. The primary investing activities for the year ended December 31, 2005 were related to a $7.5 million construction project to increase our capacity, plus equipment for the increase in production demand. We expect to use an additional $5.5 million of funds in 2006 to complete the expansion project.

Net cash used in financing activities was $4,000 for the year ended December 31, 2005. Cash provided by financing activities for the year ended December 31, 2005 was primarily related to proceeds from our line of credit offset by costs that were incurred in connection with our line of credit and our initial public offering.

In October 2005, we entered into a two-year, $7.5 million line of credit with Merrill Lynch Capital. Under the line of credit, the amount we may borrow at any given time is dependent upon our accounts receivable balance and related aging of such accounts. Borrowings under the line of credit bear an initial interest rate at the sum of the one-month LIBOR rate plus 3.75%. We are subject to certain covenants under the credit agreement. These covenants restrict our ability to incur additional debt, grant liens, carry out mergers, acquisitions and asset sales, make investments and place limitations on our ability to pay dividends or make other restricted distributions. In addition, we will be required to maintain a minimum fixed charge coverage ratio. In connection with the credit agreement, we have pledged all of our assets, with the exception of intellectual property, to Merrill Lynch. As of December 31, 2005, we had $1.5 million outstanding under the line of credit. In February 2006, we used a portion of the net proceeds from our initial public offering to repay amounts outstanding under our line of credit.

We anticipate that cash flows from sales of Vantas will reduce our need for additional financing. We expect our cash requirements to continue to increase in the foreseeable future as we continue to sponsor additional clinical trials, seek regulatory approvals of, and develop, manufacture and market our current product candidates. As we continue to expand our commercial organization to include the development of our field sales force, expand our research and development efforts and pursue additional opportunities, we anticipate significant cash requirements for hiring of personnel, capital expenditures and investment in additional internal systems and infrastructure.

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The amount and timing of cash requirements will depend on market acceptance of our lead product, Vantas, and regulatory as well as market acceptance of our product candidates, if any, and the resources we devote to researching, developing, formulating, manufacturing, commercializing and supporting our product candidates, and our ability to enter into third-party collaborations.

We believe that our existing cash, the cash generated from our initial public offering, cash generated from future sales of Vantas, and our line of credit will be sufficient to fund our operations for at least the next 12 months. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities. In addition, we may receive revenue from our sublicense agreements with Paladin Labs Inc., Key Oncologics (Pty) Ltd., BioPro Pharmaceutical, Inc. and Teva-Tuteur.

We may finance future cash needs through strategic collaboration agreements, the sale of other equity securities or debt financing. In fact, we established a line of credit in the October 2005 to partially fund the expansion of our manufacturing facility. We may not be successful in obtaining collaboration agreements or additional debt financing or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that in the future our existing cash resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or delay the launch of our product candidates.

**Intrinsic Value of Stock Options in the Twelve Months Prior to December 31, 2005**

The fair value of our common stock for options granted from January 1, 2005 through December 31, 2005 was originally estimated by our board of directors with input from management. We did not obtain contemporaneous valuations by an unrelated valuation specialist. However, to the extent available, we used third party indications of our enterprise value, such as the price at which we sold shares of our series C convertible preferred stock to unrelated parties.

In determining the fair value of our common stock at each grant date, our board of directors drew on the knowledge of its directors who have experience as venture capitalists specializing in early-stage life sciences companies and its directors who have experience with pharmaceutical and other life sciences companies. Factors considered by the directors in establishing the fair value of our common stock at the various grant dates have included the following: (i) the lack of a public market for our common stock and the considerable uncertainty of such a market developing; (ii) the uncertainty of our capital requirements prior to achieving product approvals, generating revenue and ultimately achieving profitability; (iii) the significant risks associated with our early stage of development, economic viability and market acceptance of our product candidates; (iv) our available cash, financial condition and results of operations; (v) the most recent sales of our convertible preferred stock to unaffiliated third parties; (vi) the preferential rights of the outstanding convertible preferred stock with respect to liquidation preferences, voting control and anti-dilution rights; and (vii) market conditions for life science company stocks in general.

As disclosed more fully in Note 10 to the financial statements included in Item 8 of this Form 10-K, we granted stock options with an exercise price of $6.00 during the three months ended March 31, 2005. During the following nine months ended December 31, 2005, we granted stock options at $12.00 per share. We determined that the fair value of our common stock increased from $6.00 to $12.00 per share during that period. The reasons for the difference between the $6.00 and $12.00 grant prices, the fair market values, and the initial public offering price of $9.00 per share are as follows:

During the quarter ended September 30, 2004, we raised $11.6 million through the issuance of our series C convertible preferred stock at $6.00 per share. Approximately 43% of the funds were received from outside, unrelated investors and as such the prices of the series C convertible preferred stock issued was used to determine our fair market value.

During the quarter ended December 31, 2004, our new drug application for Vantas was approved by the FDA. In addition, we hired a sales force and commenced sales of Vantas in the U.S. Initial

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sales of the product in November and December 2004 exceeded $5.0 million, which were above our expectations.

During the quarter ended March 31, 2005, we engaged investment bankers to commence our initial public offering process and we continued to experience strong sales performance.

During the quarter ended June 30, 2005, we continued to experience strong sales performance, however we experienced a product outage in mid-June (that lasted until early August), which resulted from issues with certain raw materials.

During the six months ended December 31, 2005, we recovered from the product outage and recorded total net revenue of $8.8 million, primarily from the sales of Vantas.

Based on the initial public offering price of $9.00, the intrinsic value of the in-the-money options outstanding at December 31, 2005, was $6.5 million, of which $3.6 million related to vested options and $2.9 million related to unvested options.

**Contractual Obligations and Commitments**

The following table summarizes our long-term annual contractual obligations as of December 31, 2005 (in thousands):

| | | Payments Due in | | | | | |
|---|---|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **2006** | **2007** | **2008** | **2009** | **2010** | **After 2010** |
| Operating leases | $ 13,000 | $ 1,342 | $ 1,319 | $ 1,319 | $ 1,315 | $ 1,399 | $ 6,306 |
| Capital lease obligations | 19 | 19 | | | | | |
| Line of credit | 1,525 | 1,525 | | | | | |
| Accrued royalties(1) | 438 | 438 | | | | | |
| | $ 14,982 | $ 3,324 | $ 1,319 | $ 1,319 | $ 1,315 | $ 1,399 | $ 6,306 |

(1) Royalty payments have only been determined for 2006 based upon 2005 sales. Future royalties have not been estimated as they are based on future sales levels.

In October 2005, we entered into a two year, $7.5 million line of credit with Merrill Lynch Capital. Under the line of credit, the amount we may borrow at any given time is dependent upon its accounts receivable balance and related aging of such accounts. Borrowings under the line of credit bear an initial interest rate at the sum of the one-month LIBOR rate plus 3.75%. We are subject to certain covenants under the credit agreement. These covenants restrict our ability to incur additional debt, grant liens, carry out mergers, acquisitions and asset sales, make investments and place limitations on our ability to pay dividends or make other restricted distributions. In addition, we will be required to maintain a minimum fixed charge coverage ratio. In connection with the credit agreement, we have pledged all of our assets, with the exception of intellectual property, to Merrill Lynch. As of December 31, 2005, we had $1.5 million outstanding under the line of credit. In February 2006, we used a portion of the net proceeds from our initial public offering to repay amounts outstanding under our line of credit.

**Off-balance Sheet Arrangements**

As of December 31, 2005, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not

materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

**Recent Accounting Pronouncements**

On December 16, 2004, FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS 123(R) supersedes APB No. 25 and amends SFAS No. 95 *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all

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share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Under SFAS 123(R), the options we granted in prior years as a non-public company (prior to the initial filing of our Registration Statement in March 2005) that were valued using the minimum value method, will not be expensed in 2006 or future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. Options granted as a public company will be expensed under the modified prospective method. We expect the adoption of SFAS 123(R) will have an impact of approximately $0.3 million on our results of operations. The adoption will not have an impact on our financial position or cash flows. The ultimate impact of the adoption can not be quantified as it is dependent on future option grants. We adopted SFAS 123(R) on January 1, 2006.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes* and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. This pronouncement applies to all voluntary changes in accounting principle, and revises the requirements for accounting for and reporting a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principle, unless it is impracticable to do so. This pronouncement also requires that a change in the method of depreciation, amortization, or depletion for long-lived, non-financial assets be accounted for as a change in accounting estimate that is effected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Statement does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. The adoption of this accounting pronouncement is not expected to have a material effect on the financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs an Amendment of ARB No. 43, Chapter 4*. The standard requires abnormal amounts of idle facility and related expenses to be recognized as current period charges and also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of this accounting pronouncement is not expected to have a material effect on the financial statements.

**Item 7A.** ***Quantitative and Qualitative Disclosures About Market Risk***

To date, all of our sales have been denominated in U.S. dollars, although we do conduct some clinical and safety studies with vendors located outside the U.S. All of these expenses are paid in U.S. dollars. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows. Accordingly, we believe that there is no material exposure to risk from changes in foreign currency exchange rates.

We hold no derivative financial instruments and do not currently engage in hedging activities.

Our exposure to interest rate risk is related to the investment of our excess cash into highly liquid financial investments with original maturities of three months or less. We invest in money market funds in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments. Due to the short term nature of our investments, we have assessed that there is no material exposure to interest rate risk arising from them.

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**Item 8.** ***Financial Statements and Supplementary Data***

**INDEX TO FINANCIAL STATEMENTS**

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**VALERA PHARMACEUTICALS, INC.**
**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders
Valera Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Valera Pharmaceuticals, Inc. as of December 31, 2005 and 2004, and the related statements of operations, shareholders deficit, and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the index as Item 15(b). These financial statements and schedule 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 financial position of Valera Pharmaceuticals, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. In our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

March 3, 2006
MetroPark, New Jersey

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**VALERA PHARMACEUTICALS, INC.**
**BALANCE SHEETS**
**(in thousands, except par value)**

| | December 31, 2005 | December 31, 2004 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,340 | $ 5,053 |
| Accounts receivable, net of allowances of $385 at December 31, 2005 and $91 at December 31, 2004 | 4,488 | 5,258 |
| Inventories, net | 3,191 | 1,365 |
| Prepaid and other current assets | 726 | 142 |
| Restricted cash | | 100 |
| Total current assets | 10,745 | 11,918 |
| Fixed assets, net | 4,194 | 1,704 |
| Deferred offering costs | 1,378 | |
| Deferred financing costs | 124 | |
| Security deposits | 91 | 45 |
| Total assets | $ 16,532 | $ 13,667 |
| **LIABILITIES AND SHAREHOLDERS DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,421 | $ 2,042 |
| Accrued liabilities | 4,607 | 1,552 |
| Note payable | 1,525 | |
| Deferred revenue current | 329 | |
| Capital lease obligations current | 18 | 18 |
| | 7,900 | 3,612 |
| Capital lease obligations long term | | 17 |
| Deferred revenue long term | 300 | |
| *Commitments and contingent liabilities* | | |
| Series A 6% Cumulative Convertible Preferred Stock, $0.001 par value; 7,000 shares authorized, 7,000 shares issued and outstanding; liquidation preference $7,598 and $7,161 at December 31, 2005 and 2004, respectively | 13,604 | 13,604 |
| Series B 10% Cumulative Convertible Preferred Stock, $0.001 par value; 24,500 shares authorized, 22,069 shares issued and outstanding; liquidation preference $20,221 and $18,363 at December 31, 2005, 2004, respectively | 15,082 | 15,082 |
| Series C 6% Cumulative Convertible Preferred Stock, $0.001 par value; 11,600 shares authorized, issued and outstanding; liquidation preference $12,590 and $11,866 at December 31, 2005 and 2004, respectively | 11,239 | 11,239 |
| Shareholders deficit: | | |
| | 2 | 2 |

| | | |
|---|---|---|
| Common stock, $0.001 par value; 30,000 shares authorized, 1,667 shares issued and outstanding at December 31, 2005 and 2004 | | |
| Additional paid-in capital | 8,696 | 9,961 |
| Deferred stock-based compensation | (630) | (1,533) |
| Accumulated deficit | (39,661) | (38,317) |
| Total shareholders deficit | (31,593) | (29,887) |
| Total liabilities and shareholders deficit | $ 16,532 | $ 13,667 |

See accompanying notes.

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**VALERA PHARMACEUTICALS, INC.**
**STATEMENTS OF OPERATIONS**
**(in thousands, except per share amounts)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| Net product sales | $ 26,798 | $ 5,511 | $ 7 |
| Licensing revenue | 34 | 135 | |
| Total net revenue | 26,832 | 5,646 | 7 |
| Operating costs and expenses: | | | |
| Cost of product sales | 5,966 | 608 | |
| Research and development | 5,930 | 6,376 | 5,230 |
| Selling and marketing | 10,754 | 5,025 | 509 |
| General and administrative | 5,500 | 5,897 | 1,838 |
| Total operating expenses | 28,150 | 17,906 | 7,577 |
| Loss from operations | (1,318) | (12,260) | (7,570) |
| Interest income | 70 | 65 | 27 |
| Interest expense | (21) | (71) | (14) |
| Loss before income taxes | (1,269) | (12,266) | (7,557) |
| Provision for (benefit from) income taxes | 75 | (243) | |
| Net loss | (1,344) | (12,023) | (7,557) |
| Deemed dividend | | (5,861) | (1,139) |
| Net loss attributable to common shareholders | $ (1,344) | $ (17,884) | $ (8,696) |
| Basic and diluted net loss attributable to common shareholders per share | $ (0.81) | $ (10.73) | $ (5.22) |
| Weighted average shares outstanding basic and diluted | 1,667 | 1,667 | 1,667 |

See accompanying notes.

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**VALERA PHARMACEUTICALS, INC.**
**STATEMENTS OF SHAREHOLDERS DEFICIT**
**For the Years Ended December 31, 2003, 2004 and 2005**
**(in thousands)**

| | Common Stock | | Additional Paid-in Capital | Deferred Compensation | Accumulated Deficit | Total Shareholders Deficit |
|---|---|---|---|---|---|---|
| | Shares | Par Value | | | | |
| Balance at December 31, 2002 | 1,667 | $ 2 | $ 5,270 | | $ (11,737) | $ (6,465) |
| Expense related to options granted to non-employees | | | 3 | | | 3 |
| Deemed dividend | | | | | (1,139) | (1,139) |
| Net loss | | | | | (7,557) | (7,557) |
| Balance at December 31, 2003 | 1,667 | 2 | 5,273 | | (20,433) | (15,158) |
| Deferred compensation related to stock options, net of cancellations | | | 4,637 | $ (4,637) | | |
| Amortization of deferred stock-based compensation | | | | 3,104 | | 3,104 |
| Expense related to options granted to non-employees | | | 51 | | | 51 |
| Deemed dividend | | | | | (5,861) | (5,861) |
| Net loss | | | | | (12,023) | (12,023) |
| Balance at December 31, 2004 | 1,667 | 2 | 9,961 | (1,533) | (38,317) | (29,887) |
| Exercise of stock options | | | 1 | | | 1 |
| Deferred compensation related to stock options, net of cancellations | | | (1,430) | 1,430 | | |
| Amortization of deferred stock based compensation | | | | (527) | | (527) |
| Expense related to options granted to non-employees | | | 164 | | | 164 |
| Net loss | | | | | (1,344) | (1,344) |
| Balance December 31, 2005 | 1,667 | $ 2 | $ 8,696 | $ (630) | $ (39,661) | $ (31,593) |

See accompanying notes.

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**VALERA PHARMACEUTICALS, INC.**
**STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| **Operating activities** | | | |
| Net loss | $ (1,344) | $ (12,023) | $ (7,557) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization | 502 | 257 | 153 |
| Amortization of deferred financing costs | 11 | | |
| Allowances for accounts receivable | 294 | 91 | |
| Expense related to options granted to non-employees | 164 | 51 | 3 |
| Stock-based compensation | (527) | 3,104 | |
| Change in assets and liabilities: | | | |
| Accounts receivable | 476 | (5,006) | |
| Other accounts receivable | | 574 | (573) |
| Inventories | (1,826) | (1,365) | |
| Restricted cash | 100 | (100) | |
| Prepaid and other current assets | (584) | (50) | (45) |
| Security deposits | (46) | 362 | (155) |
| Accounts payable | (621) | 856 | 201 |
| Accrued liabilities | 3,055 | 1,107 | 66 |
| Deferred revenue | 629 | | |
| Net cash provided by (used in) operating activities | 283 | (12,142) | (7,907) |
| **Investing activities** | | | |
| Capital expenditures | (2,992) | (1,610) | (148) |
| Net cash used in investing activities | (2,992) | (1,610) | (148) |
| **Financing activities** | | | |
| Net proceeds from issuance of common stock | 1 | | |
| Payment of capital lease obligations | (17) | (31) | (71) |
| Proceeds from note | 1,525 | | |
| Deferred offering costs | (1,378) | | |
| Deferred financing costs | (135) | | |
| Proceeds from officer loan | | 200 | |
| Repayment of officer loan | | (200) | |
| Net proceeds from issuance of convertible preferred stock | | 13,595 | 12,726 |
| Net cash (used in) provided by financing activities | (4) | 13,564 | 12,655 |
| Net (decrease) increase in cash and cash equivalents | (2,713) | (188) | 4,600 |
| Cash and cash equivalents at beginning of period | 5,053 | 5,241 | 641 |
| Cash and cash equivalents at end of period | $ 2,340 | $ 5,053 | $ 5,241 |

| | | | | |
|---|---|---|---|---|
| **Supplemental Disclosure of Cash Flow Information and Non-Cash Financing Activities** | | | | |
| Deemed dividends on preferred stock | | | $ 5,861 | $ 1,139 |
| Cash paid for interest | $ | 20 | $ 65 | $ 13 |
| Cash paid for income taxes | $ | 11 | | |

See accompanying notes.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS**

**1. Organization and Description of Business**

***Nature of Operations and Basis of Presentation***

Valera Pharmaceuticals, Inc. ( Valera or the Company ), is a specialty pharmaceutical company focused on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders. Valera was incorporated in the state of Delaware on May 30, 2000. On July 1, 2003, Valera changed its name from Hydro Med Sciences, Inc. Prior to May 30, 2000, the Company operated as a division of GP Strategies, and was included in their consolidated financial statements and federal tax returns. The Company s headquarters and manufacturing operations are located in Cranbury, New Jersey. In May 2005, the Company created Valera Pharmaceuticals Ireland Limited, a wholly owned subsidiary. The Company operates in a single business segment and through December 31, 2005 all of its product sales and assets were in the United States.

On February 7, 2006, the Company closed its initial public offering. The Company issued 3,862,500 shares at $9.00 per share resulting in net proceeds of $30.3 million after underwriters discounts and offering expenses. As a result of the initial public offering, all shares of the Company s preferred stock converted into 9,355,714 shares of common stock. Thus, immediately following the offering the Company had 14,885,296 common shares outstanding. In February 2006, the Company paid in full its note payable to Merrill Lynch in the amount of $1.5 million.

The Company incurred operating losses in each annual period from inception through December 31, 2005. The Company has been able to fund its cash needs to date through initial funding from one of its investors, GP Strategies Corporation, through the sale of its preferred stock, through the sales of its product and most recently through its initial public offering in February 2006.

Prior to November 2004, the Company operated as a development-stage company and did not generate any substantial revenue. In November 2004, the Company exited the development stage when it began selling its initial product Vantas.

***Reverse Stock Split***

On January 27, 2006, the Company effected a one-for-six reverse stock split. In connection with the reverse stock split, every outstanding six shares of the Company s common stock were replaced with one share of the Company s common stock. All references to common stock, common shares outstanding, average number of common shares outstanding and per share amounts in these consolidated financial statements and notes to consolidated financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-six reverse stock split on a retroactive basis. Effective upon consummation of the initial public offering, the Company reduced the number of common shares authorized for issuance to 30,000,000 and the number of preferred shares authorized for issuance to 5,000,000.

**2. Basis of Presentation and Significant Accounting Policies**

***Use of estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

***Reclassifications***

Certain reclassifications of prior year amounts have been made to conform to current year presentation.

***Cash and Cash Equivalents***

The Company considers all highly liquid instruments purchased with a maturity of three months or less to be cash and cash equivalents. At December 31, 2005, the Company had substantially all of its cash and cash equivalents deposited with one financial institution.

***Allowances for Accounts Receivable***

The Company maintains allowances for accounts receivable, which include an allowance for doubtful accounts related to the estimated losses that may result from the inability of its customers to make required payments. This allowance is determined based upon historical experience and any specific customer collection issues that have been identified. The Company began selling its first product on November 8, 2004 and has not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. Also included in the allowances for accounts receivable is an allowance for early payment discounts.

***Inventory***

Upon regulatory approval of Vantas, the Company s initial product, on October 12, 2004 the Company began capitalizing all costs associated with the manufacturing of Vantas. Inventory is valued at the lower of cost or market, on a first in first out ( FIFO ) basis. For all periods presented prior to October 12, 2004, the Company expensed all of its manufacturing costs as research and development.

***Restricted Cash***

Restricted cash at December 31, 2004 collateralized an outstanding letter of credit associated with the firm that manages some of the Company s credit card processing. This letter of credit was released during the second quarter of 2005.

***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years.

Leasehold improvements and capitalized leases are recorded at the fair market value at the inception of the leases and are amortized over the shorter period of their estimated useful life or the lease ranging from five to ten years. Amortization of assets recorded under capital leases is included in depreciation and amortization expense.

***Deferred Offering and Financing Costs***

Costs incurred in relation to the Company s initial public offering have been deferred as of December 31, 2005 and will be recognized and netted against gross proceeds raised in the offering that was completed in February 2006. Costs incurred in relation to the Company s line of credit were deferred and are being amortized over the two-year term of the loan.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

***Net Product Sales***

Net product sales are presented net of estimated returns and price adjustments, fast pay discounts, group purchasing fees and credit card fees.

***Royalties***

Licensing revenue from royalty arrangements are recorded on a cash basis due to the uncertainties regarding calculations, timing and collections. Royalty expense is recorded as the corresponding revenue is recognized. Royalty expense is included in cost of goods sold.

***Research and Development***

Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research for the Company.

***Shipping and Handling Costs***

Shipping and handling costs incurred for inventory purchases and product shipments are included within cost of product sales in the statements of operations.

***Stock-based Compensation***

As allowed by Statement of Financial Accounting Standards ( SFAS ) No. 123, Accounting for Stock-Based Compensation (SFAS 123), the Company has elected to continue to apply the intrinsic value-based method of accounting prescribed in Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees ( APB 25 ) and, accordingly, does not recognize compensation expense for stock option grants made at an exercise price equal to or in excess of the estimated fair value of the stock at the date of grant. The Company adopted SFAS 123(R) on January 1, 2006. Please refer to the recently issued accounting pronouncements in this footnote.

The Company accounts for options issued to non-employees under SFAS No. 123 and EITF Issue 96-18, Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services ( EITF 96-18 ). As such, the value of such options is periodically remeasured and income or expense is recognized during their vesting terms.

Had compensation cost for the Company s outstanding employee stock options been determined based on the Black-Scholes model for options granted since the Company became a public company (the initial filing of its Registration Statement in connection with its initial public offering in March 2005) or based on the minimum value for options granted as a non-public entity

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

under SFAS 123, the Company s net loss and basic and diluted net loss per share, would have been changed to the following pro forma amounts:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| | (in thousands) | | |
| Net loss attributable to common shareholders as reported | $ (1,344) | $ (17,884) | $ (8,696) |
| Add non-cash employee compensation as reported | (527) | 3,104 | |
| Deduct total stock-based employee compensation expense determined under fair value based method for all awards | (750) | (302) | (47) |
| SFAS 123 pro forma net loss attributable to common shareholders | $ (2,621) | $ (15,082) | $ (8,743) |
| Basic and diluted net loss attributable to common shareholders per share, as reported | $ (0.81) | $ (10.73) | $ (5.22) |
| Basic and diluted net loss attributable to common shareholders per share, SFAS 123 pro forma | $ (1.57) | $ (9.05) | $ (5.25) |

SFAS 123 pro forma information regarding net loss is required by SFAS 123. The fair value of the options was estimated at the date of grant using the minimum value pricing model with the following assumptions:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2005 | | | |
| | Public | Non-Public | 2004 | 2003 |
| Risk-free interest rate | 4.27% | 3.90% | 4.24% | 4.58% |
| Dividend yield | 0% | 0% | 0% | 0% |
| Volatility | 61% | 0% | 0% | 0% |
| Expected lives (in years) | 6.3 | 4.0 | 4.0 | 4.0 |

The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. Stock option grants are expensed ratably over their respective vesting periods.

***Deferred Stock Compensation***

During the year ended December 31, 2004, in connection with options granted to employees and directors, the Company recorded deferred stock compensation totaling $4.6 million. Included in this amount was $3.7 million, net of forfeitures, for options that were granted in 2001 and repriced in 2003. These repriced options are marked to market, using the estimated fair value of the Company s common stock at the end of each reporting period. Such deferred compensation for these repriced options is amortized over the remaining vesting period for the options. In addition, included in the total amount was $0.9 million, net of forfeitures, recorded for options that were granted below fair market value on the date of grant. The deferred compensation for these options will be recognized ratably

over the vesting period of these options, which is typically four years. During the year ended December 31, 2004, the Company amortized $3.1 million of deferred stock compensation expense, of which $3.0 million was for the repriced options and $0.1 million was for the options granted below fair market value.

During the year ended December 31, 2005, the Company recorded deferred stock compensation of $0.1 million, net of forfeitures, for options that were granted below fair market value on the date of grant. During the year ended December 31, 2005, the Company amortized $0.2 million of deferred stock compensation related to all options that were granted below fair market value at the date of grant. In addition, the Company marked to market the repriced options. In the Company s determination the fair

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

value of its common stock had declined from $16.20 per share during the first quarter of 2005 to $11.00 per share at December 31, 2005 because of the delay in the timing of its initial public offering, resulting lack of near term liquidity for such options, and the temporary disruption in supply of Vantas due to issues with the supply of histrelin, the active ingredient in Vantas. The result of this mark to market, was the reversal of $0.8 million of previously recorded stock option compensation.

***Income Taxes***

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

***Net Loss Per Share***

The Company computes its basic net loss per share in accordance with SFAS No. 128, Earnings per Share ( SFAS 128 ). Under the provisions of SFAS 128, basic net loss per common share ( Basic EPS ) is computed by dividing net loss by the weighted-average number of shares of common stock outstanding. Diluted net loss per share of common stock ( Diluted EPS ) is computed by dividing net loss by the weighted-average number of shares of common stock and dilutive common equivalent shares then outstanding as long as such impact would not be anti-dilutive. At December 31, 2005, common stock equivalent shares consisted of 9,279,399 incremental common shares issuable upon the conversion of preferred stock and the 1,265,849 shares of common stock issuable upon the exercise of stock options. Diluted EPS is identical to Basic EPS for the three years ended December 31, 2005 since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| | (In thousands, except per share amounts) | | |
| Numerator: | | | |
| Net loss | $ (1,344) | $ (12,023) | $ (7,557) |
| Deemed dividend | | (5,861) | (1,139) |
| Numerator for basic and diluted net loss attributable to common shareholders per share | $ (1,344) | $ (17,884) | $ (8,696) |
| Denominator: | | | |
| Denominator for basic and diluted net loss attributable to common shareholders per share weighted-average shares | 1,667 | 1,667 | 1,667 |
| Basic and diluted net loss attributable to common shareholders per share | $ (0.81) | $ (10.73) | $ (5.22) |

***Long-lived Assets***

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets ( SFAS 144 ), the Company assesses the recoverability of long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company

measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2005.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

***Concentration Risks***

The financial instrument that potentially subjects the Company to concentration of credit risk is cash. The Company places its cash with high-credit quality financial institutions. Concentrations of credit risk, with respect to this financial instrument, exist to the extent of amounts presented in the financial statements.

In 2005 and 2004, the Company generated all of its product sales from Vantas and all of the sales were in the U.S. In addition, for the years ended December 31, 2005 and 2004, one customer accounted for 6% and 9%, respectively, of the Company s net unit sales and 0% and 11.6% of its outstanding receivables at December 31, 2005 and 2004, respectively.

The Company is dependent on single suppliers for certain raw materials, including histrelin, the active pharmaceutical ingredient in Vantas. The Company does not have an agreement with the supplier of histrelin.

***Fair Value of Financial Instruments***

The carrying amounts of the Company s financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair values.

***Revenue Recognition***

The Company s revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin ( SAB ) No. 104, Revenue Recognition in Financial Statements ( SAB 104 ), and SFAS No. 48, Revenue Recognition When Right of Return Exists ( SFAS 48 ), which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the Securities and Exchange Commission. SFAS 48 and SAB 104 require that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on management s judgments regarding the fixed nature of the fee charged for services rendered and products delivered and the collectibility of those fees. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognition for those transactions will be delayed and the Company s revenue could be adversely affected.

Allowances have been recorded for any potential returns or adjustments in accordance with the Company s policy. Returns are allowed for damaged or outdated goods. As of December 31, 2005, we had a reserve of $339,000 for returns and adjustments, of which $51,000 related to sales made in 2004 and $288,000 related to sales made in 2005. During the year ended December 31, 2005, there was no change in return and adjustment reserve estimates related to the December 31, 2004 balance. As of December 31, 2004 and December 31, 2005, there was approximately $570,000 and $300,000 of Vantas, respectively, at distributors and there were no returns of these products subsequent to those dates.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

| | Distributors | Physicians | Total |
|---|---|---|---|
| | | (In thousands) | |
| Balance at 12/31/2003 | | | |
| Provision related to sales made in current period | $ 28 | $ 370 | $ 398 |
| Provision related to sales made in prior periods | | | |
| Returns and adjustments | | (54) | (54) |
| Balance at 12/31/2004 | 28 | 316 | 344 |
| Provision related to sales made in current period | 20 | 2,175 | 2,195 |
| Provision related to sales made in prior periods | | | |
| Returns and adjustments | (29) | (2,171) | (2,200) |
| Balance at 12/31/2005 | $ 19 | $ 320 | $ 339 |

**Customer Sales Urologists**

The Company s revenue from product sales is recognized when there is persuasive evidence an arrangement exists, the price is fixed in accordance with the Company s Customer Price List and/or approved exception pricing, or determinable from executed contracts, delivery to the customer has occurred and collectibility is reasonably assured. The Company uses contracts, purchase orders, sales orders directly taken by product specialists and sales order confirmations to determine the existence of an arrangement. Title to the product is taken upon delivery of the product, at which time risk of loss shifts to the customer. Billing does not take place until the day after shipment has occurred. The Company uses shipping documents and, the Company is provided with third party proof of delivery to verify delivery to its customers.

**Customer Sales Distributor Sales**

With respect to sales to distributors, revenue is recognized upon shipment, as the title, risks and rewards of ownership of the products pass to the distributors and the selling price of the Company s product is fixed and determinable at that point, as long as the Company believes the product will be sold by the distributor within one to three months from the shipment of the product by the Company to the distributor. If the Company believes the product will not be resold within three months, revenue will be deferred until the product is sold and the product held by the distributor will be classified as an asset on the Company s financial statements until it is sold by the distributor. At December 31, 2005 the Company deferred $329,000 of revenue and recorded $44,000 of assets related to product sold to distributors in 2005 that were not resold by distributors in accordance with the Company s policy. Payment is due based upon the agreed terms of the contract. The distributor is responsible for selling and distributing the product to its customer base and the rights for return are restricted to the Company s published return policy in effect for all customers.

In December 2004, the Company entered into two group purchasing agreement with International Physicians Networks, LLC d/b/a International Urology Network (IUN) which were subsequently amended in March and July of 2005. Under the agreements, IUN will sell to eligible members within their group purchasing organization. Under the terms of the agreement, pricing is fixed and subsequently adjusted to reflect the established price list published for IUN members. Allowances have been recorded for any potential returns in accordance with the Company s policy, as well as an estimate for uncollectible receivables.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

***Preferred Stock Dividends***

The Company records deemed dividends when modifications to its preferred stock are required in accordance with EITF 98-5 and EITF 00-27. Such modifications occurred in 2003 and 2004 resulting in deemed dividends of $1.1 million in 2003 and $5.9 million in 2004. There were no modifications in the year ended December 31, 2005.

***Recently Issued Accounting Pronouncements***

On December 16, 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ), which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation ( SFAS 123 ). SFAS 123(R) supersedes APB 25, and amends FASB Statement No. 95 Statement of Cash Flows . Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Under SFAS 123(R), the options the Company granted in prior years as a non-public company (prior to the initial filing of its Registration Statement in March 2005) that were valued using the minimum value method, will not be expensed in 2006 or future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. Options granted as a public company will be expensed under the modified prospective method. The Company expects the adoption of SFAS 123(R) will have an impact of approximately $0.3 million on the Company s results of operations. The adoption will not have an impact on the Company s financial position or its cash flows. The ultimate impact of the adoption can not be quantified as it is dependent on future option grants.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes* and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. This pronouncement applies to all voluntary changes in accounting principle, and revises the requirements for accounting for and reporting a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principle, unless it is impracticable to do so. This pronouncement also requires that a change in the method of depreciation, amortization, or depletion for long-lived, non-financial assets be accounted for as a change in accounting estimate that is effected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Statement does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. The adoption of this accounting pronouncement is not expected to have a material effect on the financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs an Amendment of ARB No. 43, Chapter 4*. The standard requires abnormal amounts of idle facility and related expenses to be recognized as current period charges and also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of this accounting pronouncement is not expected to have a material effect on the financial statements.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**3. Inventory**

Inventories consist of the following:

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| | (In thousands) | |
| Raw Materials | $ 463 | $ 708 |
| Work in process | 2,426 | 597 |
| Finished goods | 302 | 60 |
| | $ 3,191 | $ 1,365 |

The inventory balances at December 31, 2005 and 2004 are presented net of reserves of $1.2 million and $91,000, respectively, for certain raw materials and for certain products that failed to meet the Company s quality control specifications.

**4. Property and Equipment**

Property and equipment consists of the following:

| | | December 31, | |
|---|---|---|---|
| | Useful Lives | 2005 | 2004 |
| | | (In thousands) | |
| Laboratory equipment | 5 years | $ 1,531 | $ 1,390 |
| Furniture and fixtures | 7 years | 161 | 60 |
| Office equipment | 5 years | 108 | 42 |
| Computer equipment | 3 years | 417 | 326 |
| Computer software | 3 years | 200 | 159 |
| Construction in process | | 2,526 | |
| Leasehold improvements | 1-10 years | 625 | 599 |
| | | 5,568 | 2,576 |
| Less accumulated depreciation and amortization | | (1,374) | (872) |
| Fixed assets, net | | $ 4,194 | $ 1,704 |

Depreciation and amortization expense was $502,000, $257,000 and $153,000, for the years ended December 31, 2005, 2004 and 2003, respectively. There were fixed assets totaling $68,000 at December 31, 2005 and $162,000 at December 31, 2004 subject to capital lease obligations with accumulated amortization of $54,000 and $134,000 as of December 31, 2005 and 2004, respectively.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**5. Accrued Liabilities**

Accrued liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| | (In thousands) | |
| Accrued royalties | $ 396 | $ 307 |
| Accrual for sales returns and adjustments | 339 | 344 |
| Accrued auditing fees | 251 | 133 |
| Accrued distributor chargebacks | 621 | |
| Accrued legal fees | 769 | 20 |
| Accrued marketing expenses | 316 | 25 |
| Accrued compensation, bonus and benefits | 587 | 411 |
| Accrued commissions | 451 | 246 |
| Accrued printing fees | 254 | |
| Accrued income taxes | 75 | |
| Accrued clinical fees | 312 | |
| Accrued other | 236 | 66 |
| | $ 4,607 | $ 1,552 |

**6. Capital Lease Obligations**

The minimum future lease payments related to capital leases at December 31, 2005 are as follows (in thousands):

| | |
|---|---|
| 2006 | $ 19 |
| Total minimum lease payments | 19 |
| Less amount representing interest payments | 1 |
| Present value of minimum lease payments | $ 18 |

**7. Credit Line Agreement**

In October 2005, the Company entered into a two-year, $7,500,000 line of credit with Merrill Lynch Capital. Under the line of credit, the amount the Company may borrow at any given time is dependent upon its accounts receivable balance and related aging of such accounts. Borrowings under the line of credit bear an initial interest rate at the sum of the one-month LIBOR rate plus 3.75%. The Company is subject to certain covenants under the credit agreement. In connection with the credit agreement, the Company pledged all of its assets, with the exception of intellectual property, to Merrill Lynch. As of December 31, 2005, the Company had $1.5 million outstanding under the line of credit. The interest rate on the outstanding balance was 8.14% at December 31, 2005. In February 2006, the Company used a portion of the net proceeds from its initial public offering to repay amounts outstanding under the line of credit.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**8. Commitments**

The Company leases its facilities and certain equipment under noncancellable operating lease agreements. The minimum future lease payments under these leases are as follows (in thousands):

| | |
|---|---|
| Year ending December 31: | |
| 2006 | $ 1,342 |
| 2007 | 1,319 |
| 2008 | 1,319 |
| 2009 | 1,315 |
| 2010 | 1,399 |
| Thereafter | 6,306 |

Total rent expense was approximately $1.4 million, $0.7 million, and $0.4 million for the years ended December 31, 2005, 2004 and 2003, respectively. The Company s building lease expires March 31, 2015, and the equipment lease expires October 2006. The Company s building lease includes escalation clauses that go into effect in 2009 and 2010, which will result in greater rent expense from 2009 to 2015. The Company records rent expense on a straight-line basis over the term of the lease. The Company has two 5-year renewal options under its building lease.

The Company is a party to certain agreements that require the Company to pay royalties to third parties based on certain net product sales. For the years ended December 31, 2005 and 2004, the Company incurred royalty expense of $1.3 million and $0.3 million, respectively. Future royalties are dependent on future sales levels.

**9. Capitalization**

***Reverse Stock Split***

On January 27, 2006, the Company effected a one-for-six reverse stock split. In connection with the reverse stock split, every outstanding six shares of the Company s common stock were replaced with one share of the Company s common stock. All references to common stock, common shares outstanding, average number of common shares outstanding and per share amounts in these consolidated financial statements and notes to consolidated financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-six reverse stock split on a retroactive basis. Effective upon consummation of the initial public offering, the Company reduced the number of common shares authorized for issuance to 30,000,000 and the number of preferred shares authorized for issuance to 5,000,000.

***Common Stock***

The Company had 1,667,082 shares of common stock outstanding at December 31, 2005 and its par value was $0.001. The Company is authorized to issue 30,000,000 shares of common stock with a par value of $0.001 per share. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

In February 2006, the Company closed its initial public offering in which it issued 3,862,500 shares of its common stock at $9.00 per share. In conjunction with this offering all of the Company s preferred stock converted into 9,355,714 shares of common stock. As a result, the Company had 14,885,296 shares of common stock outstanding after the closing its initial public offering.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

Holders of shares of the Company s common stock are entitled to one vote for each share held of record on all matters to be voted on by stockholders. There is no cumulative voting with respect to the election of directors. The holders of the Company s common stock are entitled to receive dividends when, as and if declared by the board of directors out of funds legally available therefore subject to the rights of any class of stock having a preference as to dividends. Under our credit agreement with Merrill Lynch Capital, we agreed to not declare or pay any cash dividends.

In the event of a liquidation, dissolution or winding up of us, the holders of the Company s common stock are entitled to share ratably in all assets remaining available for distribution to them after payment of liabilities and after provision has been made for each class of stock, if any, having preference over the common stock. Holders of common stock have no conversion, preemptive or other subscription rights, and there are no redemption provisions applicable to the common stock. The rights, preferences and privileges of holders of common stock are subject to and may be affected by, the rights of the holders of any shares of preferred stock that we may designate and issue in the future.

***Convertible Preferred Stock***

At December 31, 2005, the Company was authorized to issue 43,100,000 shares of $0.001 par value convertible preferred stock of which 7,000,000 shares had been designated Series A Preferred Stock, 24,500,000 shares had been designated Series B Preferred Stock and 11,600,000 shares had been designated Series C 6% Cumulative Convertible Preferred Stock ( Series C Preferred Stock ). Such preferred stock was subject to the following rights and privileges:

*Voting*

Preferred stockholders were entitled to cast the number of votes equal to the number of shares of common stock into which such shares of Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock (together referred to as the Convertible Preferred Stock ) could then be converted and had full voting rights and powers equal to the voting rights and powers of the common stock on all matters submitted to the stockholders.

*Dividends*

The Convertible Preferred Stock was entitled to receive dividends on an as-converted basis with shares of common stock when, as and if declared by the Board of Directors out of funds legally available therefore.

In addition to the foregoing provision, each share of Series A Preferred Stock and Series C Preferred Stock accrued dividends at the rate of 6% of its respective Preferred Stock Stated Value, and each share of the Series B Preferred Stock accrued dividends at the rate of 10% of the Series B Stated Value per share (as such stated value was adjustable for any stock dividends, combinations or splits with respect to such shares) per annum, which accrued daily based on a 360-day year, payable when and as declared by the Board of Directors of the Company out of funds legally available. The Series A Preferred Stock dividends only accrued from the date of the first issuance of the shares of Series C Preferred Stock, August 16, 2004. No dividends were declared by the Board of Directors through December 31, 2005. Under our credit agreement with Merrill Lynch Capital, we agreed to not declare or pay any cash dividends.

*Liquidation*

In the event of any voluntary or involuntary liquidation, sale, dissolution or winding up of the Company, subject to the rights of the series of preferred stock that may from time to time have come into

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

existence, the holders of the Convertible Preferred Stock then outstanding were entitled to receive, out of the assets of the Company available for distribution to its stockholders, before any payment made in respect of the common stock, an amount per share of Convertible Preferred Stock equal to the Series A Stated Value, Series B Stated Value or the Series C Stated Value, as the case may be, plus all accrued but unpaid dividends thereon to the date fixed for distribution (the Convertible Preferred Liquidation Amount ). If upon the liquidation, dissolution or winding up of the Company, the assets of the Company available for distribution to its stockholders were insufficient to pay the full Convertible Preferred Liquidation Amount, then all the assets so available for distribution to its stockholders were to be distributed ratably to the holders of the Convertible Preferred Stock in proportion to the aggregate amounts that would have been payable to such holders if the assets of the Company were sufficient to pay the full amount to which they were entitled pursuant to this section and nothing more.

*Conversion*

Each share of Convertible Preferred Stock was convertible, at the option of the holder thereof, at any time and from time to time after the issuance of such share, at the office of the Company or any transfer agent for such stock, into fully paid and nonassessable shares of common stock of the Company. The number of shares of common stock to which a holder of Convertible Preferred Stock was entitled upon conversion was the product obtained by multiplying the Convertible Preferred Conversion Rate then in effect by the number of shares of Convertible Preferred Stock, being converted. The Convertible Preferred Conversion Rate in effect at any time for conversion of any series of the Convertible Preferred was the quotient obtained by dividing (i) the Convertible Preferred Stated Value for such series of Convertible Preferred Stock plus an amount equal to all accrued and unpaid dividends per share of such Convertible Preferred Stock as of the conversion date (the Dividend Amount ) by (ii) the Conversion Price for such series of Convertible Preferred Stock; provided, however that a holder of Convertible Preferred Stock was permitted to elect to receive all or a portion of the Dividend Amount in cash upon conversion of the Convertible Preferred Stock, in which event the portion of the Dividend Amount paid in cash was not to be added to the Convertible Preferred Stated Value in determining the Conversion Rate for such holder of Convertible Preferred Stock. The initial conversion price for the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock was $3.00, $4.35 and $6.00 respectively.

The initial Conversion Price for each series of Convertible Preferred Stock was adjustable from time to time in accordance with the agreement. In accordance with the anti-dilution feature in the Series A Preferred Stock, there was a deemed dividend for the years ended December 31, 2003 and 2004 of $1.1 million and $5.9 million, respectively. Conversion could occur automatically concurrent with a firm underwritten public offering of not less than $25.0 million, or on the date specified by vote or written consent or agreement of holders of at least 80% of the then outstanding shares of Convertible Preferred Stock voting together as a class on an as-if-converted basis.

The following table summarizes certain information about the Convertible Preferred Stock for each series at December 31, 2005 (in thousands):

| | Authorized Shares | Issued and Outstanding | Liquidation Preference | Shares Reserved for Conversion | Undeclared Accrued Dividends |
|---|---|---|---|---|---|
| Series A | 7,000 | 7,000 | $ 7,598 | 2,533 | $ 598 |
| Series B | 24,500 | 22,069 | 20,221 | 4,649 | 4,221 |
| Series C | 11,600 | 11,600 | 12,590 | 2,098 | 990 |
| | 43,100 | 40,669 | $ 40,409 | 9,280 | $ 5,809 |

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

In February 2006, the Company completed its initial public offering in which the Company issued 3,862,500 shares of its common stock at $9.00 per share. In conjunction with this offering all of the Company s preferred stock converted into 9,355,714 shares of common stock. As a result we had 14,885,296 shares of common stock outstanding after the closing the offering. Further, on February 6, 2006, the Company filed an amended and restated Certificate of Incorporation that removed the designations, rights and obligations of the convertible preferred stock described in this note to the financial statements.

**10. Stock Options**

In September 2002, the Company adopted the Valera Pharmaceuticals Equity Incentive Plan, which provides for the granting of nonqualified and incentive stock options, as defined by the Internal Revenue Code, to key employees of the Company at prices not less than the fair market value at the date of grant for incentive stock options granted. The option price for each share of common stock for non-qualified options is determined by the Board of Directors and may be more or less than the fair market value of a share of common stock. The options granted by the Company generally have a life of ten years and vest over a period as determined by the Board of Directors, which is typically four years.

In March 2005, the Company increased the number of shares of its common stock reserved for issuance pursuant to the Company s Equity Incentive Plan to 1,833,333.

In December 2003, the exercise price of all options issued prior to 2003 was amended to $3.00, the fair market value at that time. In accordance with FASB Interpretation ( FIN ) No. 44, the repriced options were accounted for as variable from the date of the modification to the date the options are exercised, forfeited, or expire. Under SFAS 123R, which the Company adopted on January 1, 2006, there will be no additional compensation expense for these repriced options as the vesting is complete and the requisite service period has ended. In connection with these options, the Company recorded $3.7 million, net of forfeitures, in deferred stock-based compensation in 2004. Non-cash compensation expense related to these repriced options was $3.0 million in 2004 and $(0.8) million in 2005.

The following table summarizes option activity for the Company s common stock for the years ended December 31, 2003, 2004, and 2005:

| | Common Stock Options | Weighted-Average Exercise Price |
|---|---|---|
| Outstanding at December 31, 2002 | 286,750 | |
| Granted | 489,276 | $ 3.00 |
| Exercised | | |
| Forfeited | (3,833) | $ 3.00 |
| Outstanding at December 31, 2003 | 772,193 | |
| Granted | 353,832 | $ 3.00 |
| Exercised | | |
| Forfeited | (6,600) | $ 3.00 |
| Outstanding at December 31, 2004 | 1,119,425 | |
| Granted | 193,594 | $ 11.55 |
| Exercised | (417) | $ 3.00 |
| Forfeited | (46,753) | $ 4.45 |

| | |
|---|---|
| Outstanding at December 31, 2005 | 1,265,849 |

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about vested stock options outstanding:

| | December 31, | | |
|---|---|---|---|
| | 2003 | 2004 | 2005 |
| Vested Stock Options | 141,464 | 334,164 | 605,032 |
| Weighted average exercise price | $ 3.00 | $ 3.00 | $ 3.11 |

The following table summarizes information about stock options outstanding at December 31, 2005:

| Range of Exercise Prices | Options Outstanding | Options Vested | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price |
|---|---|---|---|---|
| $ 3.00 | 1,081,007 | 597,532 | 7.9 | $ 3.00 |
| $ 6.00 | 12,666 | | 9.1 | $ 6.00 |
| $ 12.00 | 172,176 | 7,500 | 9.6 | $ 12.00 |

The weighted average fair value of options granted and outstanding as of December 31, 2005 was $4.25.

In connection with the granting of employee stock options below fair market value in 2004 and 2005, the Company recorded deferred compensation of $0.9 million and $0.1 million, respectively, net of forfeitures. Deferred compensation is being amortized over the vesting period of the options resulting in non-cash stock-based compensation expense of $0.1 million and $0.2 million for the years ended December 31, 2004 and 2005, respectively. There was no deferred compensation recorded in prior years.

For the years ended December 31, 2003, 2004 and 2005 the Company granted a total of 10,833, 5,000 and 10,833 respectively, in stock options to certain consultants. The Company has accounted for these options in accordance with EITF 96-18 and, accordingly, recorded non-cash expense of $3,000, $51,000 and $164,000 for the years ended December 31, 2003, 2004 and 2005, respectively.

During the twelve month period ended December 31, 2005, the Company granted stock options with exercise prices as follows:

| Grants Made During Quarter Ended | Number of Options Granted | Weighted Average Exercise Price | Weighted Average Fair Value per Share | Weighted Average Intrinsic Value per Share |
|---|---|---|---|---|
| March 31, 2005 | 14,499 | $ 6.00 | $ 16.20 | $ 10.20 |
| June 30, 2005 | 143,594 | $ 12.00 | $ 12.00 | $ |
| September 30, 2005 | 4,334 | $ 12.00 | $ 12.00 | $ |
| December 31, 2005 | 31,167 | $ 12.00 | $ 12.00 | $ |

The intrinsic value per share is being recognized as compensation expense over the applicable vesting period (which equals the service period).

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

## 11. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amount used for income tax purposes. The Company s deferred tax assets relate primarily to net operating loss carryforwards, research and development tax credits, and non-cash stock-based compensation. At December 31, 2005 and 2004, a valuation allowance was recorded to fully offset the net deferred tax asset. The change in the valuation allowance for the years ended December 31, 2005 and 2004 was approximately $0.6 million and $4.9 million, respectively. Significant components of the Company s deferred tax assets were as follows:

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| | (in thousands) | |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 7,770 | $ 8,050 |
| Research and development credits | 1,423 | 1,131 |
| Stock-based compensation | 904 | 1,085 |
| Amortization of stock-based compensation | 126 | 156 |
| Non-employee stock compensation | 87 | 22 |
| Other | 1,049 | 353 |
| Total gross deferred tax assets | 11,359 | 10,797 |
| Deferred tax liabilities: | | |
| Depreciation and amortization | 134 | 151 |
| Total gross deferred tax liabilities | 134 | 151 |
| Valuation allowance for deferred tax assets | (11,225) | (10,646) |
| Net deferred tax assets | $ | $ |

As of December 31, 2005, the Company had federal net operating loss carryforwards of approximately $19.4 million. The net operating loss carryforwards will expire at various dates beginning in 2022, if not utilized. The Company had research and development tax credit carry forwards at December 31, 2005, of approximately $1.4 million, which will begin to expire in 2022. If an ownership change, as defined under Internal Revenue Code Section 382, occurs the use of these carry forwards may be subject to limitation.

Provision for (benefit from) income tax consists of:

| | For the Year December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| | (in thousands) | | |
| Federal | $ 20 | $ | $ |

| | | | |
|---|---|---|---|
| State | 55 | (243) | |
| Total | $ 75 | $ (243) | $ |

In 2004, the New Jersey Economic Development Authority approved the Company s application to sell New Jersey State income tax benefits under the New Jersey Technology Tax Transfer Program (the Program ). During the fourth quarter of 2004, the Company recognized $243,000 from the sale of State of New Jersey income tax benefits. The Program requires that the Company maintain certain employment levels in New Jersey and that the proceeds from the sale of the tax benefits be spent in New Jersey.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company has incurred net operating losses since inception. However, in 2005 the Company generated taxable income as a result of certain temporary and permanent differences between book income and taxable income. As a result, the Company recorded an alternative minimum tax provision of $20,000 for federal purposes and $55,000 for state purposes.

A reconciliation of the statutory tax rates and the effective tax rates for the periods ended:

| | December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| Statutory rate | (34)% | (34)% | (34)% |
| State and local income taxes (net of federal tax benefit) | (3) | (6) | (6) |
| Research and development tax credits | (11) | (2) | (4) |
| Alternative minimum tax | 2 | | |
| Other permanent items | 6 | | |
| Change in valuation allowance | 46 | 42 | 44 |
| | 6% | 0% | 0% |

**12. Related Party Transactions**

In June 2004, David S. Tierney, the Company s President and CEO, loaned the Company $200,000 at prime plus 1% above the UBS Margin Interest Rate. The loan was repaid in November 2004. Interest in the amount of $2,000 is included in interest expense for 2004.

In August 2004, in connection with the sale of the Company s Series C Convertible Preferred Stock, the Company paid Sanders Morris Harris, Inc. a fee of $280,000 for its services as placement agent. James C. Gale, the Chairman of the Company s board of directors, is a managing director of Sanders Morris Harris, Inc.

Sanders Morris Harris, Inc. and its affiliates own approximately 40% of BioPro Pharmaceutical, Inc. and over 90% of Alpex Pharma S.A., two companies that we have agreements with to distribute product and develop and market product, respectively. During 2005, we received a payment of $0.3 million from BioPro and we made payments of $0.4 million to Alpex.

**13. Defined Contribution Plan**

The Company sponsors a 401(k) plan for eligible employees. The Company s contributions to the plan are discretionary and are 50% of the employee s contribution, not to exceed 5% of total compensation. The total Company 401(k) contributions amounted to approximately $164,000, $55,000 and $49,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

**14. Acquisition of Product**

In September 2005, the Company entered into an agreement with Anthra Pharmaceuticals, Inc. to acquire certain assets of Anthra associated with its valrubicin business in the U.S. and Canada. If the transaction closes as planned, the Company will make: (i) installment payments totaling $0.6 million; (ii) additional payments of up to 13.5% of net sales depending upon the product s formulation, indication and market share; and (iii) certain milestone payments based upon achieving certain sales levels. Anthra s valrubicin business involved the manufacture and sale of valrubicin for use in the treatment of bladder cancer. The product was distributed in the U.S. and Canada by third party partners of Anthra. In the U.S., the product was distributed under the trademark Valstar. The product is not covered by any patents and its orphan drug status has expired.

Anthra s valrubicin product was taken off the market in 2002 due to a manufacturing problem and a lack of resources to address the problem. The Company has analyzed the manufacturing issues and believe

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

that it has determined the cause of, and a solution to, the problem. As such, the Company has agreed to acquire certain assets of Anthra required for the manufacture, marketing and sale of valrubicin in the U.S. and Canada including the NDA filed with the FDA, the drug master file, the Canadian regulatory submission and all data produced by or on behalf of Anthra in support of the NDA and other governmental approvals, or in any other scientific experiment or clinical trial relating to valrubicin. The acquisition is expected to close during the first quarter of 2006, subject to various conditions. The Company initiated discussions with the FDA in the fourth quarter of 2005 regarding the Company s plan to reintroduce the product into the U.S. market and in January 2006, the FDA accepted the Company s plan. The Company expects to address reintroduction of the product in Canada following reintroduction in the U.S. and expect distribution to be handled by the existing Canadian distributor.

The purchase price payable for the product consists of guaranteed payments, revenue sharing payments based on our sales and receipt of license fees and additional payments based on the Company s sales performance. Subject to certain exceptions, Anthra s indemnification obligations survive for two years after closing and are funded by setoff against the purchase price payable to Anthra under the agreement.

## 15. Selected Quarterly Financial Data (Unaudited)

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 |
| | (In thousands, except per share amounts) | | | |
| **2005** | | | | |
| Total net revenue | $ 7,695 | $ 10,286 | $ 3,678 | $ 5,173 |
| Cost of product sales | 1,023 | 2,951 | 809 | 1,183 |
| Total operating expenses | 5,972 | 8,777 | 6,805 | 6,596 |
| Income (loss) from operations | 1,723 | 1,509 | (3,127) | (1,423) |
| Provision for income taxes | 160 | 140 | (300) | 75 |
| Net income (loss) attributable to common shareholders | 1,577 | 1,382 | (2,808) | (1,495) |
| Basic net income (loss) attributable to common shareholders per common share | $ 0.95 | $ 0.83 | $ (1.68) | $ (0.90) |
| Diluted net income (loss) attributable to common shareholders per common share | $ 0.14 | $ 0.12 | $ (1.68) | $ (0.90) |

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 |
| | (In thousands, except per share data) | | | |
| **2004** | | | | |
| Total net revenue | $ | | $ 135 | $ 5,511 |
| Cost of product sales | | | | 608 |
| Total operating expenses | 2,018 | 3,540 | 3,704 | 8,644 |
| Loss from operations | (2,018) | (3,540) | (3,569) | (3,133) |
| Benefit for income taxes | | | | 243 |
| Net loss | (2,016) | (3,545) | (3,568) | (2,894) |

| | | | | |
|---|---|---|---|---|
| Net loss attributable to common shareholders | (2,016) | (3,641) | (9,333) | (2,894) |
| Basic and diluted net loss attributable to common shareholders per common share | $ (1.21) | $ (2.18) | $ (5.60) | $ (1.74) |

Diluted EPS is identical to basic EPS since common stock equivalent shares are excluded from the calculation, as their effect is anti-dilutive in all periods presented.

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**VALERA PHARMACEUTICALS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**16. Subsequent Events**

In February 2006, the Company closed its initial public offering in which the Company issued 3,862,500 shares of the Company s common stock at $9.00 per share. In conjunction with this offering all of the Company s preferred stock converted into 9,355,714 shares of common stock. As a result the Company had 14,885,296 shares of common stock outstanding after the closing the offering. In February 2006, the Company used a portion of the net proceeds from its initial public offering to repay amounts outstanding under the line of credit.

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**VALERA PHARMACEUTICALS, INC.**
**VALUATION AND QUALIFYING ACCOUNTS SCHEDULE**
**(in thousands)**

| | Balance at Beginning of Period | Charged to Cost and Expenses | Charged to Other Accounts | Deductions | Balance at End of Period |
|---|---|---|---|---|---|
| For the year ended December 31, 2005: | | | | | |
| Allowance for Sales Returns and Adjustments | $ 344 | $ 2,195 | | $ 2,200 | $ 339 |
| For the year ended December 31, 2004: | | | | | |
| Allowance for Sales Returns and Adjustments | | 398 | | 54 | 344 |
| For the year ended December 31, 2003: | | | | | |
| Allowance for Sales Returns and Adjustments | | | | | |
| For the year ended December 31, 2005: | | | | | |
| Allowance for Doubtful Accounts and Cash Discounts | $ 91 | $ 557 | | $ 263 | $ 385 |
| For the year ended December 31, 2004: | | | | | |
| Allowance for Doubtful Accounts and Cash Discounts | | 91 | | | 91 |
| For the year ended December 31, 2003: | | | | | |
| Allowanced for Doubtful Accounts and Cash Discounts | | | | | |
| For the year ended December 31, 2005: | | | | | |
| Tax Valuation Allowance | $ 10,646 | $ 579 | | | $ 11,225 |
| For the year ended December 31, 2004: | | | | | |
| Tax Valuation Allowance | 5,733 | 4,913 | | | 10,646 |
| For the year ended December 31, 2003: | | | | | |
| Tax Valuation Allowance | 2,521 | 3,212 | | | 5,733 |
| For the year ended December 31, 2005: | | | | | |
| Inventory Valuation Reserve | $ 91 | $ 1,083 | $ 138 | $ 114 | $ 1,198 |
| For the year ended December 31, 2004: | | | | | |
| Inventory Valuation Reserve | | 91 | | | 91 |

| | |
|---|---|
| For the year ended December 31, 2003: | |
| Inventory Valuation Reserve | |

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**Item 9.** ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosures***

None

**Item 9A.** ***Controls and Procedures***

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2005 and, based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective. Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the Securities Exchange Act ), is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B.** ***Other Information***

None

**Part III**

**Item 10.** ***Directors and Executive Officers of the Registrant***

The following sets forth information for each of our directors and executive officers as of March 1, 2006.

| Name | Age | Position |
|---|---|---|
| David S. Tierney, M.D. | 42 | President, Chief Executive Officer and Director |
| Andrew T. Drechsler | 34 | Chief Financial Officer and Secretary |
| Petr F. Kužma | 62 | Vice President of Research and Development |
| Pete J. Perron | 39 | Vice President of Sales |
| Matthew L. Rue, III | 55 | Vice President of Marketing and Commercial Development |
| James C. Gale | 56 | Chairman of the Board of Directors |
| David R. Dantzker, M.D. | 62 | Director |
| Jerome Feldman | 77 | Director |
| Hubert Huckel, M.D. | 74 | Director |
| Jeffrey M. Krauss | 49 | Director |
| Ogden R. Reid | 80 | Director |
| Howard Silverman | 70 | Director |
| John T. Spitznagel | 64 | Director |

*David S. Tierney, M.D.* joined us in August 2000 as our President and Chief Executive Officer. In December 2001, Dr. Tierney became a member of our board of directors. Prior to joining us, Dr. Tierney was president of Biovail Technologies, a division of Biovail Corporation, a Canadian drug delivery

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company, from January 2000 to August 2000. Prior to Biovail, Dr. Tierney spent three years at Roberts Pharmaceutical Corporation as senior vice president of drug development from March 1997 to January 2000. Prior to joining Roberts, Dr. Tierney spent eight years at Elan Corporation, plc, a pharmaceutical company, in a variety of management positions. Dr. Tierney currently serves as a director on the boards of Able Laboratories, a pharmaceutical company, and Catalyst Pharmaceutical Partners, a pharmaceutical company. Dr. Tierney received a medical degree from the Royal College of Surgeons in Dublin, Ireland and was subsequently trained in internal medicine.

*Andrew T. Drechsler* joined us in April 2005 as our Chief Financial Officer and Secretary. Prior to joining us, from May 2001 to April 2005, Mr. Drechsler served as controller of i-STAT Corporation, a point of care diagnostics company and a division of Abbott Laboratories subsequent to its acquisition in January 2004. He also served as controller for HydraWEB Technologies, a software development firm, from September 2000 to May 2001. From April 1997 to September 2000, Mr. Drechsler served in various senior financial positions at Biomatrix, a biotech company focused on the orthopedic and ophthalmic markets until the company was acquired by Genzyme in 2000. From August 1994 to April 1997, Mr. Drechsler was a senior associate with the public accounting firm Coopers & Lybrand LLP. Mr. Drechsler graduated magna cum laude from Villanova University with a B.S. in Accountancy. Mr. Drechsler obtained his qualification as a certified public accountant in the state of New Jersey.

*Petr F. Kužma* is our Vice President of Research and Development. Mr. Kužma has been with us since 1987 serving in various roles and became Vice President of Research and Development in March 2000. Mr. Kužma has over thirty years of experience in the polymer, medical device and pharmaceutical industries. He joined GP Strategies, our former parent and a global provider of training, e-Learning solutions, management consulting, engineering and simulation services in 1975. During his tenure at GP Strategies, he held numerous research and development positions of increasing scope and responsibility with various divisions of GP Strategies. Mr. Kužma received a M.S. in chemical engineering from Slovak University of Technology in Slovakia, a B.S. in chemistry from St. Peter s College, and a B.S. in chemical technology from the Institute of Industrial Chemistry in the Czech Republic.

*Pete J. Perron* joined us in April 2004 as our Vice President of Sales. Prior to joining us, Mr. Perron was at Ortho-McNeil Pharmaceutical, Inc., a Johnson & Johnson company from July 2001 to April 2004, where he served as product director for several brands, including two with combined annual sales in excess of $500 million, and as a regional business director responsible for overseeing several district managers and more than 75 sales representatives. Prior to Ortho-McNeil, Mr. Perron was product manager at G.D. Searle/ Pharmacia from October 1999 to July 2001. Mr. Perron received a B.A. and an M.S. in business communications from the University of North Texas.

*Matthew L. Rue, III* joined us as our Vice President of Marketing and Commercial Development in January 2002. Mr. Rue served as a consultant of ours from August 2000 to December 2001. Prior to joining us, Mr. Rue previously served as director of marketing, product manager, and consultant at Roberts Pharmaceuticals Corporation from 1996 to July 2000. Mr. Rue s expertise is in prescription marketing and product launches and he has launched or re-launched three prescription brands. Prior to joining Roberts, Mr. Rue served as an account supervisor at Cline, Davis & Mann, an advertising company, and was a senior product manager at Reed & Carnick, a specialty pharmaceutical firm, where he developed and launched numerous over-the-counter and prescription pharmaceuticals. Mr. Rue received a B.F.A. in English from Emerson College.

*James C. Gale* is the Chairman of our board of directors and has served as a member of our board of directors since December 2001. Mr. Gale is a managing director of Sanders Morris Harris, Inc., a national investment management and investment banking company and affiliate of several stockholders of ours, and is the managing partner of LOF Partners, an affiliate of Sanders Morris Harris that manages several stockholders of ours and has served in this capacity since 1998. From 1992 to 1998, Mr. Gale was head of investment banking at Gruntal & Co., L.L.C., a large brokerage and investment banking company. Prior to joining Gruntal, Mr. Gale originated and managed private equity investments for the Home Insurance Co., Gruntal s parent, from 1989 to 1992. Mr. Gale also serves on the board of directors of Relm Wireless Corporation.

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*David R. Dantzker, M.D.* has served as a member of our board of directors since June 2003. Dr. Dantzker has been a general partner at Wheatley Partners, L.P., a New York-based venture capital firm and one of our stockholders, since January 2001. He has served on the faculty and in leadership positions of four major research-oriented medical schools and has authored or co-authored 130 research papers and five textbooks. He is an internationally recognized expert in the area of pulmonary medicine and critical care. Prior to serving with Wheatley Partners, Dr. Dantzker served as chief executive officer of Redox Pharmaceuticals Corporation from November 2000 until October 2001. Dr. Dantzker served as Chief Executive Officer of Long Island Jewish Medical Center from October 2004 and President of North Shore LIJ Health System from October 1997 until may 2000. Dr. Dantzker is currently chairman of the board of directors of Versamed, Inc. and Q-RNA, Inc. and a director of CNS, Visionsense, Ltd., and Advanced Biohealing Inc.

*Jerome I. Feldman* has served as a member of our board of directors since January 2005. Mr. Feldman is chairman of the board of directors and chief executive officer of National Patent Development Corporation, the parent of one of our stockholders, MXL Industries, Inc., and a holding company with interests in optical plastics, paint and hardware distribution and pharmaceuticals. Mr. Feldman was the founder of GP Strategies Corporation, and from 1959 to 2005 served as its chief executive officer. He has also served as chairman of the board of directors of GP Strategies Corporation from 1999 to 2005. Mr. Feldman was president of GP Strategies from 1959 until 2001. Mr. Feldman is currently the Chairman of the Executive Committee of GP Strategies Corporation. He has been chairman of the board of directors of Five Star Products, Inc., a wholesale distributor of home decorating, hardware and finishing products, since 1994, a director of GSE Systems, Inc., a global provider of real-time simulation and training solutions, since 1994, and chairman of the board of directors of GSE since 1997. Mr. Feldman is also chairman of the New England Colleges Fund and a Trustee of Northern Westchester Hospital Center.

*Hubert E. Huckel, M.D.* has served as a member of our board of directors since January 2002. From 1964 until his retirement in December 1992, Dr. Huckel served in various positions with the Hoechst Group, an agri-chemical company. At the time of his retirement, he was chairman of the board of Hoechst-Roussel Pharmaceuticals, Inc., chairman and president of Hoechst-Roussel Agri-Vet Company and a member of the executive committee of Hoechst Celanese Corporation. Dr. Huckel currently serves as a director on the boards of Titan Pharmaceuticals, Inc., Thermogenesis Corporation, a biotechnology firm, Concordia Pharmaceuticals, Inc. and Catalyst Pharmaceutical Partners.

*Jeffrey M. Krauss* has served as a member of our board of directors since August 2004. Mr. Krauss has been a managing member of the Psilos Group, a New York-based venture capital firm since 2000 and one of our stockholders since August 2004. Prior to joining Psilos, Mr. Krauss spent ten years at Nazem & Company as a general partner of three venture capital funds from 1990 to 2000. Prior to joining Nazem, Mr. Krauss was an attorney at the law firm of Simpson Thacher & Bartlett LLP, where he specialized in private equity transactions. Mr. Krauss is currently a member of the Healthcare Sector Group of the New York City Investment Fund. Mr. Krauss is also a certified public accountant. Mr. Krauss currently serves as a director on the boards of Quovadx, Inc. and Tegal Corporation.

*Ogden R. Reid* has served as a member of our board of directors since December 2001. Mr. Reid was formerly vice chairman of GTS Duratek, Inc. and is currently a director of GP Strategies Corporation. From 1953 to 1959, he was president and executive editor of both the New York Herald Tribune Inc. and the New York Herald Tribune S.A. As a member of the U.S. Congress from 1961 to 1974, he served on the Foreign Affairs, Education and Labor, and Government Operations Committees. A candidate for Governor of New York in 1974, he later became Commissioner of the New York State Department of Environmental Conservation. He was also chairman of the executive committee for the Board of MGM from 1956 to 1957. Mr. Reid is currently chairman of the Council of American Ambassadors.

*Howard Silverman* has served as a member of our board of directors since December 2001. From 1974 to 1995, Mr. Silverman was chairman, president and chief executive officer of Gruntal and Company, a large brokerage and investment banking company. While at Gruntal, Mr. Silverman served on numerous

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committees for the New York Stock Exchange. Mr. Silverman formerly served as a director on the boards of Getty Petroleum, Work Wear Corp., Inc., and Carteret Savings Bank. He has also served as a trustee of Long Island University and Chemotherapy Foundation. Mr. Silverman currently serves as a charter member for the Financial Analysts Federation and The New York Society of Analysts.

*John T. Spitznagel* has served as a member of our board of directors since December 2001. Since May 2005 Mr. Spitznagel has served as chairman and chief executive officer of Esprit Pharma, Inc., a specialty pharmaceutical firm. From 2002 until March 2005, Mr. Spitznagel was the chairman and chief executive officer of ESP Pharmaceuticals, Inc. Previously, from 1996 to 1999, Mr. Spitznagel served as president and chief executive officer of Roberts Pharmaceutical Corporation, a specialty pharmaceutical firm, which merged with Shire Pharmaceuticals Group plc in 1999. Prior to joining Roberts, Mr. Spitznagel was president of Reed and Carnick, a specialty pharmaceutical firm, from 1990 to 1995. Mr. Spitznagel is a director of Saturn Pharmaceuticals, Barbeau Pharma, Inc. and IRX Therapeutics, Inc. and a trustee of Rider University.

**Board Composition**

Our amended and restated certificate of incorporation provides for a classified board of directors consisting of three staggered classes of directors, as nearly equal in number as possible. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2007 for the Class I directors, 2008 for the Class II directors and 2009 for the Class III directors. Currently:

our Class I directors are Mr. Feldman, Dr. Huckel and Mr. Reid;

our Class II directors are Dr. Dantzker, Mr. Gale and Mr. Silverman; and

our Class III directors are Mr. Krauss, Mr. Spitznagel and Dr. Tierney.

The board and each committee of the board observe all criteria for independence established by The NASDAQ National Market, or Nasdaq, and other governing laws and regulations. No director will be deemed to be independent unless the board affirmatively determines that the director has no material relationship with us directly, or as an officer, stockholder or partner of an organization that has a relationship with us.

**Appointment of Directors**

Pursuant to our second amended and restated investor rights agreement dated August 16, 2004, or investor rights agreements, the following persons were elected to our board of directors: James C. Gale as representative of the Corporate Opportunities Fund, L.P., David R. Dantzker, M.D., as representative of Wheatley MedTech Partners L.P., Jeffrey M. Krauss as representative of Psilos Group Managers, LLC, and Jerome Feldman as representative of MXL Industries, Inc. The rights to appoint directors under the investor rights agreement terminated upon the effective date of the registration statement pertaining to our initial public offering. However, pursuant to our amended and restated certificate of incorporation, which became effective upon the completion of our initial public offering, we have a classified board and Messrs. Gale (Class II), Feldman (Class I), Krauss (Class III) and Dr. Dantzker (Class II) will each continue to serve as a director for his respective term and until his respective successor is duly elected and qualified. The initial terms of the directors will expire upon election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2007 for the Class I directors, 2008 for the Class II directors and 2009 for the Class III directors.

**Board Committees**

The standing committees of our board of directors consist of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. These committees are described below. Our board of directors may also establish various other committees to assist it in its responsibilities.

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**Audit Committee**

The Audit Committee is primarily concerned with the accuracy and effectiveness of the audits of our financial statements by our internal audit staff and by our independent auditors. Its duties include:

selecting independent auditors;

reviewing the scope of the audit to be conducted by them and the results of their audit;

approving non-audit services provided to us by the independent auditor;

reviewing the integrity, adequacy and effectiveness of our financial reporting process and internal controls; assessing our financial reporting practices, including the disclosures in our annual and quarterly reports and the accounting standards and principles followed; and

conducting other reviews relating to compliance by our employees with our policies and applicable laws.

Currently, the Audit Committee is comprised of Messrs. Krauss and Reid and Dr. Huckel, each of whom is independent as defined under Nasdaq rules. Mr. Krauss currently serves as Chairman of the committee. The board of directors has determined that Mr. Krauss qualifies as audit committee financial expert as that term is defined under the rules of the Securities and Exchange Commission, or SEC.

**Compensation Committee**

The Compensation Committee s primary responsibility is to discharge our board of director s responsibilities relating to compensation of our senior executives. Its duties include:

developing guidelines and reviewing the compensation and performance of our executive officers;

setting the compensation of the chief executive officer and evaluating his performance based on corporate goals and objectives;

making recommendations to the board of directors with respect to incentive compensation plans, equity-based plans and deferred compensation plans; and

reviewing director compensation levels and practices, and recommending, from time to time, changes in such compensation levels and practices to the board of directors.

Currently, the Compensation Committee is comprised of Messrs. Spitznagel and Silverman and Dr. Dantzker, each of whom is independent as defined under Nasdaq rules. Mr. Silverman currently serves as Chairman of the committee.

**Nominating and Corporate Governance Committee**

The Nominating and Corporate Governance Committee s responsibilities include the selection of potential candidates for our board of directors and the development and annual review of our governance principles. This committee also annually reviews director compensation and benefits, and oversees the annual self-evaluations of our board of directors and its committees. It also makes recommendations to our board of directors concerning the structure and membership of the other board committees.

The Nominating and Corporate Governance Committee is comprised of Messrs. Gale, Krauss and Feldman, each of whom is independent as defined under Nasdaq rules. Mr. Gale currently serves as Chairman of the committee.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our Compensation Committee were at any time an officer or employee of ours. In addition, none of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or Compensation Committee. Dr. Dantzker has voting control over 591,949 shares of common stock that were received by Wheatley Med Tech Partners, L.P. upon conversion of the Series C convertible preferred stock. Mr. Silverman invested

$126,846 in SMH Valera LLC, which purchased shares of our series C convertible preferred stock in 2004. In addition, Dr. Dantzker was elected a director

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as a representative of Wheatley Med Tech Partners, L.P. under our second amended and restated investor rights agreement dated August 16, 2004. Their right to have a representative on our board of directors terminated in February 2006, when our Registration Statement for our initial public offering was declared effective.

**Compensation of Directors**

Our directors currently do not receive, and have not received, any cash compensation for serving on our board of directors, but are eligible to receive options and restricted shares of our common stock under the Valera Pharmaceutical Equity Incentive Plan. No options were granted to our non-employee directors during 2005.

**Code of Conduct**

We have a Code of Business Conduct and Ethics, which is attached as an exhibit to this Annual Report on Form 10-K. We require all employees, officers and directors to adhere to this Code in addressing the legal and ethical issues encountered in conducting their work. The Code of Business Conduct and Ethics requires that our employees, officers and directors avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner, and otherwise act with integrity and in our best interest. Our Code of Business Conduct and Ethics is intended to comply with Item 406 of the SEC s Regulation S-K and the rules of The NASDAQ National Market.

The Code of Business Conduct and Ethics includes procedures for reporting violations of the Code, which are applicable to all employees, officers and directors. The Sarbanes-Oxley Act of 2002 requires companies to have procedures to receive, retain and treat complaints received regarding accounting, internal accounting controls or auditing matters and to allow for the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters. The Code of Business Conduct and Ethics also includes these required procedures.

We have a webpage with our Corporate Code of Business Conduct and Ethics and certain Corporate Governance information. You can access this information on our webpage through our internet site, www.valerapharma.com, by clicking on the Corporate Information link to the heading Investors. You can also access our Investor Relations webpage directly at www.valerapharma.com/investors.asp. We will post any amendments to the Code of Business Conduct and Ethics, and any waivers that are required to be disclosed by the rules of either the SEC or The NASDAQ National Market, on our internet site. You can request a copy of our Code of Business Conduct and Ethics, at no cost, by contacting Investor Relations, 7 Clarke Drive, Cranbury, NJ 08512 or (609-235-3000).

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**Item 11.** ***Executive Compensation***

The following table summarizes the compensation earned in the years ended December 31, 2004 and 2005 by our Chief Executive Officer and the other four most highly paid executive officers whose total salary and bonus awards exceeded $100,000 for the year ended December 31, 2005. In this Form 10-K we refer to these individuals as our named executive officers.

**Summary Compensation Table**

| | | Annual Compensation | | Long-term Compensation Awards | |
|---|---|---|---|---|---|
| **Name and Principal Position** | **Fiscal Year** | **Salary ($)** | **Bonus ($)(1)** | **Shares Underlying Options** | **Other Compensation(2)** |
| David S. Tierney, M.D. | 2005 | $ 312,500 | $ 117,188 | | $ 7,000 |
| *President and Chief Executive Officer* | 2004 | $ 287,500 | $ 75,000 | 79,167 | $ 6,500 |
| Andrew T. Drechsler(3) | 2005 | $ 142,500 | $ 42,577 | 79,166 | $ |
| *Chief Financial Officer* | | | | | |
| Petr F. Kužma | 2005 | $ 156,327 | $ 28,125 | | $ 7,438 |
| *Vice President of Research and Development* | 2004 | $ 135,000 | $ 20,000 | 25,000 | $ 4,801 |
| Pete J. Perron(4) | 2005 | $ 186,667 | $ 54,875 | 6,667 | $ 7,000 |
| *Vice President of Sales* | 2004 | $ 119,109 | $ 30,000 | 83,333 | $ |
| Matthew L. Rue, III | 2005 | $ 186,333 | $ 54,875 | | $ 8,800 |
| *Vice President of Marketing and Commercial Development* | 2004 | $ 168,000 | $ 25,000 | 33,333 | $ 6,324 |

(1) Bonus amounts represent the bonus earned in the year stated. The actual bonus payment was made in the subsequent year.

(2) Such amounts represent matching contributions made by Valera under our 401(k) plan.

(3) Mr. Drechsler joined Valera in April 2005 at an annual salary of $190,000.

(4) Mr. Perron joined Valera in April 2004.

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**Option Grants**

The following table contains information concerning the grant of options to purchase shares of our common stock to each of the named executive officers during the year ended December 31, 2005. The percentage of total options granted to employees set forth below is based on an aggregate of 193,594 shares subject to options granted in 2005, including options granted to named executive officers.

| | Option Grants in Last Fiscal Year(1) | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term | |
| Name | Number of Securities Underlying Options Granted | Percent of Total Options Granted to Employees in 2005 | Exercise or Base Price ($/share) | Fair Market Value on Date of Grant(2) | Expiration Date | 5%(3) | 10%(3) |
| David S. Tierney, M.D. | | % | $ | $ | | | |
| Andrew T. Drechsler | 79,166 | 40.9% | $ 12.00 | $ 12.00 | 6/27/2015 | $ 210,588 | $ 898,045 |
| Petr F. Kužma | | % | $ | $ | | | |
| Pete J. Perron | 6,667 | 3.4% | $ 12.00 | $ 12.00 | 6/27/2015 | $ 17,735 | $ 75,628 |
| Matthew L. Rue, III | | % | $ | $ | | | |

(1) These options vest at a rate of 25% on each yearly anniversary of the date of grant.

(2) There was no public trading market for our common stock during 2005. Accordingly, these prices represent the fair market value, as established by our board of directors, of our common stock on the date of grant of the options.

(3) Potential realizable values are computed by multiplying the number of shares of common stock subject to a given option by the initial public offering price of $9.00 per share assuming that the aggregate stock value derived from that calculation compounds at an annual 5% or 10% rate shown in the table for the entire ten-year term of the option and subtracting from that result the aggregate option exercise price. The 5% and 10% assumed annual rates of stock appreciation are mandated by the rules of the SEC and do not reflect our estimate or projection of future stock price growth.

**Aggregated Options Values at December 31, 2005**

The following table sets forth the number and value of securities underlying unexercised options held by the named executive officers at December 31, 2005. Because there was no public market for our common stock as of December 31, 2005, amounts described in the following table under the heading Value of Unexercised In-the-Money Options at December 31, 2005 are determined by multiplying the number of shares issued or issuable upon exercise of the option by the difference between the initial public offering price of $9.00 per share and the per share option exercise price. In 2005, none of our named executive officers exercised any options.

| | Number of Unexercised Options at December 31, 2005 | | Value of Unexercised In-the-money Options at December 31, 2005 ($)(1) | |
|---|---|---|---|---|
| **Name** | **Exercisable** | **Unexercisable** | **Exercisable** | **Unexercisable** |
| David S. Tierney, M.D. | 294,793 | 167,707 | $ 1,768,758 | $ 1,006,242 |
| Andrew T. Drechsler | | 79,166 | | |
| Petr F. Kužma | 43,751 | 39,583 | 262,506 | 237,498 |
| Pete J. Perron | 20,834 | 69,166 | 125,004 | 374,994 |
| Matthew L. Rue, III | 75,001 | 41,665 | 450,006 | 249,990 |

(1) Based upon the initial public offering price of $9.00 per share.

**Employment Agreements**

We entered into an employment agreement with David S. Tierney, M.D., our President and Chief Executive Officer, on September 16, 2003. In connection with the employment agreement, Dr. Tierney also entered into an employee confidentiality and non-competition agreement with us setting forth his obligations not to compete with us or disclose confidential information of ours. Pursuant to his employment

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agreement, Dr. Tierney is required to devote his full time, attention, skill and efforts to our business and affairs. Dr. Tierney s current base salary, as adjusted by our board of directors in accordance with the terms of the agreement, is $325,000. In addition, Dr. Tierney is eligible to participate in any annual bonus program or benefit plans and programs adopted by our board of directors. Following July 1, 2006, unless this employment agreement is renewed, Dr. Tierney will become an at-will employee. The employment agreement provides that we may terminate Dr. Tierney s employment with or without cause and that Dr. Tierney may terminate his employment with or without good reason.

In the event that Dr. Tierney s employment is terminated as a result of his death or permanent disability, Dr. Tierney and/or his spouse or dependents, as applicable, will receive 24 months in the case of death and 29 months in the case of permanent disability, of healthcare and dental insurance continuation at our expense.

In the event Dr. Tierney s employment is terminated by us other than for cause or if he resigns with good reason, Dr. Tierney will receive any earned and accrued but unpaid annual bonus and the continuation of his current base salary until the last day of the 12-month period following such termination or resignation, or 18-month period, if following a change in control.

For purposes of the employment agreement, cause means (i) the commission by the executive of an act of fraud, misappropriation or personal dishonesty relating to or involving us in any way; (ii) the executive s arrest for, conviction of, or plea of no contest to a felony, the willful failure, neglect or refusal to perform, or gross negligence, in the performance of duties and responsibilities; (iii) the violation by the executive of our rules, regulations, policies or plans regarding the conduct of our employees, where such violation continues for 10 days following the executive s receipt of notice from our board of directors; or (iv) the violation of any obligations under the employee confidentiality and non-competition agreement or the employment agreement, where such violation continues for 10 days following the executive s receipt of notice from our board of directors.

In addition, for purposes of the employment agreement, good reason means (i) a change by us in the executive s position that materially reduces his duties or responsibilities (where such change continues for 10 days following our receipt of notice from the executive); (ii) a reduction by us in the executive s base salary (other than pursuant to a company-wide reduction of base salaries for executives generally); (iii) an executive s relocation by us to a facility or location more than 50 miles from the greater Cranbury, New Jersey area, or (iv) our failure to perform any obligations under the employment agreement (where such failure continues for 10 days following our receipt of notice from the executive).

**Change in Control Agreements**

We have entered into change in control agreements with the following named executive officers: Andrew Drechsler, Petr Kužma, Pete Perron and Matthew Rue. Under the agreements, if an executive s employment is terminated by us without cause, or by the executive following a demotion, relocation or certain other similar reasons, within the period that is between 30 days prior to, and one year following, the date we consummate a change in control (as defined in the agreements), then the executive will be entitled to a severance payment equal to the sum of his or her annual base salary and bonus amount. Bonus amount is defined in the agreements as the executive s target annual bonus or, if after the first anniversary of the date the agreement was entered into, the highest annual bonus received by the executive during the past three years (or such lesser number of years the executive was employed by us). The agreements also provide for payment of any unpaid bonus earned with respect to the year ended prior to the date the executive s employment terminated and the waiver of any applicable COBRA premiums for the executive (and, if applicable, his or her spouse and dependents) for a period of twelve months following termination of employment. Under the agreements, all payments to an executive in connection with a change in control are subject to reduction to the extent that the reduction would avoid the imposition of certain golden parachute excise taxes and thereby increase the executive s net after-tax proceeds. Payment of benefits are conditioned upon execution by the executive of a release and the executives are subject to confidentiality and proprietary information covenants following cessation of employment.

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**Valera Pharmaceuticals, Inc. Equity Incentive Plan**

In September 2002, we adopted our Equity Plan, which was approved by our stockholders in May 2003. Our Equity Plan provides for the award of:

restricted shares of our common stock;

incentive stock options;

non-qualified stock options; or

any combination of the foregoing.

Grants of restricted shares and non-qualified stock options can be made to our employees, directors, consultants, and other individuals who perform services for us. Grants of incentive stock options may only be made to our employees. The principal features of our Equity Plan are summarized below, but the summary is qualified in its entirety by reference to our Equity Plan, which was filed as exhibit 10.14 to the Registration Statement in connection with our initial public offering.

***Number of shares of our common stock available under our Equity Plan***

We have reserved a total of 1,833,333 shares of our common stock for issuance pursuant to our Equity Plan. Shares subject to forfeited, cancelled, or expired awards and shares received in satisfaction of the exercise price of an option become available for grant again under our Equity Plan. In addition, shares withheld in payment of any exercise price or in satisfaction of any withholding obligation arising in connection with an award granted under our Equity Plan become available for grant again under our Equity Plan. In connection with recapitalizations, stock splits, combinations, stock dividends, and other events affecting our common stock, the Compensation Committee may make adjustments or equitable substitutions it deems appropriate in its sole discretion to the maximum number, type and issuer of the securities reserved for issuance under the Equity Plan, to the maximum number, type and issuer of shares of our common stock subject to outstanding options, to the exercise price of the options and to the number, type and issuer of restricted shares.

***Administration of our Equity Plan***

Our Compensation Committee administers our Equity Plan under authority granted to it by our board of directors in accordance with the terms of our Equity Plan. To administer our Equity Plan, our Compensation Committee must consist of at least two members of our board of directors, each of whom is a non-employee director for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, or the Exchange Act and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, an outside director for the purposes of Section 162(m). Our Compensation Committee, among other things, interprets our Equity Plan, selects award recipients, determines the type of awards to be granted to such recipients and determines the number of shares subject to each award and the terms and conditions thereof. Our Compensation Committee may also determine if or when the exercise price of an option may be paid in the form of shares of our common stock and the extent to which shares or other amounts payable with respect to an award can be deferred by the participant. Our board of directors may amend or modify our Equity Plan at any time. In addition, our board of directors is also authorized to adopt, alter and repeal any rules relating to the administration of our Equity Plan and to rescind the authority of the Compensation Committee and thereafter directly administer our Equity Plan. However, subject to certain exceptions, no amendment or modification will impair the rights and obligations of a participant with respect to an award unless the participant consents to that amendment or modification.

Our Equity Plan will continue in effect until terminated by us in accordance with its terms, although incentive stock options may not be granted more than 10 years after the adoption of our Equity Plan.

***Restricted shares under our Equity Plan***

Under the Equity Plan, we may issue restricted shares under a restricted share agreement, the terms and conditions of which will be set forth by our Compensation Committee at the time of the grant. Restricted shares are shares of our common stock issued to a participant that may not be sold or otherwise

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transferred by the participant until certain vesting conditions established by our Compensation Committee, in its discretion, at the time of grant (such as a specified period of continued employment or the fulfillment of specified individual or corporate performance goals) are met or until such time as set by our Compensation Committee. Holders of the restricted shares will not have voting rights with respect to such restricted shares until the lapse of the transfer restrictions described above. If a participant s service with us terminates prior to the end of the transfer restrictions, all of that participant s restricted shares which have not vested will be forfeited. Restricted shares may be sold under our Equity Plan (at their full value or at a discount) or may be granted solely in consideration for services.

Upon or in anticipation of a change in control, our Compensation Committee may, in its discretion:

cause restrictions on all outstanding shares of restricted stock to lapse;

cancel restricted stock in exchange for shares of restricted stock of a successor corporation; or

redeem restricted shares for cash or other substitute consideration.

***Stock options under our Equity Plan***

Our Equity Plan permits the grant of incentive stock options and non-qualified stock options. The exercise price of any incentive stock options granted under our Equity Plan may not be less than 100% of the fair market value of our common stock on the date of grant. In the case of any incentive stock option granted to a participant who owns at least 10% of the total combined voting power of all classes of our capital stock, our Equity Plan provides that the exercise price must be at least 110% of the fair market value of our common stock on the date of the grant and the incentive stock option must expire on the fifth anniversary of the date of the grant. In addition, the aggregate fair market value of shares of our common stock into which incentive stock options are exercisable, for the first time by a participant, in any calendar year may not exceed $100,000. Options granted under our Equity Plan may be exercised for cash and/or in exchange for previously acquired shares of our common stock owned by the option holder having a combined value on the date of exercise equal to the option exercise price.

Under our Equity Plan, each option will vest and be exercisable at such time and to such extent as specified in the pertinent option agreement between us and the option recipient. However, no award will be exercisable with respect to any shares of our common stock more than 10 years after the date of such award. Unless otherwise specified by our Compensation Committee with respect to a particular option, all options are non-transferable, except upon death. If a participant s service with us terminates due to death or disability, any options held by the participant may be exercised until (i) such time specified by the Compensation Committee, (ii) if not specified by the Compensation Committee, 12 months from termination of service, or (iii) if earlier than the foregoing, the expiration for the stated term of the option. If a participant s service with us is terminated for cause, any unexercised options will be automatically forfeited, and any shares of our common stock into which options are exercisable but for which certificates have not been issued, will be automatically forfeited and any exercise price paid for such shares will be refunded. In addition, if a participant s service with us is terminated for any other reason, any option held by the participant may be exercised until (i) such time specified by the Compensation Committee, (ii) if not specified by the Compensation Committee, 90 days from termination of service, or (ii) if earlier than the foregoing, the expiration of the stated term of the option.

Upon our change in control, our Compensation Committee may:

cause outstanding options to become immediately and fully vested and exercisable;

require that the grantees surrender their outstanding options in exchange for a payment by us of an amount equal to the amount by which the fair market value of the shares of stock subject to the option exceeds the option exercise price; or

cancel any outstanding option in exchange for an option to purchase common stock of any successor corporation.

Effective upon the pricing of our initial public offering in February 2006, we granted options to purchase shares of our common stock under our Equity Plan to all of our employees. The exercise price of

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these options was $9.00, equal to the initial public offering price of the shares offered, and, subject to the terms and conditions of the Equity Plan, will fully vest on the fourth anniversary of the grant date. Pursuant to these grants, we granted Dr. Tierney options to purchase 40,000 shares of our common stock, Mr. Drechsler options to purchase 30,000 shares of our common stock, Mr. Kužma options to purchase 10,000 shares of our common stock, and Messrs. Perron and Rue options to purchase 20,000 shares of our common stock each. We also granted our other employees options to purchase an aggregate of up to 85,700 shares of our common stock under our Equity Plan.

***401(k) plan***

We maintain a retirement plan for all employees who satisfy certain eligibility requirements, including requirements, including requirements relating to age and length of service. The retirement plan is intended to qualify as a tax-qualified plan under Section 401 of the Internal Revenue Code. The retirement plan provides that each participant may contribute up to a statutory limit, which for most employees is $14,000 in 2005 and $15,000 in 2006. Under the plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan s trustee at the direction of the employee. The retirement plan also permits us to make discretionary contributions and matching contributions, subject to established limits and vesting schedule. To date, we have not made any discretionary contributions to the retirement and deferred savings plan on behalf of participating employees.

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**Item 12.** ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The following table sets forth information regarding the beneficial ownership of our common stock as of March 1, 2006, for the following individuals, entities or groups:

each person or entity who we know beneficially owns more than 5% of our outstanding common stock;

each of the named executive officers;

each of our directors; and

all directors and named executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options held by that person that are currently exercisable or will become exercisable within 60 days of March 1, 2006 are deemed outstanding and are included in the number of shares beneficially owned and are also are shown separately in the column below entitled Options Exercisable within 60 Days of March 1, 2006 , while the shares are not deemed outstanding for purposes of computing percentage ownership of any other person. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Applicable percentage ownership in the following table is based on 14,885,546 shares of common stock outstanding as of March 1, 2006. Unless otherwise indicated, the address for each stockholder listed in the table is c/o Valera Pharmaceuticals, Inc., 7 Clarke Drive, Cranbury, New Jersey 08512.

| Name | Number of Shares Beneficially Owned | Options Exercisable within 60 Days of March 1, 2006 | Percentage of Shares Outstanding |
|---|---|---|---|
| *Five Percent Stockholders:* | | | |
| Sanders Morris Harris, Inc.(1) | 5,453,730 | 3,750 | 36.6% |
| MXL Industries, Inc.(2) | 2,070,670 | | 13.9% |
| Wheatley Partners(3) | 1,293,518 | | 8.7% |
| Wasatch Advisors Inc. | 1,000,000 | | 6.7% |
| *Directors and Named Executive Officers:* | | | |
| David S. Tierney, M.D. | 300,293 | 294,793 | 2.0% |
| Andrew T. Drechsler | 21,393 | 19,793 | * |
| Petr F. Kužma | 44,851 | 43,751 | * |
| Pete J. Perron | 21,334 | 20,834 | * |
| Matthew L. Rue, III | 75,001 | 75,001 | * |
| James C. Gale(4) | 5,456,439 | 6,459 | 36.6% |
| David R. Dantzker, M.D.(5) | 599,449 | 7,500 | 4.0% |
| Jerome I. Feldman(6) | 2,074,420 | 3,750 | 13.9% |
| Hubert Huckel, M.D. | 24,550 | 21,250 | * |
| Jeffrey M. Krauss(7) | 731,787 | 3,750 | 4.9% |
| Ogden R. Reid | 25,703 | 25,703 | * |

| | | | |
|---|---|---|---|
| Howard Silverman | 7,500 | 7,500 | * |
| John T. Spitznagel | 21,250 | 21,250 | * |
| All Directors and Named Executive Officers as a group | 9,403,970 | 551,334 | 60.9% |

* Less than 1%.

(1) Represents shares held by SMH Hydro Med, LLC, SMH Hydro Med II, LLC, SMH Valera, LLC, Corporate Opportunities Fund, L.P., by Corporate Opportunities Fund (Institutional), L.P., Life

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Sciences Opportunities Fund, L.P., Life Sciences Opportunities Fund (Institutional), L.P., each an affiliate of Sanders Morris Harris, Inc., or SMH. Mr. Gale has sole voting and dispositive power over the shares held by Sanders Morris Harris Inc. The address for Sanders Morris Harris, Inc. is 3100 JP Morgan Chase Tower, 600 Travis, Suite 3100, Houston, TX 77002.

(2) MXL Industries, Inc. is a wholly-owned subsidiary of National Patent Development Corporation, a publicly held corporation. Mr. Feldman is the chairman of the board of directors and chief executive officer of National Patent Development Corporation. The address for MXL Industries, Inc. is 777 Westchester Avenue, Fourth Floor, White Plains, NY 10604.

(3) Represents shares held by Wheatley MedTech Partners, L.P., Wheatley Partners III, L.P., Wheatley Associates III, L.P., Wheatley Foreign Partners III, L.P., each an affiliate of Wheatley Partners. Mr. David Dantzker shares voting and dispositive power as to 591,949 shares held by Wheatley MedTech Partners, L.P. with Barry Rubenstein, Irwin Lieber, Barry Fingerhut, Jonathan Lieber, Seth Lieber, Nancy Casey and Brian Rubenstein. Barry Rubenstein, Irwin Lieber, Barry Fingerhut, Jonathan Lieber, Seth Lieber and Nancy Casey share voting and dispositive power over the remaining 701,569 shares held by the other Wheatley entities. The address for Wheatley Partners is 80 Cuttermill Road, Great Neck, NY 11021.

(4) Includes 5,453,730 shares held by Sanders Morris Harris Inc. described in footnote 1 above. The number of options exercisable within 60 days of March 1, 2006 includes 3,750 options held by affiliates of SMH. Mr. Gale is an affiliate of SMH and manages the funds described in footnote 1 above. Mr. Gale disclaims beneficial ownership of the 5,453,730 shares held by SMH except to the extent of his pecuniary interest in the funds described in footnote 1 above.

(5) Includes 591,949 shares held by Wheatley MedTech Partners, L.P. described in footnote 3 above. Dr. Dantzker is a voting member of Wheatley MedTech Partners LLC, the general partner of Wheatley MedTech Partners, L.P. Dr. Dantzker disclaims beneficial ownership of the 591,949 shares held by Wheatley MedTech Partners, L.P. except to the extent of his pecuniary interest in that fund.

(6) Includes 2,070,670 shares held by MXL Industries, Inc. Mr. Feldman is the chairman of the board of directors and chief executive officer of National Patent Development Corporation, the parent of MXL Industries, Inc. Mr. Feldman disclaims beneficial ownership of the 2,070,670 shares held by MXL Industries, Inc.

(7) Includes 728,037 shares held by Psilos Group. Mr. Krauss is a managing director of Psilos Group. Mr. Krauss disclaims beneficial ownership of the 728,037 shares held by Psilos Group, except to the extent of his pecuniary interest in the fund.

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**Item 13.** ***Certain Relationships and Related Transactions***

We have entered into certain agreements or transactions with certain officers, directors and 5% stockholders. These agreements or transactions are each summarized below. The following description is only a summary of what we believe are the material provisions of the agreements.

**Loan from Our President and Chief Executive Officer**

We issued a promissory note to our President and Chief Executive Officer, David S. Tierney, M.D. for the aggregate principal amount of $200,000 on June 23, 2004. The note bore interest at the UBS Margin Interest Rate charged to Dr. Tierney plus 1.0% and was due and immediately payable upon our receipt of at least $1,000,000 in other debt or subscriptions to purchase shares of our series B or series C convertible preferred stock. We satisfied our obligations under this note on November 3, 2004.

**Preferred Stock Issuances**

In 2004, we sold 11,600,000 shares of our series C convertible preferred stock at a price of $1.00 per share to the following holders of more than 5% of our securities and their affiliated entities: Sanders Morris Harris, Inc. 4,500,000; Wheatley Partners 1,000,000; Psilos Group 4,000,000; and NJTC Venture Fund 1,000,000. All of our shares of series C convertible preferred stock were sold at the same price, which was determined by our board of directors to be the fair market value based upon arm s length negotiations between us and those purchasers and a managing director of Sanders Morris Harris Inc., who at the time were not our stockholders. Sanders Morris Harris Inc. acted as placement agent with respect to the shares of series C convertible preferred stock that we sold to SMH Valera LLC, an affiliate of Sanders Morris Harris, Inc. for which we paid Sanders Morris Harris Inc. a fee of $280,000. James C. Gale, one of our directors and a managing director of Sanders Morris Harris Inc., has voting and dispositive power over all of the shares of common stock that were received upon conversion of the series C convertible preferred stock purchased by Sanders Morris Harris Inc; David R. Dantzker, a director, has voting control over 591,949 shares of common stock that were received upon conversion of the series C convertible preferred stock purchased by Wheatley MedTech Partners, L.P.; and Howard Silverman, a director, invested $126,846, and David S. Tierney, M.D., our President and Chief Executive Officer and a director, invested $50,000 in SMH Valera LLC. All of the shares of preferred stock described above were converted into common stock in February 2006, when we closed our initial public offering.

**Appointment of Directors**

Pursuant to our second amended and restated investor rights agreement dated August 16, 2004, or investor rights agreements, the following persons were elected to our board of directors: James C. Gale as representative of the Corporate Opportunities Fund, L.P., David R. Dantzker, M.D., as representative of Wheatley MedTech Partners L.P., Jeffrey M. Krauss as representative of Psilos Group Managers, LLC, and Jerome Feldman as representative of MXL Industries, Inc. The rights to appoint directors under the investor rights agreement terminated upon the effective date of the registration statement pertaining to our initial public offering. However, pursuant to our amended and restated certificate of incorporation, which became effective upon the completion of our initial public offering, we have a classified board and Messrs. Gale (Class II), Feldman (Class I), Krauss (Class III) and Dr. Dantzker (Class II) will each continue to serve as a director for his respective term and until his respective successor is duly elected and qualified. The initial terms of the directors will expire upon election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2007 for the Class I directors, 2008 for the Class II directors and 2009 for the Class III directors.

The purchasers of our preferred stock are entitled to certain registration rights under the investor rights agreement.

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**Item 14.** ***Principal Accountant Fees and Services***

Fees for Ernst & Young LLP for the years ended December 31, 2005 and 2004 (in thousands):

| | 2005 | 2004 |
|---|---|---|
| Audit Fees | $ 566 | $ 144 |
| Audit-Related Fees | | |
| Tax Fees | | |
| All Other Fees | 2 | |
| Total | $ 568 | $ 144 |

*Audit Fees* consists of fees for the audit of our annual financial statements, review of the financial statements and services that are normally provided by the independent auditors in connection with statutory and regulatory filings or engagements for those fiscal years. This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit or the review of interim financial statements and the preparation of an annual management letter on internal control matters. The 2005 fees include $371,000 related to the Company s initial public offering.

*Audit-Related Fees* consists of assurance and related services by Ernst & Young LLP that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under Audit Fees.

*Tax Fees* consists of professional services rendered by Ernst & Young LLP for tax compliance and tax planning. The services for the fees disclosed under this category include tax return preparation and technical tax advice.

*All Other Fees* for fiscal year 2005 was related to accounting research software.

*Pre-approval Policy.* The Audit Committee has established a policy governing our use of Ernst & Young LLP for non-audit services. Under the policy, the Audit Committee is required to pre-approve all audit and non-audit services performed by the Company s independent auditors in order to ensure that the provision of such services does not impair the auditors independence. The Audit Committee pre-approves certain Audit and Audit-Related Services, subject to certain fee levels. Any proposed services that are not a type of service that has been pre-approved or that exceed pre-approval cost levels require specific approval by the Audit Committee in advance. The Committee periodically revises the lists of pre-approved service types set forth in the policy as required. In fiscal years 2005 and 2004, all fees identified above under the captions Audit Fees, Audit-Related Fees, Tax Fees and All Other Fees tha were billed by Ernst & Young LLP were approved by the Audit Committee in accordance with SEC requirements.

**Part IV**

**Item 15.** ***Exhibits and Financial Statement Schedules***

(a) Exhibits.

| Exhibit Number | Exhibit |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation(2) |
| 3.2 | Amended and Restated Bylaws(2) |
| 4.1 | Specimen Common Stock Certificate(2) |
| 4.2 | Second Amended and Restated Investor Rights Agreement dated August 16, 2004(6) |
| 4.3 | Form of Incentive Stock Award Agreement(6) |

| | |
|---|---|
| 4.4 | Form of Non-Qualified Stock Option Agreement(6) |

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| Exhibit Number | Exhibit |
|---|---|
| 10.1 | Executive Employment Agreement between Valera Pharmaceuticals, Inc. and David S. Tierney dated September 16, 2003(6) |
| 10.2 | License and Distribution Agreement between Hydro Med Sciences, Inc. and Paladin Labs, Inc. dated October 3, 2002(5) |
| 10.3 | Investment Agreement between Hydro Med Sciences, Inc. and Paladin Labs, Inc. dated October 3, 2002(5) |
| 10.4 | License and Distribution Agreement between Valera Pharmaceuticals, Inc. and Key Oncologics dated September 17, 2003(5) |
| 10.5 | Termination Agreement, License Back and Option between Hydro Med Sciences, Inc. and Shire US Inc. dated December 21, 2001(6) |
| 10.6 | Termination of Agreement dated September 12, 1990 between National Patent Development Corporation and The Population Council, Inc. dated October 1, 1997(6) |
| 10.7 | Amendment to the Termination of the Joint Development Agreement between GP Strategies Corporation and The Population Council, Inc. dated November 29, 2001(6) |
| 10.8 | Amendment No. 2 to Termination Agreement between Valera Pharmaceuticals, Inc. and The Population Council, Inc. dated August 31, 2004(6) |
| 10.9 | Lease Agreement between National Patent Development Corporation and Cedar Brook Corporate Center, L.P. dated October 6, 1997(6) |
| 10.10 | Amendment to Lease between Valera Pharmaceuticals, Inc. and Cedar Brook Corporate Center, L.P. dated January 7, 2004(6) |
| 10.11 | Lease Agreement between Valera Pharmaceuticals, Inc. and Cedar Brook 7 Corporate Center, L.P. dated March 8, 2005(6) |
| 10.12 | Contribution Agreement between Hydro Med Sciences, Inc. and GP Strategies Corporation dated June 30, 2000(6) |
| 10.13 | License and Distribution Agreement between Valera Pharmaceuticals, Inc. and BioPro Pharmaceutical, Inc. dated January 28, 2005(6) |
| 10.14 | Valera Pharmaceuticals, Inc. 2002 Equity Incentive Plan(6) |
| 10.15 | Group Purchasing Agreement between Valera Pharmaceuticals, Inc. and International Physician Networks, LLC dated as of March 21, 2005**(5) |

| | |
|---|---|
| 10.16 | Group Purchasing Agreement between Valera Pharmaceuticals, Inc. and International Physician Networks, LLC (on behalf of U.S. Urology Practices) dated as of March 21, 2005**(5) |
| 10.17 | Agreement between National Patent Development Corporation and Dento-Med Industries, Inc. dated November 30, 1989(6) |
| 10.18 | Fee for Services Agreement between Valera Pharmaceuticals, Inc. and Besse Medical Supply dated as of March 21, 2005**(5) |
| 10.19 | Collaboration and Development Agreement between Valera Pharmaceuticals, Inc. and Alpex Pharma S.A. dated April 6, 2005**(5) |
| 10.20 | Form of Change in Control Agreement with Executive Officers(4) |
| 10.21 | Asset Purchase Agreement between Valera Pharmaceuticals, Inc. and Anthra Pharmaceuticals, Inc. dated as of September 28, 2005**(1) |
| 10.22 | Credit Agreement between Valera Pharmaceuticals, Inc. and Merrill Lynch Capital dated October 20, 2005(3) |
| 10.23 | Distribution Agreement between Valera Pharmaceuticals, Inc. and Teva-Tuteur dated December 9, 2005(3) |
| 14.1 | Corporate Code of Business Conduct and Ethics* |
| 21.1 | List of Subsidiary(4) |
| 31.1 | Certificate of the Chief Executive Officer of Valera Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.* |

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| Exhibit Number | Exhibit |
|---|---|
| 31.2 | Certificate of the Chief Financial Officer of Valera Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.* |
| 32 | Certificate of the Chief Executive Officer and the Chief Financial Officer of Valera Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. § 1350.* |

* Filed herewith

** Portions omitted pursuant to a request for confidential treatment under Rule 406.

(1) Filed as an Exhibit to Amendment No. 6 to Registration Statement on Form S-1 (File No. 333-123288) filed on January 30, 2006.

(2) Filed as an Exhibit to Amendment No. 5 to Registration Statement on Form S-1 (File No. 333-123288) filed on January 17, 2006.

(3) Filed as an Exhibit to Amendment No. 4 to Registration Statement on Form S-1 (File No. 333-123288) filed on December 9, 2005.

(4) Filed as an Exhibit to Amendment No. 3 to Registration Statement on Form S-1 (File No. 333-123288) filed on September 29, 2005.

(5) Filed as an Exhibit to Amendment No. 2 to Registration Statement on Form S-1 (File No. 333-123288) filed on April 20, 2005.

(6) Filed as an Exhibit to Registration Statement on Form S-1 (File No. 333-123288) filed on March 14, 2005.

(b) Financial Statement Schedules.

Financial statements and schedule filed as a part of this Form 10-K are listed in the Index to Financial Statements on page 59. All other financial statement schedules are omitted because they are not applicable or not required, or because the required information is included in the financial statements or notes thereto.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 20, 2006.

VALERA PHARMACEUTICALS, INC.
By: /s/ Andrew T. Drechsler

Name: Andrew T. Drechsler
Title: Chief Financial Officer

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

| Signature | Title | Date |
|---|---|---|
| /s/ David S. Tierney, M.D.<br>David S. Tierney, M.D. | President, Chief Executive Officer and Director (Principal Executive Officer) | March 20, 2006 |
| /s/ Andrew T. Drechsler<br>Andrew T. Drechsler | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | March 20, 2006 |
| /s/ James C. Gale<br>James C. Gale | Chairman of the Board of Directors | March 20, 2006 |
| /s/ David Dantzker, M.D.<br>David Dantzker, M.D. | Director | March 20, 2006 |
| /s/ Jerome Feldman<br>Jerome Feldman | Director | March 20, 2006 |
| /s/ Hubert Huckel, M.D.<br>Hubert Huckel, M.D. | Director | March 20, 2006 |
| /s/ Jeffrey Krauss<br>Jeffrey Krauss | Director | March 20, 2006 |
| /s/ Ogden R. Reid | Director | March 20, |

| | | |
|---|---|---|
| | | 2006 |
| Ogden R. Reid | | |
| /s/ Howard Silverman | Director | March 20, 2006 |
| Howard Silverman | | |
| /s/ John T. Spitznagel | Director | March 20, 2006 |
| John T. Spitznagel | | |