



*Advancing New Cancer Therapies*



*2005 Annual Report*

# LETTER TO SHAREHOLDERS

2005 was an important year for Vion and one in which we made significant progress in advancing our lead medicine Cloretazine® (VNP40101M), a novel alkylating agent, to large-scale clinical trials which will, if successful, form the basis for our application for regulatory approval. To date, we remain proud of our accomplishments but acknowledge that the ultimate test of any biotechnology company developing medicines is regulatory approval. The principles of even the most ardent investors are put to the test during the drug development process. We feel that updating you, our shareholders, on our substantive progress in 2005 will support our belief in the value of this inventive medicine as an important breakthrough in the treatment of leukemia.

We are rapidly advancing our pivotal Phase III trial of Cloretazine® (VNP40101M) in combination with cytarabine (Ara-C) in relapsed acute myelogenous leukemia (AML). This Phase III trial, which was designed under the Special Protocol Assessment process with the U.S. Food and Drug Administration (FDA), is now up and running in 65 sites in North America and Europe. We are working to expeditiously accrue the 420 patients and expect that we will reach the midpoint of accrual in 2006, and complete accrual in 2007.

Our Phase III trial in AML is just part of Vion's significant commitment to this challenging disease. In 2005, we observed and announced positive results of our single agent Phase II trial of Cloretazine® (VNP40101M). Based on two Phase I trials in advanced hematologic malignancies and this large Phase II trial in AML and high-risk myelodysplastic syndrome (MDS), we have expanded our registration efforts by initiating a pivotal Phase II trial in elderly poor-risk *de novo* AML patients in the second quarter of 2006. This 85 patient trial is focused on a patient population which represents an unmet medical need: patients at least sixty years of age with poor-risk *de novo* AML.

At several clinical conferences throughout the year, Vion reported the compelling results for the elderly stratum of our single agent Phase II study, in which 107 elderly AML and high-risk MDS patients were treated with Cloretazine® (VNP40101M) as induction therapy. Thirty-one percent of these patients were able to achieve a complete remission or a complete remission with reduced platelet count. Additional analysis of patients with *de novo* AML demonstrated a 47% overall response rate. These data presented at the American Society of Hematology in December 2005 demonstrated that the patients were representative of the unmet need patient population. This encouraging data and experience anchors the additional second Phase II trial in this important patient population. We will continue our commitment to reporting clinically meaningful events as we progress in 2006.

In 2005, we were granted Fast Track designation from the FDA and along with the designations obtained in 2004, Cloretazine® (VNP40101M) now has Fast Track designation in both AML populations—first relapse and elderly poor-risk in the U.S. and Orphan Drug status in AML in both the U.S. and Europe.

In addition to our trials in AML and MDS, we are evaluating this novel agent in other cancer indications. We have single agent trials underway in small-cell lung cancer, chronic lymphocytic leukemia, adult and pediatric brain tumors, and a combination trial with temozolomide in advanced hematologic malignancies.

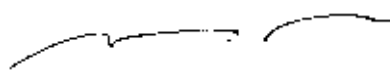
Trials of our second clinical compound, Triapine®, continued under our collaboration with the National Cancer Institute in 2005. We expect initial data from these trials to be available in 2006.

We are also pleased with the progress made on the preclinical development of our third compound, VNP40541, which releases the same active agent as Cloretazine® (VNP40101M), but does so selectively in hypoxic (low oxygen) conditions. We plan on filing an Investigational New Drug application and initiating the first clinical trial in 2006.

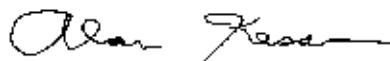
We ended 2005 with \$52.8 million in cash, a financial position we believe is sufficient to carry on our efforts for registration of Cloretazine® (VNP40101M) into 2007. As the development of all of our anticancer compounds continues to advance, we remain committed to maintaining a strong financial position.

We are excited about our two pivotal trials of Cloretazine® (VNP40101M) in AML and look forward to completion of accrual in 2007. We believe that Cloretazine® (VNP40101M) will be a valuable agent in both frontline and second-line AML and improve the standard of care in this disease. As our clinical trials advance and an ultimate decision on regulatory approval approaches, we have entered the pre-launch phase and with worldwide registration rights are evaluating all commercialization opportunities that maximize shareholder value.

We thank you, our shareholders, for your continued support, and our employees for their hard work and dedication. We look forward to the day when we are actively involved in advancing a better treatment for patients and their families.



William R. Miller  
*Chairman of the Board*



Alan Kessman  
*Chief Executive Officer*



**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

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File Number 000-26534**

**VION PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**13-3671221**

(I.R.S. Employer Identification No.)

**4 Science Park**

**New Haven, Connecticut**

(Address of principal executive offices)

**06511**

(Zip Code)

Registrant's telephone number, including area code: **(203) 498-4210**

Securities registered pursuant to Section 12(b) of the Act:  
None

Securities registered pursuant to Section 12(g) of the Act:  
Title of Class

Common Stock, \$0.01 par value (together with associated Common Stock Purchase Rights)

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

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

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

Indicate by check mark 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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  Accelerated filer  Non-accelerated filer

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2005 was \$145,363,483 based on the last sale price for the common stock on that date as reported by the Nasdaq Capital Market<sup>SM</sup>.

The number of shares outstanding of the registrant's common stock as of March 10, 2006 was 67,860,117.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

# VION PHARMACEUTICALS, INC.

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### SIGNATURES

In this report, unless the context otherwise requires, the terms "we," "us," "our," "the Company" and "Vion" refer to Vion Pharmaceuticals, Inc., a Delaware corporation.

All statements other than statements of historical fact included in this Annual Report on Form 10-K, including without limitation statements under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” regarding our financial position, business strategy, and plans and objectives of our management for future operations, are forward-looking statements. When used in this Annual Report on Form 10-K, words such as “may,” “will,” “should,” “could,” “potential,” “seek,” “project,” “predict,” “anticipate,” “believe,” “estimate,” “expect,” “intend” and similar expressions, as they relate to us or our management, identify forward-looking statements. Forward-looking statements are based on the beliefs of our management as well as assumptions made by and information currently available to our management. These statements are subject to risks and uncertainties that may cause actual results and events to differ significantly. A detailed discussion of risks attendant to the forward-looking statements is included under “Item 1A - Risk Factors”. The information contained in this Annual Report on Form 10-K is believed to be current as of the date of filing with the Securities and Exchange Commission. We do not intend to update any of the forward-looking statements after the date of this filing to conform these statements to actual results or to changes in our expectations, except as required by law.

## PART I

### ITEM 1: *Business*

#### General

We are a development stage pharmaceutical company engaged in the development of therapeutics for the treatment of cancer. We were incorporated in March 1992 as a Delaware corporation and began operations on May 1, 1994. For the years ended December 31, 2005, 2004 and 2003, we spent \$16.6 million, \$13.8 million and \$9.7 million, respectively, on research, development and clinical activities.

Our portfolio of potential products consists of two distinct small molecule anticancer agents in clinical development, and additional small molecules in preclinical development. We also have developed a drug delivery technology for the treatment of cancer. ‘Preclinical development’ or ‘preclinical studies’ indicate that the product candidates selected for development are being evaluated for potency, specificity, manufacturability and pharmacologic activity *in vitro*, or cell culture, and *in vivo*, or animal models. Typically, clinical evaluation involves a three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the tolerated drug dose, early safety profile, proper scheduling and the pattern of drug distribution, absorption and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine efficacy, dose-response relationships and expanded evidence of safety. In Phase III, large-scale, multi-center, controlled clinical trials are conducted in order to:

- provide enough data for statistical proof of safety and efficacy;
- compare the experimental therapy to existing therapies;
- uncover any unexpected safety problems, such as side-effects; and
- generate product labeling.

Our product development programs are based on technologies that we license from Yale University (Yale) and other cancer research centers. We have largely engaged in product development with respect to anticancer therapeutics through in-house preclinical and clinical development and through collaboration with academic, research and governmental institutions. As our proposed products advance through trials depending on financial and pharmaceutical market conditions and required resources, we will determine the best method and/or partnership to develop, and eventually market, our products.

### ***Products in Clinical Development***

- Our lead product, Cloretazine<sup>®</sup> (VNP40101M), is an alkylating (DNA-damaging) agent. Our primary registration strategy for this compound is for the treatment of acute myelogenous leukemia (AML). A Phase III trial of Cloretazine<sup>®</sup> in combination with cytosine arabinoside (Ara-C) in relapsed AML commenced in March 2005. In January 2006, we announced that we will conduct a pivotal Phase II trial in elderly patients with *de novo* poor-risk AML. This trial is expected to commence in the second quarter of 2006. In addition to these two trials in AML, Cloretazine<sup>®</sup> is being evaluated in clinical trials as a single agent in chronic lymphocytic leukemia, small cell lung cancer, and adult and pediatric brain tumors, and in combination with temozolomide in advanced hematologic malignancies. Cloretazine<sup>®</sup> has received two fast track designations from the U.S. Food and Drug Administration (FDA) for the treatment of: (i) relapsed AML and (ii) elderly poor-risk AML. Cloretazine<sup>®</sup> has also received orphan drug designation for the treatment of AML in the United States and the European Union.
- Our second clinical compound, Triapine<sup>®</sup>, is a small molecule that in preclinical models inhibits the enzyme ribonucleotide reductase, and therefore prevents the replication of tumor cells by blocking a critical step in DNA synthesis. Intravenous Triapine<sup>®</sup> is being evaluated in Phase I and Phase II single agent and combination clinical trials sponsored by the National Cancer Institute (NCI). The NCI is also expected to sponsor a Phase I clinical trial of an oral formulation of Triapine<sup>®</sup> which should be initiated in 2006.

### ***Products in Preclinical Development***

- VNP40541 (formerly called KS119W) is an additional cytotoxic (cell-damaging) compound from the sulfonylhydrazine class. VNP40541 has been demonstrated in preclinical studies to be highly selective for hypoxic (poorly oxygenated) cells which are found in tumors and are often hard to treat with conventional anticancer agents. We plan to file an Investigational New Drug (IND) application and commence a Phase I trial of VNP40541 in 2006.
- Heterocyclic hydrazones are anticancer compounds that have demonstrated potent anti-tumor effects in preclinical studies. The mechanisms of action for these compounds are unidentified at this time but appear to be unlike any known commercially available anticancer agents. In September 2005, we entered into an exclusive license for these compounds. We plan to evaluate these compounds in preclinical studies in 2006.

### ***Drug Delivery Technology***

- TAPET<sup>®</sup> (Tumor Amplified Protein Expression Therapy), our drug delivery system using modified *Salmonella* bacteria, is designed to deliver anticancer agents directly to solid tumors. In 2006, we will continue to seek a development partner for TAPET<sup>®</sup>.

### **Overview of Cancer and Treatment Methods**

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. In 2005, the American Cancer Society estimated that 1.4 million new cases of cancer would be diagnosed in the United States and 570,280 Americans would die from cancer.

Cancer is a heterogeneous group of diseases characterized by uncontrolled cell division and growth resulting in the development of a mass of cells or tumor, as well as the invasion and spreading of these cells to other organs of the body (metastasis). Cancerous tumors can arise in any tissue or organ within the human body and generally cause clinical problems to the patient when the tumor affects the function of that organ or when the tumor spreads to other organs. Cancers which arise in the bone marrow (e.g. acute and chronic leukemias and multiple myeloma) or the lymph nodes (Hodgkin's disease and lymphomas) spread through the bone marrow and lymphatic systems, affecting the growth of normal blood and lymphatic cells. Cancer is believed to occur as a result of a number of factors, such as genetic predisposition, chemical agents, viruses and radiation. These factors result in genetic changes affecting the ability of cells to regulate their growth and differentiation.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. A cancer patient often receives treatment with a combination of methods. Surgery and radiation therapy are particularly effective in patients where the disease is localized. The most common method of treating patients with cancer that has spread beyond the primary site is to administer systemic anticancer drugs (chemotherapy). Chemotherapy seeks to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of malignant tumor cells. In many cases, chemotherapy consists of the administration of several different drugs in combination. Chemotherapy can cause patient weakness, loss of appetite, nausea and vomiting, and damage to various organs that can result in loss of normal body functions.

The effectiveness of current cancer treatments with respect to any particular patient varies greatly, depending upon the cancer diagnosis and the tolerance of the patient to treatment. Therefore, a significant need exists for new therapies which are more effective and have less toxicity.

### **Our Product Development Programs**

We are developing several potential products for the treatment of cancer. Two of our small molecule anticancer agents are in human clinical trials, and additional small molecules are in preclinical development. In addition, we are seeking a partner to develop a drug delivery technology. The discussion below sets forth the development status of our product candidates (except as otherwise specifically noted below) as of December 31, 2005.

### **Products in Clinical Development**

#### ***Cloretazine***<sup>®</sup>

Cloretazine<sup>®</sup> is an alkylating agent. Alkylating agents damage DNA, which results in cell death. Alkylating agents are generally known to be among the most highly effective agents in the treatment of cancer.

Preclinical data on Cloretazine<sup>®</sup> showed broad anti-tumor activity in *in vivo* models. It was curative in certain preclinical leukemia models, including mice bearing certain derivatives of a leukemia cell line that was resistant to standard alkylating agents. Cloretazine<sup>®</sup> was also active against solid tumor models, including lung, colon, and brain cancer, and melanoma. It was curative in mouse models in which a human glioma (brain tumor) or a mouse colon cancer was implanted and growing under the skin. The drug has been shown in preclinical studies to be capable of crossing the blood-brain barrier with great efficiency. The blood-brain barrier has been a common obstacle in achieving active concentrations of most drugs within the brain.

Based on early indications of activity in the trials conducted to date, our primary registration strategy for Cloretazine<sup>®</sup> is for the treatment of AML, but we also are evaluating it in other hematologic malignancies and solid tumors. Below is a table with a list of all completed, ongoing and planned Cloretazine<sup>®</sup> clinical trials.

<b>Trial</b>	<b>Indication</b>	<b>Sponsor</b>	<b>Commencement Date</b>	<b>Status</b>
Phase III trial in combination with Ara-C	AML, relapsed	Vion	March 2005	Ongoing
Phase II single agent trial	AML, elderly poor-risk	Vion	To be determined	Planned
Phase II single agent trial	Small cell lung cancer	Vion	September 2005	Ongoing
Phase II single agent trial	Brain tumors, adult	Investigator-sponsored	June 2004	Ongoing
Phase II single agent trial	AML and high-risk myelodysplastic syndromes	Vion	March 2004	Ongoing
Phase I/II single agent trial	Chronic lymphocytic leukemia	Vion	July 2005	Ongoing
Phase I trial	Brain tumors, pediatric	Investigator-sponsored	April 2005	Ongoing
Phase I trial in combination with temozolomide	Hematologic malignancies	Vion	October 2004	Ongoing
Phase I trial in combination with Ara-C	Hematologic malignancies	Vion	July 2003	Completed
Phase I single agent trial	Solid tumors	Vion	February 2003	Completed
Phase I single agent trial	Hematologic malignancies	Vion	August 2002	Completed
Phase I single agent trial	Solid tumors	Vion	June 2001	Completed

In March 2004, we received fast track designation from the FDA for Cloretazine<sup>®</sup> in relapsed or refractory AML. In October 2005, we received fast track designation for Cloretazine<sup>®</sup> in elderly poor-risk AML. The FDA's fast track programs are designed to facilitate the development of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Although fast track status may expedite development and FDA review of an application, there can be no assurance that Cloretazine<sup>®</sup> will be reviewed more expeditiously for its "fast track" indications than would otherwise have been the case or will be approved promptly, or at all. Further, the FDA could revoke fast track status for Cloretazine<sup>®</sup>.

In October 2004, we received orphan drug designation from the FDA for Cloretazine<sup>®</sup> in AML in the United States. Orphan drug designation may be granted to products that treat rare diseases or conditions that affect fewer than 200,000 people in the United States. Orphan drug designation does not convey any advantage or shorten the duration of the FDA review and approval process. The designation may provide eligibility for a seven-year period of market exclusivity for the indication of AML after marketing approval, potential tax credits for research, grant funding for research and development, possibly reduced filing fees for marketing applications, and assistance with the review of clinical trial protocols.

In January 2006, we received orphan drug designation from the European Medicines Agency (EMA) for Cloretazine<sup>®</sup> in AML in the European Union. Orphan drug status is granted by the European Commission to promote development of drugs to treat rare diseases or conditions. Orphan drug designation in Europe does not convey any advantage or shorten the duration of the EMA review and approval process. Orphan drug designation in Europe may entitle Cloretazine<sup>®</sup> to: (i) ten years of market exclusivity for the indication of AML; (ii) protocol assistance from the European Medicines Agency to optimize drug development in preparing a dossier that will meet regulatory requirements; (iii) reduced fees associated with applying for market approval; and (iv) access to European Union research funding.

### ***Cloretazine<sup>®</sup> in Hematologic Malignancies***

We are conducting a Phase III trial of Cloretazine<sup>®</sup> in combination with Ara-C in relapsed AML in over 50 clinical sites in North America and Europe. This trial started in March 2005. In February 2005, we reached agreement with the FDA for this Phase III trial on a Special Protocol



Assessment (SPA), a procedure by which the FDA provides official evaluation and guidance on proposed protocols for pivotal Phase III clinical trials. In January 2006, we announced that we will conduct an additional pivotal Phase II trial of Cloretazine<sup>®</sup> as a single agent in elderly patients with *de novo* poor-risk AML. Elderly *de novo* poor-risk AML patients are those elderly patients whose poor-risk AML has not evolved from a prior myelodysplastic syndrome. We plan to start this trial in the second quarter of 2006. We are evaluating Cloretazine<sup>®</sup> in a Phase II single agent trial in AML and high risk myelodysplastic syndromes that commenced in March 2004, and was amended to accept additional patients in a strata with elderly previously untreated patients in the fall of 2005. We are also evaluating Cloretazine<sup>®</sup> as a single agent in a Phase I/II trial in chronic lymphocytic leukemia and in combination with temozolomide in a Phase I trial in advanced hematologic malignancies.

### ***Cloretazine<sup>®</sup> in Solid Tumors***

We are conducting a Phase II trial of Cloretazine<sup>®</sup> as a single agent in small cell lung cancer. This trial started in September 2005. A Phase II trial of Cloretazine<sup>®</sup> as a single agent in adult brain tumors is ongoing under an investigator's IND. An additional Phase I trial in pediatric glioma was initiated in April 2005 under an investigator's IND and continues to accrue patients.

### ***Triapine<sup>®</sup>***

Triapine<sup>®</sup> inhibits the enzyme ribonucleotide reductase in preclinical models. Ribonucleotide reductase inhibition is thought to arrest the growth of, or kill, cancer cell lines, by blocking a critical step in DNA synthesis. Inhibition of this enzyme has also been shown *in vitro* and *in vivo* to enhance the anti-tumor activity of several standard anticancer agents.

We have evaluated an intravenous formulation of Triapine<sup>®</sup> in five single agent Phase I trials, three single agent Phase II trials, four Phase I combination trials, and two Phase II combination trials. At this time, we are not sponsoring any additional trials of the intravenous formulation of Triapine<sup>®</sup>.

In November 2002, we announced that the NCI's Division of Cancer Treatment and Diagnosis had approved a collaboration for the clinical development of Triapine<sup>®</sup>. As part of this collaboration, the NCI's Cancer Therapy Evaluation Program will sponsor clinical trials of Triapine<sup>®</sup> to further explore its activity as a single agent or in combination with other agents in patients with cancer. We provide the product used in these trials. In early 2003, we announced that a Clinical Trials Agreement had been executed with the NCI and in January 2004, the first trial opened under NCI sponsorship.

An intravenous formulation of Triapine<sup>®</sup> is being evaluated in Phase I and Phase II combination trials sponsored by the NCI. Data from some of these trials should be available in 2006.

Clinical testing of new single agent administration schedules may be possible with the oral form of Triapine<sup>®</sup>, which to date has been studied in a small number of patients to determine its absorption in the bloodstream following a single dose. We expect that a Phase I trial sponsored by the NCI of an oral formulation of Triapine<sup>®</sup> will commence in 2006.

### ***License Agreement with Beijing Pason Pharmaceuticals, Inc.***

In October 2003, we entered into a license with Beijing Pason Pharmaceuticals, Inc. (Pason) whereby we granted Pason the exclusive rights to develop, manufacture and market Triapine<sup>®</sup> in the People's Republic of China, Taiwan, Hong Kong and Macao.

## **Products in Preclinical Development**

### ***VNP40541***

VNP40541 (formerly known as KS119W), an additional compound from the sulfonyl hydrazine class, has been demonstrated in preclinical studies to be highly selective for hypoxic (poorly oxygenated) cells which are found in tumors and are often hard to treat with conventional anticancer agents. We are evaluating VNP40541 in preclinical studies and plan to file an IND application and initiate a Phase I trial of this compound in 2006.

### ***Heterocyclic Hydrazones***

Heterocyclic hydrazones are anticancer compounds that have demonstrated potent anti-tumor effects in preclinical studies. The mechanisms of action for these compounds are unidentified at this time but appear to be unlike any commercially available anticancer agents of which we know. In December 2003, we entered into an exclusive research collaboration and option agreement related to these compounds with a group of inventors from the Institute of Pharmacy and the Institute of Medicinal Chemistry and Biochemistry at the University of Innsbruck, and Austria Wirtschaftsservice Gesellschaft m.b.H, a bank specializing in Austrian business promotion. In September 2005, we entered into an exclusive license for these compounds. We plan to evaluate heterocyclic hydrazones in preclinical studies in 2006.

### **Drug Delivery Technology**

#### ***TAPET<sup>®</sup> (Tumor Amplified Protein Expression Therapy)***

TAPET<sup>®</sup> is a proprietary technology that uses genetically-altered *Salmonella* bacteria to deliver cancer-fighting drugs preferentially to solid tumors. Extensive preclinical studies in *in vivo* models have shown that TAPET<sup>®</sup> bacteria migrate to and penetrate throughout solid tumors. Inside the tumors, TAPET<sup>®</sup> bacteria double in quantity every 30 to 45 minutes, achieving very high bacterial counts, reaching ratios in tumor versus normal tissues of 1000:1. In addition, TAPET<sup>®</sup> can be genetically engineered to deliver anticancer agents continuously within the tumor.

We conducted clinical trials of TAPET<sup>®</sup> from 1999 to 2002. In 2006, we will continue to seek a partner to assist with future development of TAPET<sup>®</sup> technology.

### **Other Products and Product Candidates for Conditions Other than Cancer**

#### ***MELASYN<sup>®</sup>***

MELASYN<sup>®</sup> is a patented, synthetic form of melanin that dissolves readily in water. Melanin is a pigment formed by cells in the skin that gives skin its color and protects it from sun damage by absorbing ultraviolet rays. We believe that MELASYN<sup>®</sup> is the first water-soluble, synthetic version of melanin, making it a potentially useful ingredient for formulation of skin care products and cosmetics. Our MELASYN<sup>®</sup> patent and technology is licensed from Yale.

In March 2004, we entered into a non-exclusive sublicense agreement for MELASYN<sup>®</sup> with Johnson and Johnson Consumer Companies, Inc. The terms of the agreement do not include any upfront or milestone payments. If products including our technology are developed, we will receive a royalty based on sales in countries where we have issued patents. In March 2005, we entered into a non-exclusive sublicense agreement for MELASYN<sup>®</sup> with B&P Company, Incorporated. The terms of the agreement do not include any upfront or milestone payments. When products including our technology are developed, we receive a royalty based on sales in countries where we have issued patents.

### ***Novel Nucleoside Analogs***

We have licensed patents and patent applications related to a nucleoside analogue, or synthetic molecule, known as  $\beta$ -L-Fd4C from Yale.  $\beta$ -L-Fd4C is an antiviral drug capable of inhibiting the replication of the hepatitis B virus (HBV).  $\beta$ -L-Fd4C may also be useful for the treatment of the human immunodeficiency virus (HIV).

In February 2000, we signed a sublicense agreement for  $\beta$ -L-Fd4C with Achillion Pharmaceuticals, Inc. (Achillion), a privately-held biopharmaceutical company developing and commercializing innovative antiviral therapies. Under the terms of the sublicense agreement, Achillion will fund the development of  $\beta$ -L-Fd4C. In return, we received a small equity position in Achillion and could receive milestone payments and royalties based on product revenue.

## **License and Research Agreements**

### ***Agreements with Yale University***

Since 1988, we, or predecessors of our company, have entered into a series of agreements under which we have funded research at Yale and licensed inventions from Yale. The license agreements with Yale grant us exclusive licenses to make, use, sell and practice the inventions covered by various patents and patent applications. Each license agreement requires us to pay royalties, and in some cases milestone payments, to Yale. Certain licenses are terminable in the event we do not exercise due diligence in commercializing the licensed technology.

Subsequent to entering into a license agreement with Yale in August 1994, we have paid approximately \$10.3 million through December 31, 2005 to fund certain research at Yale, including research in the laboratories of Dr. Alan Sartorelli, one of our directors, and Dr. Yung-Chi Cheng, a member of our scientific advisory board. We have agreed to pay an additional \$250,000 to support the research activities of Dr. Sartorelli through the first quarter of 2007. Yale has sole discretion to use these funds to conduct research relating to products that it desires to pursue. Additionally, to the extent that such research results in technologies not covered by our license agreements with Yale, we may be unable to utilize such technologies unless we negotiate additional license agreements.

### ***Yale/Vion (formerly MelaRx Pharmaceuticals, Inc.) License Agreement – September 1990***

Under a license agreement with Yale dated September 1990, we have a license to a synthetic form of melanin, which we have named MELASYN<sup>®</sup>. Under the terms of the license agreement, we pay a license fee to Yale based on a percentage of net sales and sublicensing revenues.

### ***Yale/Vion (formerly OncoRx, Inc.) License Agreement – August 1994***

We are a party to a license agreement with Yale entered into in August 1994 and subsequently amended in five amendments. Under this amended license, Yale granted us a non-transferable worldwide exclusive license to make, have made, use, sell and practice inventions under certain patents and patent applications for therapeutic and diagnostic purposes. We also have a non-exclusive license to an additional patent under this amended license. The patents and patent applications under this amended license cover Cloretazine<sup>®</sup>, Triapine<sup>®</sup>, KS119 (an analogue of VNP40541), and  $\beta$ -L-Fd4C. The term of the license is dictated by the expiration of any patents relating to any inventions or, with respect to non-patented inventions or research, 17 years from 1994 (i.e. through 2011). Yale has retained the right to make, use and practice the inventions for non-commercial purposes and, with respect to two of the patents, Yale and its licensees have additional rights. This agreement as amended also provides that if Yale, as a result of its own research, identifies potential commercial opportunities for the licensed inventions, Yale will give us a first option to negotiate a commercial license for the commercial opportunities. Yale is entitled to royalties on sales, if any, of resulting products, sublicensing revenues and, with regard to several patents, milestone payments based on the status of clinical trials and/or regulatory approvals.

We have agreed with Yale that we will plan and implement appropriate research and development with respect to commercialization of products based on the licensed inventions. In the event that the agreement is terminated for breach, all rights under licenses previously granted terminate. Accordingly, a default as to one product could affect our rights in other products. In addition, Yale, at its sole option, can terminate any sublicenses that we grant.

Pursuant to the original agreement, we issued to Yale 159,304 shares of our common stock and made a payment of \$50,000. In June 1997, this license agreement and another license agreement dated December 1995 were amended pursuant to which Yale agreed to reduce certain amounts payable by us in exchange for 150,000 shares of our common stock issued to Yale and valued at \$600,000.

### ***Yale/Vion (formerly OncoRx, Inc.) License Agreements – December 1995***

In December 1995, we entered into a license agreement with Yale pursuant to which we received a non-transferable worldwide exclusive license, expiring over the lives of the patents, to three

inventions relating to gene therapy for melanoma. Technology licensed by us under this agreement relates to TAPET<sup>®</sup>. Pursuant to the license agreement, we paid Yale a \$100,000 fee.

In December 1995, we entered into another license agreement with Yale pursuant to which we received a non-transferable worldwide exclusive license, expiring over the lives of the patents, to an invention relating to whitening skin.

Under the licensing agreements, Yale is entitled to milestone payments based on the status of clinical trials and regulatory approvals. In addition, Yale is entitled to royalties on sales, if any, of resulting products and sublicense revenues.

### ***Other Agreements***

#### ***License Agreement with Beijing Pason Pharmaceuticals, Inc.***

In October 2003, we entered into a license with Pason providing them with the exclusive rights to develop, manufacture and market Triapine<sup>®</sup> in the People's Republic of China, Taiwan, Hong Kong and Macao (the Pason Territory). The terms of the agreement included an initial payment of \$500,000 which we received in November 2003, \$4.75 million in potential additional milestone payments, and potential royalty payments of 11% of any Triapine<sup>®</sup> revenues in the Pason Territory. Pason will fund the preclinical and clinical development necessary for regulatory approval of Triapine<sup>®</sup> in the Pason Territory.

#### ***License Agreement with Austrian Inventors and Austria Wirtschaftsservice Gesellschaft m.b.H.***

In December 2003, we entered into a research collaboration and option agreement for certain novel compounds, heterocyclic hydrazones, with a group of inventors from the Institute of Pharmacy and the Institute of Medical Chemistry and Biochemistry at the University of Innsbruck, and Austria Wirtschaftsservice Gesellschaft m.b.H, a bank specializing in Austrian business promotion.

In December 2003, we made an initial payment of \$25,000 to enter into the agreement. In September 2005, we entered into an exclusive license for these compounds and made an additional payment of \$37,500. Under this license agreement, we must make milestone payments based on the progress of product development, and pay royalties based on product revenues.

#### ***Consulting Agreement with Gemin X, Inc.***

In January 2004, we entered into a consulting agreement with Gemin X, Inc. (Gemin X), a privately-held company developing oncology therapeutics. Under this agreement, our chief scientific officer, Dr. Terrence Doyle, renders consulting services to Gemin X. Gemin X pays us, based on an hourly rate, for up to 80% of Dr. Doyle's time per year. This agreement has been extended through March 31, 2006, which is Dr. Doyle's planned retirement date. We do not anticipate extending this agreement beyond that date.

### **Competition**

Competition in the biopharmaceutical industry is intense and based on scientific and technological factors, the availability of patent and other protection for technology and products, the ability to finance and commercialize technological developments, and the ability to obtain governmental approval for testing, manufacturing and marketing drugs. Numerous pharmaceutical and biotechnology companies have publicly announced their intention to develop drugs that target the replication of tumor cells including, in some instances, agents to be used for the treatment of AML or alkylating agents like our compound Cloretazine<sup>®</sup>, or agents that target ribonucleotide reductase like our compound Triapine<sup>®</sup>. These companies include, but are not limited to Amgen Inc., AstraZeneca PLC, Bioenvision, Inc., Bristol-Myers Squibb Company, Chiron Corporation, Eli Lilly and Co., Genentech Inc., Genzyme Corporation, ImClone Systems Inc., Johnson & Johnson, Lorus Therapeutics Inc., MGI Pharma, Inc., OSI Pharmaceuticals, Inc., Pfizer Inc., Pharmion Corp., Schering-Plough Corporation and SGX Pharmaceuticals, Inc. Our competitors may have substantially

greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products. In addition, many of these companies have extensive experience in preclinical testing and human clinical trials, and in obtaining regulatory approvals. Our competitors may succeed in obtaining approval for products more rapidly and in developing and commercializing products that are safer and more effective than those that we propose to develop. The existence of these products, other products or treatments of which we are not aware or products or treatments that may be developed in the future may adversely affect the marketability of our products by rendering them less competitive or obsolete. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in acquiring rights to products or technologies from universities, and recruiting and retaining highly qualified scientific personnel and consultants.

The timing of market introduction of our potential products or of the products of others will be an important competitive factor. Accordingly, the relative speed with which we can develop products, complete preclinical testing, clinical trials and regulatory approval processes, and supply commercial quantities to market will influence our ability to bring a product to market. In addition, we may apply for orphan drug designation by the FDA for our proposed products. To the extent that a competitor of ours develops and receives orphan drug designation and marketing approval for a drug to treat the same indication prior to us, we may be precluded from marketing our product for a period of seven years.

### **Patents, Licenses and Trade Secrets**

Our policy is to protect our technology by, among other means, filing patent applications for technology that we consider important to the development of our business. We intend to file additional patent applications, when appropriate, relating to new developments or improvements in our technology and other specific products that we develop. We also rely on trade secrets, know-how and continuing technological innovations, as well as patents we have licensed or may license from other parties to develop and maintain our competitive position.

In connection with our license agreement with Yale dated August 1994, we are the exclusive licensee, subject to certain rights retained by Yale, of a number of issued patents and pending U.S. and foreign patent applications relating to:

- Cloretazine<sup>®</sup>, KS119 (an analogue of VNP40541), and other compounds in the sulfonylhydrazine class;
- Triapine<sup>®</sup> and other ribonucleotide reductase inhibitors; and
- $\beta$ -L-Fd4C, its composition and its use for the treatment of HBV and HIV infections, and its use in combination with other anti-AIDS drugs.

We are also the exclusive licensee of Yale of one issued U.S. and a number of foreign patents and pending patent applications relating to synthetic melanin and methods for using synthetic melanin, such as for sunscreen or self-tanning agents relevant to our MELASYN<sup>®</sup> technology.

Pursuant to our license agreement with Yale dated December 1995, we are the exclusive licensee of a number of issued patents and pending patent applications, U.S. and foreign, relating to our TAPET<sup>®</sup> technology, which include claims for methods of diagnosing and/or treating various solid tumor cancers, including melanoma, lung cancer, breast cancer and colon cancer. We also have rights, either by license and/or by assignment, to issued patents and pending patent applications, U.S. and foreign, relating to our TAPET<sup>®</sup> technology. In addition, we have pending a number of U.S. provisional and non-provisional patent applications, an international patent application and a number of foreign patent applications related to this technology.

We or our licensors are prosecuting the patent applications related to products we license both with the U.S. Patent and Trademark Office (PTO) and various foreign patent agencies, but we do not know whether any of our applications will result in the issuance of any patents or, whether any issued patent will provide significant proprietary protection or will be circumvented or invalidated. During

the course of patent prosecution, patent applications are evaluated for, among other things, utility, novelty, non-obviousness, written description and enablement. The PTO may require that the claims of an initially filed patent application be amended if it is determined that the scope of the claims include subject matter that is not useful, novel, non-obvious, described adequately or enabled. Furthermore, in certain instances, the practice of a patentable invention may require a license from the holder of dominant patent rights.

We cannot predict whether our patent applications or our competitors' patent applications will result in valid patents being issued. An issued patent is entitled to a presumption of validity. The presumption may be challenged in litigation; a court could find any patent of ours or of our competitors invalid and/or unenforceable. Litigation, which could result in substantial cost to us, may also be necessary to enforce our patent and proprietary rights and/or to determine the scope and validity of the proprietary rights of others.

The patent position of biotechnology and pharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents.

### **Government Regulation**

*Overview.* Regulation by state and federal governmental authorities in the U.S. and foreign countries is a significant factor in the development of our anticancer products, and will be a significant factor in manufacturing and marketing of these products, if they are successfully developed and approved for sale. All of our products will require regulatory clearances or approvals prior to commercialization. In particular, drugs, biological agents and medical devices are subject to rigorous testing and other approval requirements by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and its regulations, as well as by similar health authorities in foreign countries. Various federal statutes and regulations also govern or influence the testing, manufacturing, safety, labeling, packaging, advertising, storage, registration, listing and recordkeeping related to marketing of such products. Regulatory approval often takes a number of years and involves the expenditure of substantial resources. Approval time also depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. We cannot be certain that any required FDA or other regulatory approval will be granted or, if granted, will not be withdrawn.

The development of a therapeutic drug typically first requires preclinical testing. Preclinical development of therapeutic drugs and biological agents is generally conducted in the laboratory to evaluate the safety and the potential efficacy of a compound by relevant *in vitro* and *in vivo* testing. When a product is tested prospectively to determine its safety for purposes of obtaining FDA approvals or clearances, such testing must be performed in accordance with good laboratory practices for non-clinical studies. The results of preclinical testing are submitted to the FDA as part of an IND. The IND must become effective, the study must be approved by an institutional review board, and informed consent must be obtained from the clinical subjects, before human clinical trials can begin.

Typically, clinical evaluation involves a three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the tolerated drug dose, early safety profile, proper scheduling and the pattern of drug distribution, absorption and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine efficacy, dose-response relationships and expanded evidence of safety. In Phase III, large-scale, multi-center, controlled clinical trials are conducted in order to:

- provide enough data for statistical proof of safety and efficacy;
- compare the experimental therapy to existing therapies;
- uncover any unexpected safety problems, such as side-effects; and
- generate product labeling.

In the case of drugs for cancer and other life-threatening diseases, the initial human testing is generally conducted in patients rather than in healthy volunteers.

Tests of our product candidates and human clinical trials may be delayed or terminated due to factors such as unfavorable results or insufficient patient enrollment. Furthermore, the FDA may suspend clinical trials at any time on various grounds. Delays in tests and trials may have a material adverse effect on our business.

The results of the preclinical and clinical testing are submitted to the FDA either as part of a new drug application (NDA) for drugs, or a biologics license application (BLA) for biologics, for approval to commence commercial distribution. For a biologic drug, the manufacturer generally must also obtain approval of an establishment license application. In responding to an NDA or BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. It may take several years to obtain approval after submission of an NDA or BLA, although approval is not assured. The FDA also normally conducts a pre-approval inspection and other occasional inspections of an applicant's facilities to ensure compliance with current good manufacturing practices. Further, stringent FDA regulatory requirements continue after a product is approved for marketing, and changes to products or labeling can require additional approvals. If any of our products is approved for marketing, we will be subject to stringent post-marketing requirements.

We also will be subject to widely varying foreign regulations governing clinical trials and pharmaceutical sales. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before marketing the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. We intend, to the extent possible, to rely on foreign licensees to obtain regulatory approval to market our products in foreign countries.

In October 2004, we received orphan drug designation for Cloretazine<sup>®</sup> in AML. Under the Orphan Drug Act, a sponsor may obtain designation by the FDA of a drug or biologic as an 'orphan' drug for a particular indication. Orphan drug designation is granted to drugs for rare diseases or conditions, including many cancers, with a prevalence of less than 200,000 cases in the United States. The sponsor of a drug that has obtained orphan drug designation and which is the first to obtain approval of a marketing application for such drug, which approval cannot be assured, is entitled to marketing exclusivity for a period of seven years for the designated indication. This means that no other company can market the same orphan drug for the same indication approved by the FDA for seven years after approval unless such company proves its drug is clinically superior or the approved orphan drug marketer cannot supply demand for the drug. Legislation is periodically considered that could significantly affect the Orphan Drug law. We intend to seek additional orphan drug designations for our products where appropriate. There can be no assurance that future changes to the Orphan Drug Act would not diminish the value of any orphan drug designation obtained by us.

FDA regulatory procedures established in 1988 are intended to speed further the availability of new drugs intended to treat life-threatening and severely debilitating illnesses. These procedures provide for early and continuous consultation with the FDA regarding preclinical and clinical studies necessary to gain marketing approval. This regulatory framework also provides that if Phase I results demonstrate potential, Phase II clinical trials may be designed that obviate the need for lengthy, expensive Phase III testing. Notwithstanding the foregoing, approval may be denied by the FDA or traditional Phase III studies may be required. The FDA may also seek our agreement to perform post-approval Phase IV studies, which confirm product safety and efficacy.

In January 2006, we received orphan drug designation for Cloretazine<sup>®</sup> for the treatment of AML in Europe. Orphan drug status is granted by the European Commission to promote development of drugs to treat rare diseases or conditions. Orphan drug designation does not convey any advantage or shorten the duration of the EMEA review and approval process. Orphan drug designation may entitle Cloretazine<sup>®</sup> to: (i) ten years of market exclusivity for the indication of AML; (ii) protocol assistance from the European Medicines Agency to optimize drug development in preparing a dossier that will meet regulatory requirements; (iii) reduced fees associated with applying for market approval; and (iv) access to European Union research funding.

In addition to regulations relating to drug development, we are subject to federal, state and local environmental laws and regulations, including those promulgated by the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC), that govern activities or operations that may have adverse environmental effects, such as discharges to air and water, as well as handling and disposal practices for solid and hazardous wastes. These laws also impose strict liability for the costs of cleaning up, and for damages resulting from, sites of past spills, disposals or other releases of hazardous substances and materials for the investigation and remediation of environmental contamination at properties operated by us and at off-site locations where we have arranged for the disposal of hazardous substances.

We have made, and will continue to make, expenditures for our facilities to comply with current and future environmental laws. To date, we have not incurred significant costs and are not aware of any significant liabilities associated with our compliance with federal, state and local environmental laws and regulations. However, environmental laws have changed in recent years and we may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and are uncertain whether we will be able to pay for significantly large capital expenditures. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

All of our operations are performed under strict environmental and health safety controls consistent with OSHA, EPA and NRC regulations. We cannot be certain that we will be able to control all health and safety problems. If we cannot control those problems, we may be held liable and may be required to pay the costs of remediation. These liabilities and costs could be material.

### **Manufacturing and Marketing**

We do not have experience in manufacturing or marketing products and have not yet commercially introduced any products. We do not currently have the resources to manufacture or market on a commercial scale any products that we develop. We currently use third parties to manufacture limited quantities of our products for use in clinical activities.

If our products are approved for sale by regulatory authorities, we will need to develop manufacturing and marketing capability or make arrangements with third parties to manufacture, distribute and sell our products. In the event we decide to establish a manufacturing and distribution facility or a marketing and sales force, we will require substantial additional funds and will be required to hire and retain additional personnel.

### **Employees**

As of December 31, 2005, we had 40 full-time employees.



## Executive Officers and Directors

The following table contains the names and positions of our executive officers and directors:

<u>Name</u>	<u>Position</u>
Alan Kessman . . . . .	Chief Executive Officer and Director
Howard B. Johnson . . . . .	President and Chief Financial Officer
Ann Cahill . . . . .	Vice President of Clinical Development
Meghan Fitzgerald . . . . .	Vice President and Chief Business Officer
Ivan King . . . . .	Vice President of Research and Development
Karen Schmedlin . . . . .	Vice President of Finance, Chief Accounting Officer and Secretary
Terrence W. Doyle, Ph.D. <sup>(4)</sup> . . . . .	Vice President and Chief Scientific Officer
William Miller <sup>(1,2,3)</sup> . . . . .	Director
George Bickerstaff <sup>(1,2)</sup> . . . . .	Director
Stephen K. Carter, M.D. <sup>(3)</sup> . . . . .	Director
Alan C. Sartorelli, Ph.D. <sup>(3)</sup> . . . . .	Director
Mario Sznol, M.D . . . . .	Director
Gary Willis <sup>(1,2)</sup> . . . . .	Director

(1) Member of the Compensation Committee of the Board of Directors.

(2) Member of the Audit Committee of the Board of Directors.

(3) Member of the Nominating and Governance Committee of the Board of Directors.

(4) Dr. Doyle has informed us of his plan to retire as of March 31, 2006.

*Alan Kessman*, age 59, has been our Chief Executive Officer since January 1999 and has served on our Board of Directors since October 1998. Mr. Kessman also served as our President from April 1999 to January 2004. Mr. Kessman is a partner of PS Capital LLC, an international investment and management advisor. From 1983 to 1998, Mr. Kessman was chairman, chief executive officer and president of Executone Information Systems, Inc., a developer and marketer of voice and data communications systems.

*Howard B. Johnson*, age 46, has been our President since January 2004 and our Chief Financial Officer since March 2002. Mr. Johnson was a vice president and a consultant for Nutrition 21, Inc., a nutri-ceutical company, from November 2001 until March 2002. From May 1999 until February 2001, Mr. Johnson was chief financial officer of IBS Interactive, Inc. (now Digital Fusion, Inc.), an information technology services company. Mr. Johnson founded and from 1996 to 1999 was chairman and chief executive officer of MedWorks Corporation, a privately held medical device company. From 1983 to 1993, Mr. Johnson was an investment banker at PaineWebber Group, Inc.

*Ann Lee Cahill*, age 45, has been our Vice President of Clinical Development since October 2004. Ms. Cahill was our Senior Director of Clinical Affairs from October 2003 to October 2004 and Director of Clinical Affairs from January 2002 to October 2003. From 1997 to 2002, Ms. Cahill was a member of the project management group of Schering-Plough Corporation, including leadership roles in clinical affairs for hepatitis and medical oncology. From 1985 to 1997, Ms. Cahill was a physician associate in a medical oncology practice.

*Meghan Fitzgerald*, age 35, has been our Vice President and Chief Business Officer since January 2006. From 2005 to January 2006, Ms. Fitzgerald was Senior Director of Strategic Planning and Business Development and from 2001 to 2005 World Wide Marketing Director of Life Cycle Management for Pfizer Human Health. From 1997-2001 Ms. Fitzgerald held marketing positions at Merck, Forest Labs and Sanofi-Synthelabo. Prior to 1997, Ms. Fitzgerald was a registered nurse.

*Ivan King, Ph.D.*, age 50, has been our Vice President of Research and Development since January 2004. Dr. King was our Vice President of Research from July 1998 to January 2004, Senior Director of Biology from April 1997 to July 1998 and Director of Biology from October 1995 to April 1997. From 1990 to 1995, Dr. King was a section leader in the department of tumor biology at

Schering-Plough Research Institute in charge of the cell biology and in vivo biology groups where he was responsible for identifying targets, developing high throughput assays, evaluating in vitro and in vivo activities of drug candidates and recommending candidates for clinical development. Dr. King's first industrial position was as a senior research scientist at Bristol-Myers Squibb Company.

*Karen Schmedlin*, age 43, has been our Vice President, Finance and Chief Accounting Officer since March 8, 2006 and our Secretary since April 2001. Ms. Schmedlin was our Controller from October 2000 to March 2006. From 1990 to 2000, Ms. Schmedlin held various finance and marketing positions at Executone Information Systems, Inc., a developer and marketer of voice and data communications systems, including director of marketing operations, division controller and manager of financial reporting. From 1984 to 1990, Ms. Schmedlin was an auditor with Arthur Andersen & Co.

*Terrence W. Doyle, Ph.D.*, age 63, has been our Vice President and Chief Scientific Officer since January 2004. Prior to that, Dr. Doyle was our Vice President of Research and Development since the merger with OncoRx, Inc. and served in the same capacity for OncoRx, Inc. from January 1994 until the merger. From 1967 to 1993, Dr. Doyle was an employee of the Bristol-Myers Squibb Company, including from 1990 to 1993 an executive director with Bristol-Myers Squibb Company. Dr. Doyle is the original holder of 49 U.S. patents for anti-infective, anti-inflammatory and anti-tumor agents and the author of over 175 published research articles and abstracts on cancer chemotherapy. Dr. Doyle has informed the Company that his planned retirement date is March 31, 2006.

*William R. Miller*, age 77, has been Chairman of our Board since April 1995. From February 1995 until April 1995, Mr. Miller was Chairman of the Board of OncoRx, Inc., which merged into the Company (then known as MelaRx, Inc.) in April 1995. Mr. Miller is currently a director of ImClone Systems, Inc., a biotechnology company. From 1964 until his retirement in 1991, Mr. Miller was employed by Bristol-Myers Squibb Company in various positions, including vice chairman of the board commencing in 1985.

*George Bickerstaff*, age 50, has been a director since June 2005. Mr. Bickerstaff is a director of Oracle Healthcare Acquisition Corp, a blank check company. Mr. Bickerstaff is Managing Director of CRT Capital Group LLC, an investment banking company, since June 2005. From October 2000 to May 2004, Mr. Bickerstaff held various positions with Novartis, including chief financial officer of Novartis Pharma AG. From 1998 to September 2000, Mr. Bickerstaff held senior finance and operating roles in venture-funded businesses and, prior to that, held various financial positions with the Dun and Bradstreet Corporation, including Chief Financial Officer of IMS Healthcare.

*Stephen K. Carter, M.D.*, age 68, has been a director since 2001. Dr. Carter is a director of Cytogen Corp., Alfacell Corp., Tapestry Pharmaceuticals, Inc. and Emisphere Technologies Inc. (each a biotechnology company). From 1998 to 2000, Dr. Carter was senior vice president, clinical and regulatory affairs of SUGEN, Inc. (subsequently acquired by Pharmacia & Upjohn, Inc.). From 1995 to 1996, Dr. Carter was senior vice president, research and development with Boehringer Ingelheim Pharmaceuticals, Inc. and from 1982 to 1995 held various positions with Bristol-Myers Squibb Company, including senior vice president, worldwide clinical research and development.

*Alan C. Sartorelli, Ph.D.*, age 74, has been a director since 1995. Dr. Sartorelli has been an Alfred Gilman Professor of Pharmacology at Yale University School of Medicine since 1967 and Chairman of our Scientific Advisory Board since April 1995. Dr. Sartorelli was Chairman of the OncoRx, Inc. Scientific Advisory Board from May 1993 to April 1995 and director of Yale Comprehensive Cancer Center from 1984 to 1993.

*Mario Sznol, M.D.*, age 48, has been a director since October 2004. Dr. Sznol is an associate professor of medicine at Yale University School of Medicine since October 2004. Dr. Sznol was our vice president of clinical affairs from September 1999 to October 2004. From 1994 to 1999, Dr. Sznol served as head of the Biologics Evaluation Section, Investigational Drug Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis of the National Cancer Institute, or NCI, an institute of the National Institutes of Health.

*Gary Willis*, age 60, has been a director since June 2005. Mr. Willis is a director of Rofin-Sinar Technologies, Benthos Corporation and Plug Power Inc. From 1992 to 2000, Mr. Willis was Chairman,

President and Chief Executive Officer of the Zygo Corporation, a developer and marketer of optical systems and components. From 1984 to 1990, Mr. Willis was Chairman, President and Chief Executive Officer of the Foxboro Company, a supplier of instruments, systems, and services for industrial process automation.

Our directors are elected annually to serve until the next annual meeting of stockholders and until their successors shall have been duly elected and shall qualify. Our executive officers are elected by the board annually and serve for such period or until their earlier resignation or removal by the board.

### **Available Information**

The following information can be found on our website at <http://www.vionpharm.com> or may be obtained free of charge by contacting our Investor Relations Department at (203) 498-4210 or by sending an e-mail message to [info@vionpharm.com](mailto:info@vionpharm.com):

- our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;
- our policies related to corporate governance, including the charter for the Nominating and Governance Committee of our Board of Directors, our code of ethics and business conduct applying to our directors, officers and employees, and our code of ethics applying to our chief executive officer and senior financial officials; and
- the charter of the Audit Committee of our Board of Directors.

### **ITEM 1A. Risk Factors**

This Annual Report on Form 10-K contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. Our actual results could differ materially. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under “Risk Factors” below, as well as those discussed elsewhere in this Annual Report on Form 10-K.

An investment in our securities is risky. Prior to making a decision about investing in our securities, you should carefully consider the specific risks discussed below. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. If any of the risks or uncertainties described below or any such additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected. In this case, the trading price of our securities could decline and you might lose all or part of your investment.

#### ***If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.***

We will need to raise substantial additional capital to fund operations and complete our product development. As of December 31, 2005, we had \$52.8 million in cash and cash equivalents to fund our operations and continue our product development. We will not have an approved and marketable product for the foreseeable future. Accordingly, we will need to raise substantial additional capital to have sufficient capital to fund our operations in 2007 and beyond.

We may not get funding when we need it or on favorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate our research and development activities, clinical studies or future operations. We might have to license our technology to others. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including:

- the progress, timing and scope of our product development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- the time and cost necessary to develop sales, marketing and distribution capabilities;
- our ability to enter into and maintain collaborative, licensing and other commercial relationships; and
- our partners' commitment of time and resource to the development of our products.

***We have limited access to the capital markets and, if we can raise additional funding, stockholders may experience extreme dilution.***

We have limited access to the capital markets to raise capital. The capital markets have been unpredictable in the past, especially for drug development companies and unprofitable companies such as ours. In addition, it is difficult to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control, such as the share price of our stock and its trading volume. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our technology licenses, relationships with key suppliers, results of operations, financial condition and our continued viability will be materially adversely affected.

To the extent we encounter additional opportunities to raise cash, we would likely sell additional equity or debt securities. Due to our current stock price and market conditions, and the amount of capital we need, any such debt or equity securities are likely to be sold at relatively low prices, including prices which are below the market prices of our stock, and may have substantial rights to control the Company. For example, in our private placement in June 2003, shares of common stock were sold at \$1.30 per share which was approximately 64% of market price at the time. Stockholders are likely to experience extreme dilution as well as subordination of their rights. We do not have any contractual restrictions on our ability to incur debt. Any indebtedness could contain covenants that restrict our operations.

***If we continue to incur operating losses, we may be unable to continue our operations.***

We have incurred losses since inception. As of December 31, 2005, we had an accumulated deficit of approximately \$149.8 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. Since we began our business, we have focused on research, development and clinical trials of product candidates. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our future profitability depends on our receiving regulatory approval of our product candidates and our ability to successfully manufacture and market approved drugs. The extent of our future losses and the timing of our profitability are highly uncertain.

***If we do not obtain regulatory approval for our products, we will not be able to sell our products and the value of our company and our financial results will be harmed.***

We cannot sell or market our drugs without regulatory approval. If we cannot obtain regulatory approval for our products, the value of our company and our financial results will be harmed. In the

United States, we must obtain approval from the U.S. Food and Drug Administration (FDA) for each drug that we intend to sell. The current status of our potential products is as follows:

- Cloretazine<sup>®</sup> is being evaluated in five clinical trials sponsored by us including a Phase III trial in relapsed acute myelogenous leukemia in combination with Ara-C, a Phase II trial as a single agent in small cell lung cancer, a Phase I/II trial in refractory or relapsed chronic lymphocytic leukemia, a Phase II trial in acute myelogenous leukemia and high-risk myelodysplasia, and a Phase I trial in combination with temozolomide, as well as two investigator-sponsored trials in pediatric and adult brain tumors;
- The National Cancer Institute is sponsoring Phase I and Phase II trials of Triapine<sup>®</sup> as a single agent and in combination with standard chemotherapies; and
- VNP40541 and heterocyclic hydrazones are being evaluated in preclinical studies.

If and when we complete the several phases of clinical testing for each drug candidate, we will submit our test results to the FDA. FDA review may generally take up to two years and approval is not assured. Foreign governments also regulate drugs distributed outside the United States. A delay in obtaining regulatory approvals for any of our drug candidates will also have a material adverse effect on our business.

***If our drug trials are delayed or achieve unfavorable results, we will not be able to obtain regulatory approvals for our products.***

We must conduct extensive testing of our product candidates before we can obtain regulatory approval for our products. We need to conduct human clinical trials. These tests and trials may not achieve favorable results. We would need to reevaluate any drug that did not test favorably and either alter the drug or dose, or abandon the drug development project. In such circumstances, we would not be able to obtain regulatory approval on a timely basis, if ever.

Factors that can cause delay or termination in our clinical trials include:

- slow patient enrollment;
- long treatment time required to demonstrate safety and effectiveness;
- lack of sufficient supplies of the product candidate;
- adverse medical events or side effects in treated patients;
- lack of effectiveness of the product candidate being tested; and
- lack of sufficient funds.

***If the testing or use of our potential products harms people, we could be subject to costly and damaging product liability claims.***

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of drug products. These risks are particularly inherent in human trials of our proposed products. Unacceptable side effects may be discovered during preclinical and clinical testing of one or more of our potential products. Side effects and other liability risks could give rise to viable product liability claims against us. While we have obtained insurance coverage for patients enrolled in clinical trials, we may not be able to maintain this insurance on acceptable terms, insurance may not provide adequate coverage against potential liabilities and we may need additional insurance coverage for expanded clinical trials and commercial activity. As a result, product liability claims, even if successfully defended, could have a material adverse effect on our business, financial condition and results of operations. If the side effects are determined to be unacceptable, we will not be able to commercialize our products.

***If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our drug development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.***

Our manufacturing processes and potential products may conflict with patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the drug development industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

***We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.***

We rely on trade secrets that we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business and compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

***If we fail to recruit and retain key personnel, our research and development programs may be delayed.***

We are highly dependent upon the efforts of our senior management and scientific personnel, particularly, Alan Kessman, our chief executive officer and director; Howard Johnson, our president and chief financial officer; Ann Lee Cahill, our vice president, clinical development; Ivan King, Ph.D., our vice president, research and development; and Meghan Fitzgerald, our vice president and chief business officer. There is intense competition in the drug development industry for qualified scientific and technical personnel. Since our business is very technical and specialized, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business, particularly in light of our need to raise substantial additional financing in order to continue our operations in 2007 and beyond. We have no key man insurance policies on any of the officers listed above and we only have an employment agreement with Mr. Kessman. If we lose the services of our management and scientific personnel or fail to recruit other scientific and technical personnel, our research and product development programs will be significantly and detrimentally affected.

***We face intense competition in the market for anticancer products, and if we are unable to compete successfully, our business will suffer.***

Numerous pharmaceutical and biotechnology companies have publicly announced their intention to develop drugs that target the replication of tumor cells including, in some instances, the development of agents which treat AML and are alkylating agents similar to our compound Cloretazine<sup>®</sup> and agents which target ribonucleotide reductase similar to our compound Triapine<sup>®</sup>. These companies include, but are not limited to Amgen Inc., AstraZeneca PLC, Bioenvision, Inc., Bristol-Myers Squibb Company, Chiron Corporation, Eli Lilly and Co., Genentech Inc., Genzyme Corporation, ImClone Systems Inc., Johnson & Johnson, Lorus Therapeutics Inc., MGI Pharma, Inc., OSI Pharmaceuticals, Inc., Pfizer Inc., Pharmion Corp., Schering-Plough Corporation and SGX Pharmaceuticals, Inc. These and other large pharmaceutical companies have substantially greater financial and other resources and development capabilities than we do and have substantially greater

experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. In addition, our competitors may succeed in obtaining approval for products more rapidly than us and in developing and commercializing products that are safer and more effective than those that we propose to develop. The existence of these products, other products or treatments of which we are not aware or products or treatments that may be developed in the future may adversely affect the marketability of our products by rendering them less competitive or obsolete. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we may compete with other companies in acquiring rights to products or technologies from universities.

***If our corporate partners, licensors, licensees, collaborators at research institutions and others do not conduct activities in accordance with our arrangements, our research and development efforts may be delayed.***

Our strategy for the research, development and commercialization of our products entails entering into various arrangements with corporate partners, licensors, licensees, collaborators at research institutions and others. We currently depend on the following third parties:

- The National Cancer Institute (NCI) with respect to clinical development of Triapine<sup>®</sup> in Phase I and Phase II single agent and combination trials;
- Yale University (Yale) for collaborative research and for technologies that are licensed by them to us;
- Beijing Pason Pharmaceuticals, Inc. for the development of Triapine<sup>®</sup> in the People's Republic of China, Hong Kong, Macao and Taiwan;
- Duke University Comprehensive Cancer Center for clinical development of Cloretazine<sup>®</sup> in adult patients with recurrent gliomas (brain cancer) under an investigator's IND;
- The Pediatric Brain Tumor Consortium (PBTC) for clinical development of Cloretazine<sup>®</sup> in pediatric brain tumors under an investigator's IND.
- Healthcare facilities in the United States and other countries to perform human clinical trials of our products;
- Clinical research organizations in the United States and other countries to monitor and collect data related to human clinical trials; and
- Contract manufacturers to produce our products for use in preclinical and clinical activities.

If the third parties do not conduct activities in accordance with the arrangements we have with them, our research and development efforts may be delayed. We may also rely on other collaborative partners to obtain regulatory approvals and to manufacture and market our products. The amount and timing of resources to be devoted to these activities by these other parties may not be within our control.

***If Yale does not conduct research relating to products we would like to pursue, we may never realize any benefits from our funding provided to Yale.***

Through December 31, 2005, we have paid approximately \$10.3 million to Yale for research funding. We have agreed to pay an additional \$250,000 to support the research activities of one of our directors, an affiliate of Yale, through March 31, 2007. We may continue to support certain research projects at Yale. We generally do not have the right to control the research that Yale is conducting with our funding, and our funds may not be used to conduct research relating to products that we would like to pursue. Additionally, if the research being conducted by Yale results in technologies that Yale has not already licensed or agreed to license to us, we may need to negotiate additional license agreements or we may be unable to utilize those technologies.

***Even if we obtain regulatory approval for our products, we currently lack the ability and resources to commercialize the products.***

If our products are approved for sale by regulatory authorities, we will need to develop manufacturing and marketing capability or make arrangements with third parties to manufacture,

distribute and sell our products for commercial use. We do not currently have arrangements for manufacturing or marketing products on a commercial basis.

***If environmental laws become stricter in the future, we may face large capital expenditures in order to comply with environmental laws.***

We cannot accurately predict the outcome or timing of future expenditures that we may be required to expend to comply with comprehensive federal, state and local environmental laws and regulations. We must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, we have not incurred significant costs and are not aware of any significant liabilities associated with our compliance with federal, state and local laws and regulations. However, environmental laws have changed in recent years and we may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and are uncertain whether we will be able to pay for significantly large capital expenditures. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

All of our operations are performed under strict environmental and health safety controls consistent with the Occupational Safety and Health Administration, the Environmental Protection Agency and the Nuclear Regulatory Commission regulations. We cannot be certain that we will be able to control all health and safety problems. If we cannot control those problems, we may be held liable and may be required to pay the costs of remediation. These liabilities and costs could be material.

***We may expand our business through new acquisitions that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.***

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions to do so. Acquisitions involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- diverting our management's attention away from other business concerns;
- risks of entering markets in which we have limited or no direct experience; and
- the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our stock, which could dilute current stockholder's ownership interest in our company.

***We rely on third party manufacturers to manufacture our product candidates. If these third party manufacturers fail to manufacture product candidates of satisfactory quality, in a timely manner, in sufficient quantities or at acceptable costs, development and commercialization of our products could be delayed.***

We have no manufacturing facilities, and we have no experience in the commercial manufacturing of drugs or in designing drug manufacturing processes. We have contracted with third party



manufacturers to produce our product candidates for clinical trials. We have limited supplies of our product candidates for clinical trials. If our supplies are damaged or destroyed, either during storage or shipping or otherwise, our clinical trials may be delayed, which could have a material adverse effect on our business. We intend to rely on third party contract manufacturers to manufacture, supply, store and distribute commercial quantities of our product candidates. We will also rely on our third party manufacturing partners to work with us to complete the Chemistry, Manufacturing and Control, or CMC, section of any NDAs or other marketing approval application we may file.

Contract manufacturers are obliged to operate in accordance with government mandated obligations, including FDA-mandated current good manufacturing practices (cGMPs). A failure of any of our contract manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials and may delay or prevent filing or approval of marketing applications for our products.

Changing contract manufacturers may be difficult, and the number of potential manufacturers is limited. Changing manufacturers requires re-validation of the manufacturing processes and procedures in accordance with government mandated obligations, including FDA-mandated cGMPs. Such re-validation may be costly and time-consuming. It may be difficult or impossible for us to find replacement manufacturers on acceptable terms quickly, if at all. Either of these factors could delay or prevent the completion of our clinical trials, the approval of our product candidates by the FDA or other regulatory agencies, or the commercialization of our products, result in higher costs, or cause a decline in potential product revenues.

Drug manufacturers are subject to on-going, periodic unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third party contractors, we do not have control over our third party manufacturers' compliance with these regulations and standards. Failure by our third party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension of clinical trials, withdrawal of approvals, seizures, detentions or recalls of product, operating restrictions and criminal prosecution.

To date, our product candidates have been manufactured in small quantities by third party manufacturers for preclinical and clinical trials. In order to obtain marketing approval for any of these product candidates, we will need to enter into long-term supply agreements with our existing or new third party manufacturers and demonstrate that we can manufacture sufficient quantities for commercial sale. Our third party manufacturers may not be able to successfully increase their manufacturing capacity or apply at commercial scale the current manufacturing process for any of our product candidates in a timely or economic manner, or at all. This may require seeking out additional manufacturing partners who may have different equipment requiring additional validation studies, which the relevant government regulator must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. Our product candidates require precise, high-quality manufacturing. The failure of our third party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business.

***Our common stock could be delisted from the Nasdaq Capital Market<sup>SM</sup>.***

If the price of our common stock declines below \$1.00 per share, we may fail to meet Nasdaq's maintenance criteria, which may result in the delisting of our common stock from the Nasdaq Capital Market<sup>SM</sup>.

In such the event of delisting, trading, if any, in our common stock may then continue to be conducted in the non-Nasdaq over-the-counter market in what are commonly referred to as the

electronic bulletin board and the “pink sheets”. As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock. In addition, we would be subject to a Rule promulgated by the Securities and Exchange Commission that, if we fail to meet criteria set forth in such Rule, imposes various practice requirements on broker-dealers who sell securities governed by the Rule to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser’s written consent to the transactions prior to the sale. Consequently, the Rule may have a materially adverse effect on the ability of broker-dealers to sell our securities, which may materially affect the ability of stockholders to sell our securities in the secondary market.

A delisting from the Nasdaq Capital Market<sup>SM</sup> will also make us ineligible to use Form S-3 to register shares of our common stock with the Securities and Exchange Commission, thereby making it more difficult and expensive for us to register our common stock and raise additional capital. We would also incur additional costs under state blue-sky laws to sell equity if we are delisted.

***The rights that have been and may in the future be granted to our stockholders may allow our Board and management to deter a potential acquisition in which the Board and management are to be replaced.***

We have in place a stockholder rights plan, or “poison pill”, which enables our board of directors to issue rights to purchase common stock when someone acquires 20% or more of the outstanding shares of our common stock. As a result of the plan, anyone wishing to take over the company would most likely be forced to negotiate a transaction with our Board and management in order not to trigger the pill. The need to negotiate with the Board or management could frustrate a proposed takeover particularly where the Board and management wish to remain entrenched. This would prevent our stockholders from participating in a takeover or tender offer, which might be of substantial value to them.

***The large number of our shares that may be held in the market may depress the market price of our stock and could result in substantial dilution to the holders of our shares of common stock.***

Sale or issuance of a substantial number of shares of our common stock in the future could cause the market price of our common stock to decline. It may also impair our ability to obtain additional financing. As of March 1, 2006, we had outstanding warrants to purchase 9,198,971 shares of our common stock at exercise prices ranging from \$2.20 to \$3.25 per share. All such shares have been registered for resale on registration statements filed with the Securities and Exchange Commission and will be freely tradable when issued upon exercise of the warrants. In addition, as of March 1, 2006, there were 4,720,480 shares of common stock issuable upon exercise of options granted by us. We may also grant awards under our 2005 Stock Incentive Plan to purchase up to an additional 5,708,738 shares of common stock.

**ITEM 1B. *Unresolved Staff Comments***

Not applicable.

**ITEM 2. *Properties***

Our principal facility consists of approximately 20,000 square feet of leased laboratory and office space in New Haven, Connecticut. The facility lease expires in December 2010. The current annual rental rate is approximately \$217,000. We believe our space is sufficient for our preclinical development, clinical and administrative activities.

**ITEM 3. *Legal Proceedings***

In the normal course of business, we may be subject to proceedings, lawsuits and other claims. We are not a party to any legal proceedings that may have a material adverse effect on our business.

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

At our annual meeting of stockholders held on October 25, 2005, three proposals were voted upon by our stockholders. A description of each proposal and a tabulation of the votes for each of the proposals follows:

1. To elect seven directors to hold office until the 2006 annual meeting of stockholders or until their successors are elected and qualified. All seven nominees were elected:

	<u>For Nominee</u>	<u>Authority Withheld From Nominee</u>
William R. Miller .....	57,714,246	829,932
George Bickerstaff .....	57,979,534	564,644
Stephen K. Carter, M.D. ....	57,787,683	756,495
Alan Kessman .....	57,501,199	1,042,979
Alan C. Sartorelli, Ph.D. ....	56,703,164	1,841,014
Mario Sznol, M.D. ....	57,124,413	1,419,765
Gary K. Willis .....	57,979,634	564,544

2. To approve the Vion Pharmaceuticals, Inc. 2005 Stock Incentive Plan. The Plan was approved:

<u>For</u>	<u>Against</u>	<u>Abstentions and Broker Non-Vote</u>
20,624,279	2,021,992	35,897,907

3. Ratification of the appointment of Ernst & Young LLP as the Company's independent auditors for the year ending December 31, 2005. The appointment of Ernst & Young LLP was ratified:

<u>For</u>	<u>Against</u>	<u>Abstentions and Broker Non-Vote</u>
58,005,001	236,303	302,874

## PART II

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

#### Market Information for Common Stock

Our common stock is traded under the symbol "VION" on the Nasdaq Capital Market<sup>SM</sup>. The following table reflects the range of high and low closing sales prices of our common stock for each of the calendar quarters in 2005 and 2004 as reported by the Nasdaq Capital Market<sup>SM</sup>.

	2005		2004	
	High	Low	High	Low
First Quarter .....	\$4.47	\$2.64	\$4.01	\$1.59
Second Quarter .....	2.88	2.09	5.31	3.32
Third Quarter .....	2.84	2.17	4.46	2.89
Fourth Quarter .....	2.20	1.57	5.06	4.14

#### Holders

At March 10, 2006, there were 463 holders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company (DTC). All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder.

#### Dividends

We have never paid cash dividends on our common stock. We currently intend to retain all future earnings for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future.

### ITEM 6. *Selected Financial Data*

The following selected financial data for each of the five years in the period ended December 31, 2005, and for the period from May 1, 1994 (inception) through December 31, 2005, are derived from our audited financial statements. The selected financial data should be read in conjunction with the consolidated financial statements, related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere herein.

	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>For the Period From May 1, 1994 (Inception) through December 31, 2005</u>
<b>Statement of Operations Data:</b>						
Total revenues . . . . .	\$ 23	\$ 275	\$ 375	\$ 238	\$ 650	\$ 12,942
Loss from operations . . . . .	(19,821)	(16,501)	(11,923)	(13,021)	(15,014)	(138,129)
Net loss . . . . .	(18,041)	(16,055)	(11,838)	(12,310)	(13,810)	(131,062)
Preferred stock dividends and accretion . . . . .	—	—	—	—	—	(18,489)
Loss applicable to common shareholders . . . . .	(18,041)	(16,055)	(11,838)	(12,310)	(13,810)	(149,551)
Basic and diluted loss applicable to common shareholders per share . . . . .	(0.28)	(0.30)	(0.36)	(0.43)	(0.51)	
<b>Balance Sheet Data:</b>						
Cash, cash equivalents and short-term investments . . . . .	\$ 52,762	\$ 41,729	\$ 15,719	\$ 10,131	\$ 22,644	
Total assets . . . . .	53,719	42,644	16,376	10,923	23,601	
Long-term obligations and redeemable preferred stock . . . . .	—	—	—	—	—	

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

**Overview**

We are a development stage pharmaceutical company engaged in the development of therapeutics for the treatment of cancer. Our activities to date have consisted primarily of research and product development, preclinical trials of product candidates, obtaining regulatory approval for clinical trials, conducting clinical trials, negotiating and obtaining collaborative agreements, and obtaining financing in support of these activities. Historically, our revenues have primarily consisted of contract research grants, technology license fees, and research and laboratory support service fees. Since inception, we have generated minimal revenues and have incurred substantial operating losses from our activities. We expect to incur substantial operating losses for the next several years due to expenses associated with our activities.

We have five research and development projects, which include two product candidates in clinical trials (Cloretazine<sup>®</sup> and Triapine<sup>®</sup>), two product development programs in preclinical development (VNP40541 and heterocyclic hydrazones) and one drug delivery technology (TAPET<sup>®</sup>) for which we are seeking a development partner. The following table provides information on clinical trials sponsored by us that were open for patient accrual as of March 1, 2006.

<b>Product</b>	<b>Trial</b>	<b>Trial Commencement Date</b>
Cloretazine <sup>®</sup>	Phase III trial in relapsed acute myelogenous leukemia in combination with Ara-C	March 2005
Cloretazine <sup>®</sup>	Phase II trial in small cell lung cancer	September 2005
Cloretazine <sup>®</sup>	Phase II trial in acute myelogenous leukemia and high-risk myelodysplasia	March 2004
Cloretazine <sup>®</sup>	Phase I/II trial in refractory or relapsed chronic lymphocytic leukemia	July 2005
Cloretazine <sup>®</sup>	Phase I trial in combination with temozolomide in patients with hematologic malignancies	October 2004

In addition to the above-listed clinical trials for Cloretazine<sup>®</sup> which are sponsored by us, a Phase II trial in adult brain tumors was initiated in May 2004 under an investigator's IND. Additionally, a Phase I trial in pediatric brain tumors was initiated in April 2005 by the Pediatric Brain Tumor Consortium (PBTC) under an investigator's IND. We provide product for these trials and incur certain costs related to patient enrollment.

The National Cancer Institute (NCI) is sponsoring Phase I and Phase II clinical trials of Triapine<sup>®</sup>. We provide product for the NCI trials.

Completion of clinical trials may take several years or more and the length of time can vary substantially according to the type, complexity, novelty and intended use of a product candidate. The types of costs incurred during a clinical trial vary depending upon the type of product candidate, the disease treated and the nature of the study.

We budget and monitor our research and development costs by category. Significant categories of costs include personnel, clinical, third party research and development services, and laboratory supplies. The cost to take a product candidate through clinical trials is dependent upon, among other things, the disease indications, the timing, the size and dosing schedule of each clinical trial, the number of patients enrolled in each trial and the speed at which patients are enrolled and treated. We could incur increased product development costs, if we experience delays in trial enrollment, the evaluation of clinical trial results or in applying for or obtaining regulatory approvals. Significant delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. These uncertainties and variability make it difficult to accurately predict the future cost of or timing to complete our product development projects.

We cannot be certain that any of our products will prove to be safe or effective, will achieve the safety and efficacy needed to proceed through Phase III or registrational clinical trials, will receive regulatory approvals, or will be successfully commercialized. Our clinical trials might prove that our product candidates may not be effective in treating disease or may have undesirable or unintended side effects, toxicities or other characteristics that require us to cease further development of the product.

We expect that we will need to enter into and complete Phase III or registrational clinical trials of our products in order to apply for regulatory approval. If we achieve successful completion of Phase III or registrational trials, which have commenced or which we may in the future commence, of which there can be no certainty, we intend to submit the results to the U.S. Food and Drug Administration (FDA) to support an application for regulatory approval of the product.

Given the uncertainties related to pharmaceutical product development, we are currently unable to reliably estimate when, if ever, our product candidates will generate revenue and cash flows. We do

not expect to receive net cash inflows from any of our major research and development projects until and unless a product candidate becomes a profitable commercial product.

### **Critical Accounting Policies and Estimates**

The accompanying discussion and analysis of our financial condition and results of operations are based upon our financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

#### ***Revenue Recognition***

We record revenue under technology license agreements related to the following:

- Nonrefundable upfront license fees for which no further performance obligations exist are recognized as revenue on the earlier of when payments are received or collection is assured;
- Nonrefundable upfront license fees including guaranteed, time-based payments that require continuing involvement in the form of development or other efforts by us are recognized as revenue ratably over the performance period; and
- Milestone payments are recognized as revenue when milestones, as defined in the agreement, are achieved.

Actual license fees received may vary from recorded estimated revenues.

We record revenue from royalties, if any, based on licensees' sales of our products or technologies. Revenues are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured. Royalty estimates are made in advance of amounts collected based on historical and forecasted trends.

We record revenue from research and laboratory support, if any, as the services are provided. Actual research and laboratory support fees collected may vary from revenue recognized.

We record revenue from contract research grants, if any, as the costs are incurred. We are reimbursed for eligible costs after submission of grant reports. We are subject to grant audits as required by the Department of Health and Human Services. Audits may result in adjustments to the amount of grant revenues recorded and funds received.

The effect of any change in revenues from technology license agreements, research and laboratory support, or contract research grants would be reflected in revenues in the period such determination was made. Historically, such adjustments have been insignificant.

#### ***Research and Development Expenses***

We record research and development expenses as incurred. We disclose clinical trials expenses, and other research and development expenses as separate components of research and development expense in our consolidated statements of operations to provide more meaningful information to our investors. The expenses are based, in part, on estimates of certain costs when incurred. The effect of any change in the clinical trials expenses and other research and development expenses would be reflected in the period such determination was made.

#### ***Income Taxes***

We provide deferred income taxes for the future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities, and on

operating loss and tax credit carryforwards. Except for the provisions recorded for minimum state capital taxes and the sale recorded in 2003 of certain research and development tax credits to the State of Connecticut, we have not recorded a provision or benefit for income taxes in the financial statements due to recurring historical losses. Accordingly, we have provided a full valuation allowance for our deferred income tax asset as of December 31, 2005. In the event we were to determine that we would be able to realize deferred income tax assets in the future, an adjustment to the valuation allowance would be made in the period of determination.

### ***Stock-Based Compensation***

We measure stock-based compensation expense under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related Interpretations (APB 25), and provide required pro forma disclosures under the fair value recognition provisions of Financial Accounting Standards No. 123, *Accounting for Stock – Based Compensation* (SFAS 123), as amended by Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure* (SFAS 148).

### ***Recently Issued Accounting Standards***

There may be potential new accounting pronouncements or regulatory rulings, which may have an impact on our future financial position and results of operations. In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123R, *Share-Based Payment* (SFAS 123R), which replaces SFAS 123 and supersedes APB 25. SFAS 123R requires the recognition of the fair value of stock-based compensation to employees and non-employees in net earnings. We currently account for stock-based compensation expense for restricted stock, grants of stock options and purchases under the employee stock purchase plan under APB 25 and provide pro forma disclosures required by SFAS 123, as amended by SFAS 148. We will adopt SFAS 123R and recognize an expense for share-based compensation in our consolidated financial statements beginning January 1, 2006. See Note 2 in our Notes to Consolidated Financial Statements for the pro forma net loss and net loss per share amounts for the periods presented as if we had used a fair-value-based method similar to the methods required under SFAS 123R to measure compensation expense for share-based payments. We expect the adoption of SFAS 123R to have a significant adverse impact on our consolidated statements of operations and net loss per share. We estimate the maximum expense to be recognized for options granted prior to January 1, 2006 will be \$620,000 for 2006, \$330,000 for 2007, \$320,000 for 2008 and \$5,000 for 2009. In addition, we will recognize an expense each year beginning in 2006 for compensation expense associated with restricted stock awards, purchases under the employee stock purchase plan and option grants on or after January 1, 2006, if any.

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS 154), which applies to all voluntary changes in accounting principle, and changes the requirements for accounting for and reporting of a change in accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements of a voluntary change in accounting principle unless it is impracticable. Previously, most voluntary changes in accounting principle were recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors made occurring in fiscal years beginning after June 1, 2005.

### **Results of Operations**

#### ***Year Ended December 31, 2005 Compared to the Year Ended December 31, 2004***

**Revenues.** Revenues for the year ended December 31, 2005 were \$23,000 as compared to \$275,000 for 2004. The decrease was due primarily to lower revenues from research and laboratory support service fees and contract research grants. All revenues under contract research grants have been fully recognized as of December 31, 2004 as all grants have expired. Accordingly, we have no material source of revenues.



**Research and Development Expenses.** Total research and development (R&D) expenses were \$16.6 million for the year ended December 31, 2005, compared to \$13.8 million for 2004 as a result of higher other R&D expenses of \$2.2 million and higher clinical trials expenses of \$623,000. The increase in other R&D expenses resulted from late-stage clinical development of Cloretazine<sup>®</sup>, including expenses not directly related to clinical trials, as well as preclinical development costs related to VNP40541 (formerly KS119W). The increase in clinical trials expenses was due to higher spending for Cloretazine<sup>®</sup> trials of \$2.5 million (primarily as a result of patient accrual to our Phase III trial beginning in March 2005) partially offset by lower spending for Triapine<sup>®</sup> trials of \$1.9 million due to fewer trials being open to patient accrual. We expect total research and development expenses to increase over the next two years mainly due to conducting larger clinical trials, including our Phase III trial and the planned commencement of a pivotal Phase II clinical trial in 2006, as well as additional development of our preclinical products.

**General and Administrative Expenses.** General and administrative expenses were \$3.2 million for the year ended December 31, 2005, compared to \$3.0 million in 2004. The increase was primarily due to higher professional fees for recruiting and benefit consulting.

**Interest Income.** Interest income was \$1.8 million for the year ended December 31, 2005, compared to \$547,000 for 2004. The increase was due to higher interest rates and higher levels of invested funds in 2005 as a result of net proceeds received from a registered direct offering of our common stock in January 2005.

**Other Expense.** Other expense related to foreign currency transaction losses was \$4,000 for the year ended December 31, 2005, compared to \$73,000 for 2004. The foreign currency transaction losses are related to contracts with a vendor outside the U.S. that are denominated in a foreign currency.

**Income Tax Provision.** Income tax provisions of \$40,000 and \$28,000 were recorded for the years ended December 31, 2005 and 2004, respectively, for minimum state capital taxes paid.

**Net Loss.** The net loss was \$18.0 million, or \$0.28 per share based on weighted-average shares outstanding of 65.2 million, for the year ended December 31, 2005, compared to \$16.1 million, or \$0.30 per share based on weighted-average shares outstanding of 53.5 million, for 2004.

#### **Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003**

**Revenues.** Revenues for the year ended December 31, 2004, were \$275,000 as compared to \$375,000 for 2003. The decrease was due primarily to lower revenues from contract research grants. All revenues under contract research grants have been fully recognized as all grants have expired.

**Research and Development Expenses.** Total research and development expenses were \$13.8 million for the year ended December 31, 2004, compared to \$9.7 million for 2003 as a result of higher clinical trials expenses of \$3.6 million and higher other R&D expenses of \$471,000. The increase in clinical trials expenses was due primarily to higher spending for Cloretazine<sup>®</sup> trials of \$3.2 million primarily as a result of patient accrual to a Phase II trial in acute myeloid leukemia and myelodysplastic syndromes initiated in March 2004, as well as higher drug production expense of \$645,000 for Triapine<sup>®</sup> and Cloretazine<sup>®</sup>, and higher clinical consulting fees of \$331,000, partially offset by lower spending of \$809,000 for Triapine<sup>®</sup> trials. The increase in other R&D expenses was primarily due to costs associated with two preclinical product development programs (KS119W and heterocyclic hydrazones) and higher payroll-related costs.

**General and Administrative Expenses.** General and administrative expenses were \$3.0 million for the year ended December 31, 2004, as compared to \$2.6 million in 2003. The increase was primarily due to higher payroll-related costs and higher professional fees for financial services and employee recruiting as we moved into late-stage clinical trials of products, partially offset by lower legal fees as a result of non-recurring legal fees in 2003 for license agreements and assistance with other transactions.

**Interest Income.** Interest income was \$547,000 for the year ended December 31, 2004, compared to \$136,000 for 2003. The increase was primarily due to higher levels of invested funds in 2004 as a

result of net proceeds received from a private placement of our common stock in February 2004 and net proceeds from warrant exercises during 2004.

**Other Expense.** Other expense related to foreign currency transaction losses was \$73,000 for the year ended December 31, 2004, compared to \$45,000 for 2003. The foreign currency transaction losses were related to contracts with a vendor outside the U.S. that are denominated in a foreign currency.

**Income Tax Provision.** An income tax provision of \$28,000 was recorded for the year ended December 31, 2004, for minimum state capital taxes paid. For the year ended December 31, 2003, an income tax provision of \$4,000 was recorded for minimum state capital taxes paid net of proceeds from the sale of certain research and development tax credits to the State of Connecticut.

**Net Loss.** The net loss was \$16.1 million, or \$0.30 per share based on weighted-average shares outstanding of 53.5 million, for the year ended December 31, 2004, as compared to \$11.8 million, or \$0.36 per share based on weighted-average shares outstanding of 32.8 million, for 2003.

### **Liquidity and Capital Resources**

At December 31, 2005, we had cash and cash equivalents of \$52.8 million, compared to \$41.7 million at December 31, 2004. The increase in 2005 was primarily due to net proceeds of \$30.2 million from a registered direct offering of common stock, described below, and proceeds of \$245,000 from common stock issuances under employee stock plans, offset by cash used to fund operating activities of \$19.0 million and acquisitions of capital equipment of \$417,000. Cash used in operations was primarily to fund clinical and preclinical product development activities as well as for working capital and general corporate purposes.

#### ***Cash Used in Operating Activities***

Cash used in operating activities is primarily a result of our net loss. However, operating cash flows differ from net loss as a result of non-cash charges, changes in operating assets and liabilities, or differences in the timing of cash flows and earnings/expense recognition. Significant components of cash used in operating activities are as follows:

Receivables and prepaid expenses decreased \$149,000 during the year ended December 31, 2005 compared to an increase of \$113,000 for 2004. The decrease in 2005 was primarily due to a reduction in a deposit paid to a clinical research organization as well as a reduction of prepaid insurance expense as the timing of insurance premium payments differs from the recognition of insurance expense. The increase in 2004 was primarily due to a deposit paid to a clinical research organization, partially offset by a reduction of prepaid insurance expense.

Current liabilities decreased \$1.3 million during the year ended December 31, 2005 compared to an increase of \$2.0 million for 2004. The decrease in 2005 was primarily due to a reduction in the accrual for clinical trial costs as the timing of payments to clinical vendors differs from the recognition of clinical trials expenses as well as a reduction of \$683,000 as actual expenses for two clinical trials were less than original estimates. The increase of \$2.0 million in 2004 was primarily due to an increase in the accrual for clinical trial costs as the timing of payments to clinical vendors differs from the recognition of clinical trials expenses.

#### ***Cash Provided by or Used in Investing Activities***

Cash provided by or used in investing activities primarily relates to acquisitions of capital equipment and, in prior years, the purchases and maturities of investments. Capital expenditures were \$417,000 and \$358,000 for the years ended December 31, 2005 and 2004, respectively. Capital expenditures for 2005 included purchases of computer software and laboratory equipment. Capital expenditures for 2004 included the purchase of laboratory equipment. Capital expenditures for fiscal 2006 are not expected to exceed \$1 million. For the year ended December 31, 2004, purchases of marketable securities totaled \$61.9 million and maturities of marketable securities totaled \$76.4 million. Cash provided by the maturities of these short-term investments in marketable securities was reinvested during the second quarter of 2004 in U.S. Treasury securities classified as cash equivalents. As a result, short-term investments were reduced to \$0.

### ***Cash Provided by Financing Activities***

Cash provided by financing activities is primarily related to capital raised, warrant exercise proceeds and proceeds from common stock issuances under our employee stock plans. For the year ended December 31, 2005, we received net proceeds of \$30.2 million from a registered direct offering of common stock in January 2005, described below, and proceeds of \$245,000 from common stock issuances through employee stock plans. For the year ended December 31, 2004, we received net proceeds of \$33.0 million from a private placement of common stock in February 2004 and proceeds of \$7.3 million from exercises of warrants, described below.

In February 2004, we completed a private placement of 13,553,845 shares of our common stock at \$2.60 per share. The investors also received warrants to purchase 3,388,463 shares of common stock at \$3.25 per share and the placement agent received a warrant to purchase an additional 300,000 shares of common stock at \$3.25 per share. All of these warrants expire on February 11, 2009. Net proceeds from this private placement totaled \$33 million.

For the year ended December 31, 2004, we issued 2,987,567 shares of our common stock upon exercises of warrants issued in connection with private placements in 2003 and 2004, resulting in proceeds of \$7.3 million.

In January 2005, we received net proceeds of \$30.2 million from a registered direct offering of 10 million shares of our common stock at \$3.25 per share.

All proceeds are being and will be used to fund clinical and preclinical product development activities, and for working capital and general corporate purposes.

### ***Future Cash Requirements***

Based on our current operating plan, we estimate that our existing cash and cash equivalents totaling \$52.8 million at December 31, 2005 will be sufficient to fund our operations into 2007. Our operating plans and cash requirements may vary materially from the foregoing due to the results of preclinical development, clinical trials, product testing, relationships with strategic partners, changes in focus and direction of our preclinical and clinical development programs, competitive and technological advances, the regulatory process in the United States and abroad, and other factors. In the future, we will need to raise capital to complete our product development and clinical trials and to fund operations in 2007 and beyond, however, we cannot assure you that we will be able to raise additional capital, nor can we predict what the terms of any financing might be.

### ***Off-Balance Sheet Financing***

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial position or results of operations.

### ***Contractual Obligations***

The following table summarizes our significant contractual obligations which are not recorded on the balance sheet at December 31, 2005 and the future periods in which such obligations are expected to be settled in cash. Additional details regarding these obligations are provided in footnotes to the consolidated financial statements, as referenced in the table:

<u>(In thousands)</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Employment agreement (Note 10) . . . . .	\$1,236	\$ 412	\$ 824	\$ —	\$ —
Operating lease obligations (Note 10) . . .	1,123	248	441	434	—
Research and development commitment (Note 11) . . . . .	250	200	50	—	—
Purchase obligations <sup>(1)</sup> . . . . .	<u>2,272</u>	<u>2,272</u>	<u>—</u>	<u>—</u>	<u>—</u>
Total . . . . .	<u>\$4,881</u>	<u>\$3,132</u>	<u>\$1,315</u>	<u>\$434</u>	<u>\$ —</u>

<sup>(1)</sup> Purchase obligations include commitments related to contract drug manufacturing and outside testing.

Under our executed license agreements (refer to Note 3), we are obligated to make milestone payments totaling \$2,625,000 upon achieving specified milestones and to pay royalties to our licensors. These contingent milestone and royalty payment obligations are not included in the above table.

Under various agreements with contract research organizations, clinical sites and contract drug manufacturers, we expect to incur costs relating to the progress of clinical trials. These costs are expensed as incurred and are based upon patient enrollment, services rendered or other expenses as incurred. The accrual for clinical trials costs expensed but not yet paid is included on our balance sheet. In the event of termination, certain agreements provide for cancellation fees to be paid by us and for reimbursement of noncancellable commitments that may have been entered into on our behalf. These potential cancellation fees are not included in the above table.

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

We are exposed to market risk, including changes to interest rates associated with our cash equivalents and investments, and foreign currency exchange rates. The following describes the nature of these risks which we do not believe to be material to us.

Our cash equivalents are generally highly liquid investments in money market funds and U.S. government securities. These investments are subject to interest rate risk and, as such, our future investment income may fall short of expectations due to changes in interest rates. However, the conservative nature of our investments mitigates our interest rate exposure. Our investments are held for purposes other than trading and we believe that we currently have no material adverse market risk exposure. The weighted-average interest rate on cash equivalents held at December 31, 2005 was approximately 4.2%.

We have contracts with a vendor outside the U.S. that are denominated in a foreign currency. To date, fluctuations in this currency have not materially impacted our results of operations. We have no derivative financial instruments. We do not believe we have material exposures to changes in foreign currency exchange rates.

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

**Report of Independent Registered Public Accounting Firm**

**The Board of Directors and Shareholders of Vion Pharmaceuticals, Inc.**

We have audited the accompanying consolidated balance sheets of Vion Pharmaceuticals, Inc. and subsidiary as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 and for the period from May 1, 1994 (inception) to December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Vion Pharmaceuticals, Inc. and subsidiary at December 31, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 and the period from May 1, 1994 (inception) to December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Vion Pharmaceuticals, Inc's internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut  
March 8, 2006

## **Report of Independent Registered Public Accounting Firm**

### **The Board of Directors and Shareholders of Vion Pharmaceuticals, Inc.**

We have audited management's assessment, included in the accompanying Form 10-K, that Vion Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Vion Pharmaceuticals, Inc's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that Vion Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Vion Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Vion Pharmaceuticals, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 and the period from May 1, 1994 (inception) to December 31, 2005 and our report dated March 8, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Hartford, Connecticut  
March 8, 2006

Vion Pharmaceuticals, Inc.  
(A Development Stage Company)  
Consolidated Balance Sheets

<i>(In thousands, except share and per share data)</i>	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 52,762	\$ 41,729
Accounts receivable .....	31	13
Prepaid expenses .....	195	362
Total current assets .....	52,988	42,104
Property and equipment, net .....	706	515
Security deposits .....	25	25
Total assets .....	\$ 53,719	\$ 42,644
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accrued expenses .....	\$ 3,305	\$ 5,130
Accounts payable .....	855	567
Accrued payroll and payroll-related expenses .....	560	354
Deferred revenue .....	18	18
Total current liabilities .....	4,738	6,069
Deferred revenue .....	342	360
Total liabilities .....	5,080	6,429
Shareholders' equity:		
Preferred stock, \$0.01 par value, authorized: 5,000,000 shares; issued and outstanding: none .....	—	—
Common stock, \$0.01 par value, authorized: 150,000,000 shares; issued and outstanding: 66,177,892 and 55,860,313 shares at December 31, 2005 and 2004, respectively .....	662	559
Additional paid-in capital .....	197,916	167,421
Deferred compensation .....	(133)	—
Deficit accumulated during the development stage .....	(149,806)	(131,765)
Total liabilities and shareholders' equity .....	\$ 53,719	\$ 42,644

*See Notes to Consolidated Financial Statements*

Vion Pharmaceuticals, Inc.  
(A Development Stage Company)  
Consolidated Statements of Operations

<i>(In thousands, except share and per share data)</i>	For the Year Ended December 31,			For the Period from May 1, 1994 (Inception) through December 31, 2005
	2005	2004	2003	
Revenues:				
Technology license fees .....	\$ 22	\$ 26	\$ 30	\$ 4,509
Research and laboratory support fees ...	1	149	136	5,932
Contract research grants .....	—	100	209	2,501
Total revenues .....	23	275	375	12,942
Operating expenses:				
Clinical trials .....	9,996	9,373	5,772	46,508
Other research and development .....	6,609	4,434	3,963	73,615
Total research and development .....	16,605	13,807	9,735	120,123
General and administrative .....	3,239	2,969	2,563	30,948
Total operating expenses .....	19,844	16,776	12,298	151,071
Loss from operations .....	(19,821)	(16,501)	(11,923)	(138,129)
Interest income .....	1,828	547	136	7,248
Interest expense .....	(4)	—	(2)	(214)
Other expense .....	(4)	(73)	(45)	(122)
Loss before income taxes .....	(18,001)	(16,027)	(11,834)	(131,217)
Income tax provision (benefit) .....	40	28	4	(155)
Net loss .....	(18,041)	(16,055)	(11,838)	(131,062)
Preferred stock dividends and accretion ...	—	—	—	(18,489)
Loss applicable to common shareholders ..	\$ (18,041)	\$ (16,055)	\$ (11,838)	\$(149,551)
Basic and diluted loss applicable to common shareholders per share .....	\$ (0.28)	\$ (0.30)	\$ (0.36)	
Weighted-average number of shares of common stock outstanding .....	65,161,176	53,464,140	32,808,228	

*See Notes to Consolidated Financial Statements*



Vion Pharmaceuticals, Inc.  
(A Development Stage Company)  
Consolidated Statement of Changes in Shareholders' Equity

	Class A Convertible Preferred Stock		Class B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>(In thousands, except share data)</i>												
Issuance of common stock — July and August 1994 . . . . .					2,852,548	\$29					\$ (21)	\$ 8
Net loss . . . . .											(476)	(476)
Balance at December 31, 1994 . . . . .	—	\$—	—	\$—	2,852,548	\$29	\$—	\$ —	\$—	\$—	\$ (497)	\$ (468)
Stock options issued for compensation — February 1995 . . . . .								540				540
Reverse acquisition of MelaRx Pharmaceuticals, Inc. — April 1995 . . .					2,000,000	20		4,300				4,320
Shares repurchased pursuant to employment agreements — April 1995 . .					(274,859)	(3)					2	(1)
Private placement of common stock — April 1995 . . . . .					76,349	—		205				205
Warrants issued with bridge notes — April 1995 . . . . .								200				200
Initial public offering of Unit Purchase Options — August 1995 and September 1995 . . . . .					2,875,000	29		9,667				9,696
Issuance of common stock . . . . .					1,250	—		1				1
Net loss . . . . .											(9,531)	(9,531)
<b>BALANCE AT DECEMBER 31, 1995 . .</b>	<b>—</b>	<b>\$—</b>	<b>—</b>	<b>\$—</b>	<b>7,530,288</b>	<b>\$75</b>	<b>\$—</b>	<b>\$14,913</b>	<b>\$—</b>	<b>\$—</b>	<b>\$(10,026)</b>	<b>\$ 4,962</b>
Issuance of Class A convertible preferred stock . . . . .	1,250,000	13						22,890			(11,371)	11,532
Conversion of Class A convertible preferred stock . . . . .	(164,970)	(1)			458,255	5		(4)				—
Class A convertible preferred stock dividend . . . . .	21,998	—						256			(256)	—
Issuance of common stock . . . . .					29,418	—		104				104
Compensation associated with stock option grants . . . . .								190	(190)			—
Amortization of deferred compensation . .									83			83
Net loss . . . . .											(7,609)	(7,609)
<b>BALANCE AT DECEMBER 31, 1996 . .</b>	<b>1,107,028</b>	<b>\$12</b>	<b>—</b>	<b>\$—</b>	<b>8,017,961</b>	<b>\$80</b>	<b>\$—</b>	<b>\$38,349</b>	<b>\$(107)</b>	<b>\$—</b>	<b>\$(29,262)</b>	<b>\$ 9,072</b>
Conversion of Class A convertible preferred stock . . . . .	(396,988)	(4)			1,102,757	11		(7)				—

	Class A Convertible Preferred Stock		Class B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>(In thousands, except share data)</i>												
Class A convertible preferred stock dividend . . . . .	47,592	—						623			(623)	—
Issuance of Class B convertible preferred stock . . . . .			4,850	—				4,852			(370)	4,482
Conversion of Class B convertible preferred stock . . . . .			(258)	—	64,642	1		(1)				—
Accretion of dividend payable on Class B convertible preferred stock . . . . .								138			(138)	—
Extension/reissuance of underwriter warrants . . . . .								168				168
Exercise of warrants . . . . .					238	—		—				—
Issuance of common stock . . . . .					598,336	6		3,464				3,470
Exercise of stock options . . . . .					50,000	—		20				20
Compensation associated with stock option grants . . . . .								56				56
Amortization of deferred compensation . .									35			35
Net loss . . . . .											(5,344)	(5,344)
BALANCE AT DECEMBER 31, 1997 . .	<u>757,632</u>	<u>\$ 8</u>	<u>4,592</u>	<u>\$—</u>	<u>9,833,934</u>	<u>\$98</u>	<u>\$—</u>	<u>\$47,662</u>	<u>\$(72)</u>	<u>\$—</u>	<u>\$(35,737)</u>	<u>\$11,959</u>

Vion Pharmaceuticals, Inc.  
(A Development Stage Company)  
Consolidated Statement of Changes in Shareholders' Equity (continued)

	Class A Convertible Preferred Stock		Class B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>(In thousands, except share data)</i>												
Accretion of dividend payable on Class B convertible preferred stock . . . . .								\$ 287			\$ (287)	\$ —
Conversion of Class B convertible preferred stock . . . . .			(4,592)	\$—	1,205,178	\$ 12		(12)				—
Premium on conversion dividend on Class B convertible preferred stock . . . . .					585,898	6		2,044			(2,049)	1
Conversion of Class A convertible preferred stock . . . . .	(174,981)	\$(2)			486,062	5		(3)				—
Class A convertible preferred stock dividend . . . . .	34,005	—						329			(329)	—
Discount on Series 1998 convertible preferred stock . . . . .								1,597			(1,597)	—
Series 1998 convertible preferred stock accretion . . . . .											(151)	(151)
Common stock issued in exchange for cancellation of outstanding warrants . . .					1,792,952	18		(61)				(43)
Exercise of stock options . . . . .					32,750	—		120				120
Exercise of warrants . . . . .					16,272	—		11				11
Compensation associated with stock option grants . . . . .								51				51
Amortization of deferred compensation . .									\$ 35			35
Net loss . . . . .											(10,478)	(10,478)
BALANCE AT DECEMBER 31, 1998 . .	616,656	\$ 6	—	\$—	13,953,046	\$139	\$ —	\$52,025	\$(37)	\$—	\$(50,628)	\$ 1,505
Conversion of Class A convertible preferred stock . . . . .	(144,612)	(1)			401,707	4		(3)				—
Class A convertible preferred stock dividend . . . . .	26,150	—						385			(385)	—
Series 1998 convertible preferred stock accretion . . . . .											(325)	(325)
Common stock issued in exchange for cancellation of outstanding warrants . . .					102	—						—
Exercise of stock options . . . . .					470,886	5	(196)	650			(40)	419
Retirement of treasury stock . . . . .					(35,659)	—	196				(196)	—
Exercise of warrants . . . . .					26,296	—						—
Issuance of common stock . . . . .					3,425,741	34		14,955				14,989

	Class A Convertible Preferred Stock		Class B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>(In thousands, except share data)</i>												
Amortization of deferred compensation . .									34			34
Net loss . . . . .											(10,769)	(10,769)
BALANCE AT DECEMBER 31, 1999 . .	498,194	\$ 5	—	\$—	18,242,119	\$182	\$—	\$ 68,012	\$(3)	\$—	\$(62,343)	\$ 5,853
Conversion of Class A convertible preferred stock . . . . .	(502,928)	(5)			1,397,035	14		(9)				—
Redemption of Class A convertible preferred stock . . . . .	(545)	—						(5)				(5)
Class A convertible preferred stock dividend . . . . .	5,279	—						248			(248)	—
Series 1998 convertible preferred stock accretion . . . . .											(358)	(358)
Conversion of Series 1998 convertible preferred stock . . . . .					1,507,024	15		5,523				5,538
Exercise of stock options . . . . .					650,409	7		2,868				2,875
Exercise of warrants . . . . .					4,371,055	44		23,270				23,314
Compensation associated with stock option grants . . . . .								120				120
Amortization of deferred compensation . .									3			3
Change in net unrealized gains and losses . . . . .										120		120
Net loss . . . . .											(14,803)	(14,803)
Comprehensive loss . . . . .												(14,683)
BALANCE AT DECEMBER 31, 2000 . .	—	\$—	—	\$—	26,167,642	\$262	\$—	\$100,027	\$—	\$120	\$(77,752)	\$ 22,657

Vion Pharmaceuticals, Inc.  
(A Development Stage Company)  
Consolidated Statement of Changes in Shareholders' Equity (continued)

	Class A Convertible Preferred Stock		Class B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>(In thousands, except share data)</i>												
Public offering of common stock —												
August 2001 . . . . .					2,500,000	\$ 25		\$ 11,386				\$ 11,411
Exercise of stock options . . . . .					191,527	2		777				779
Exercise of warrants . . . . .					4,015	—		14				14
Compensation associated with stock option grants . . . . .								111				111
Issuances under employee benefit plans . .					10,189	—		62				62
Change in net unrealized gains and losses . . . . .										\$(126)		(126)
Net loss . . . . .											\$ (13,810)	<u>(13,810)</u>
Comprehensive loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	<u>(13,936)</u>
BALANCE AT DECEMBER 31, 2001 . .	—	\$—	—	\$—	28,873,373	\$289	\$—	\$112,377	\$—	\$ (6)	\$ (91,562)	\$ 21,098
Exercise of stock options . . . . .					10,395	—		32				32
Issuances under employee benefit plans . .					25,104	—		38				38
Change in net unrealized gains and losses . . . . .										6		6
Net loss . . . . .											(12,310)	<u>(12,310)</u>
Comprehensive loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	<u>(12,304)</u>
BALANCE AT DECEMBER 31, 2002 . .	—	\$—	—	\$—	28,908,872	\$289	\$—	\$112,447	\$—	\$—	\$(103,872)	\$ 8,864
Private placement — June 2003 . . . . .					3,846,150	38		4,436				4,474
Private placement — September 2003 . . .					6,475,000	65		10,340				10,405
Exercise of stock options . . . . .					5,552	—		3				3
Issuances under employee benefit plans . .					41,181	1		13				14
Net loss and comprehensive loss . . . . .	—	—	—	—	—	—	—	—	—	—	(11,838)	<u>(11,838)</u>
BALANCE AT DECEMBER 31, 2003 . .	—	\$—	—	\$—	39,276,755	\$393	\$—	\$127,239	\$—	\$—	\$(115,710)	\$ 11,922
Private placement — February 2004 . . . . .					13,553,845	136		32,791				32,927
Exercise of stock options . . . . .					35,454	—		71				71
Exercise of warrants . . . . .					2,987,567	30		7,311				7,341
Issuances under employee benefit plans . .					6,692	—		9				9
Net loss and comprehensive loss . . . . .	—	—	—	—	—	—	—	—	—	—	(16,055)	<u>(16,055)</u>
BALANCE AT DECEMBER 31, 2004 . .	—	\$—	—	\$—	55,860,313	\$559	\$—	\$167,421	\$—	\$—	\$(131,765)	\$ 36,215

	Class A Convertible Preferred Stock		Class B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>(In thousands, except share data)</i>												
Direct offering — January 2005 . . . . .					10,000,000	100		30,094				30,194
Restricted stock awards . . . . .					77,610	1		158	(159)			—
Amortization of deferred compensation . .									26			26
Exercise of stock options . . . . .					217,798	2		202				204
Issuances under employee benefit plans . .					22,171	—		41				41
Net loss and comprehensive loss . . . . .	—	—	—	—							(18,041)	(18,041)
BALANCE AT DECEMBER 31, 2005 . .	—	\$—	—	\$—	66,177,892	\$662	\$—	\$197,916	\$(133)	\$—	\$(149,806)	\$ 48,639

See Notes to Consolidated Financial Statements

Vion Pharmaceuticals, Inc.  
(A Development Stage Company)

Consolidated Statements of Cash Flows

<i>(In thousands)</i>	For the Year Ended December 31,			For the Period From May 1, 1994 (Inception) through December 31, 2005
	2005	2004	2003	
Cash flows from operating activities:				
Net loss .....	<b>\$(18,041)</b>	\$(16,055)	\$ (11,838)	\$(131,062)
Adjustments to reconcile net loss to net cash used in operating activities—				
Depreciation and amortization .....	<b>226</b>	213	195	3,054
Non-cash compensation .....	<b>26</b>	—	—	1,094
Loss on equipment disposals .....	—	—	8	12
Purchased research and development .....	—	—	—	4,481
Stock issued for services .....	—	—	—	600
Amortization of financing costs .....	—	—	—	346
Extension/re-issuance of placement agent warrants ..	—	—	—	168
Changes in operating assets and liabilities—				
Receivables and prepaid expenses .....	<b>149</b>	(113)	45	(225)
Other assets .....	—	—	4	(22)
Current liabilities .....	<b>(1,331)</b>	1,992	2,000	4,685
Deferred revenue .....	<b>(18)</b>	(17)	395	360
Net cash used in operating activities .....	<b><u>(18,989)</u></b>	<u>(13,980)</u>	<u>(9,191)</u>	<u>(116,509)</u>
Cash flows from investing activities:				
Acquisition of equipment .....	<b>(417)</b>	(358)	(117)	(2,828)
Purchases of marketable securities .....	—	(61,901)	(119,100)	(321,052)
Maturities of marketable securities .....	—	76,401	113,950	321,052
Net cash provided by (used in) investing activities .....	<b><u>(417)</u></b>	<u>14,142</u>	<u>(5,267)</u>	<u>(2,828)</u>
Cash flows from financing activities:				
Net proceeds from issuance of common stock .....	<b>30,439</b>	33,007	14,896	112,231
Net proceeds from initial public offering .....	—	—	—	9,696
Net proceeds from issuance of preferred stock .....	—	—	—	20,716
Net proceeds from exercise of Class A Warrants .....	—	—	—	5,675
Net proceeds from exercise of Class B Warrants .....	—	—	—	17,538
Net proceeds from exercise of other warrants .....	—	7,341	—	7,456
Repayment of equipment capital leases .....	—	—	—	(927)
Other financing activities, net .....	—	—	—	(286)
Net cash provided by financing activities .....	<b><u>30,439</u></b>	<u>40,348</u>	<u>14,896</u>	<u>172,099</u>
Change in cash and cash equivalents .....	<b>11,033</b>	40,510	438	52,762
Cash and cash equivalents, beginning of period .....	<b>41,729</b>	1,219	781	—
Cash and cash equivalents, end of period .....	<b><u>\$ 52,762</u></b>	<u>\$ 41,729</u>	<u>\$ 1,219</u>	<u>\$ 52,762</u>
Supplemental disclosure of cash flow information:				
Cash paid for interest .....	<b><u>\$ 4</u></b>	<u>\$ —</u>	<u>\$ 2</u>	<u>\$ 214</u>
Cash paid for taxes .....	<b><u>\$ 43</u></b>	<u>\$ 7</u>	<u>\$ 17</u>	<u>\$ 67</u>

*See Notes to Consolidated Financial Statements*

Vion Pharmaceuticals, Inc.  
(A Development Stage Company)  
Notes to Consolidated Financial Statements

## **1. The Company**

Vion Pharmaceuticals, Inc. (the “Company”) is a development stage company engaged in the development of therapeutics for the treatment of cancer. The Company was incorporated in March 1992 as a Delaware corporation and began operations on May 1, 1994.

In April 1995, the Company merged into OncoRx Research Corp., a wholly-owned subsidiary of MelaRx Pharmaceuticals Inc. (“MelaRx”), and the Company’s name was changed to OncoRx, Inc. The stockholders of the Company were issued 2,654,038 common shares and 23,859 preferred shares of MelaRx in exchange for all 2,000,000 outstanding shares of common stock of the Company valued at \$2.16 per share (fair value). As the shareholders of the Company obtained a majority interest in the merged company, for accounting purposes the Company is treated as the acquirer. Therefore, the transaction was recorded as a purchase in the Company’s financial statements, which include the results of operations of the Company from inception and MelaRx from the date of acquisition. The \$4.5 million excess of cost over the fair value of MelaRx’s net tangible assets was treated as purchased research and development and expensed immediately.

In August 1995, the Company completed an initial public offering (refer to Note 5) resulting in net proceeds to the Company of \$9.7 million and in April 1996 the Company’s name was changed to Vion Pharmaceuticals, Inc.

In November 2004, the Company established a wholly-owned subsidiary in the United Kingdom to act as the Company’s legal representative for clinical trials sponsored by the Company in the European economic area.

## **2. Summary of Significant Accounting Policies**

### **Principals of Consolidation**

The consolidated financial statements of the Company include the accounts of Vion Pharmaceuticals, Inc. and its subsidiary after elimination of intercompany accounts and transactions.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and notes thereto. Actual results may differ materially from those estimates.

During the year ended December 31, 2005, the Company recorded a reduction in clinical trials expenses of \$683,000 as a result of actual clinical trial costs for two Phase II trials being less than original estimates. This has been accounted for as a change in estimate in accordance with APB Opinion No. 9, *Reporting the Results of Operations*, and APB Opinion No. 20, *Accounting Changes*.

### **Cash Equivalents**

Cash equivalents include investments with maturities of three months or less when purchased.

### **Fair Value of Financial Instruments**

The estimated fair value of amounts reported in the financial statements has been determined by using available market information and appropriate valuation methodologies. Carrying values for all financial instruments included in current assets and current liabilities approximate fair value, because of their short-term nature.



## Property and Equipment

Property and equipment are stated at cost. Depreciation of equipment is computed under the straight-line method over the estimated useful lives of the assets ranging from three to seven years. Leasehold improvements are carried at cost and amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the assets.

The following is a summary of property and equipment as of December 31 (in thousands):

	<u>2005</u>	<u>2004</u>
Office and computer equipment .....	\$ 631	\$ 412
Furniture and fixtures .....	208	210
Laboratory equipment .....	2,212	2,034
Leasehold improvements .....	403	381
	<u>3,454</u>	<u>3,037</u>
Accumulated depreciation and amortization .....	<u>(2,748)</u>	<u>(2,522)</u>
Property and equipment, net .....	<u>\$ 706</u>	<u>\$ 515</u>

Depreciation expense was approximately \$226,000, \$213,000 and \$195,000 for the years ended December 31, 2005, 2004 and 2003, respectively, and \$3.1 million for the period from May 1, 1994 (inception) through December 31, 2005.

## Income Taxes

Deferred income taxes are recognized for the future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities, and for net operating loss and tax credit carryforwards. A valuation allowance is provided to reduce deferred income tax assets to an estimated realizable value.

## Revenue Recognition

**Technology License Fees.** The Company has recognized revenue from fees, including non-refundable upfront fees, under license agreements with Beijing Pason Pharmaceuticals, Inc. and others (refer to Note 3) totaling \$22,000, \$26,000, \$30,000 and \$4.5 million for the years ended December 31, 2005, 2004, and 2003, and the period from May 1, 1994 (inception) through December 31, 2005, respectively. Non-refundable upfront fees are recognized as revenue ratably over the performance period.

**Research and Laboratory Support Fees.** The Company recognizes revenue from research and laboratory support as the services are performed.

**Contract Research Grants.** The Company has received grants in prior years from the National Cancer Institute for various research projects. The grants provide for reimbursement of project costs. Revenues from these grants of \$0, \$100,000, \$209,000, and \$2.5 million have been recognized as the costs were incurred for the years ended December 31, 2005, 2004 and 2003, and for the period from May 1, 1994 (inception) to December 31, 2005, respectively. The Company currently does not have any contract research grants.

## Research and Development Expenses

The Company records research and development expenses as incurred. The Company discloses clinical trials expenses and other research and development expenses as separate components of research and development expense in its statements of operations to provide more meaningful information to investors. The classification of expenses into these components of research and development expense are based, in part, on estimates of certain costs when incurred. The effect of any change in the clinical trials expenses and other research and development expenses would be reflected in the period such determination was made.

## Other Expense

Other expense of \$4,000, \$73,000, \$45,000 and \$122,000 for the years ended December 31, 2005, 2004 and 2003, and for the period from May 1, 1994 (inception) through December 31, 2005, respectively,

represents foreign currency transaction losses related to contracts that are denominated in a foreign currency with a vendor outside the U.S.

### Per Share Data

The following table sets forth the computation of basic and diluted loss per share (in thousands, except per share data):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss .....	<b>\$(18,041)</b>	\$(16,055)	\$(11,838)
Weighted-average number of shares of common stock outstanding .....	<u>65,161</u>	<u>53,464</u>	<u>32,808</u>
Basic and diluted loss per share .....	<u><b>\$ (0.28)</b></u>	<u>\$ (0.30)</u>	<u>\$ (0.36)</u>

For additional disclosures regarding warrants and preferred stock, refer to Note 5. For additional disclosures regarding stock options, refer to Note 6. As the Company has not generated net income in the periods presented, there is no dilutive per share calculation and therefore, these options and warrants have been excluded from the per share computations presented.

### Stock-Based Compensation

The Company accounts for stock options and restricted stock utilizing the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (“APB 25”) and related interpretations. Under APB 25, no compensation expense is recognized because the exercise price of our employee stock options equals the market price of the underlying stock at the date of grant. The Company has adopted the disclosure only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (“SFAS 123”), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure* (“SFAS 148”). The issuance of SFAS No. 123R, *Share-Based Payment* (“SFAS 123R”) will significantly change the way the Company accounts for grants of stock options as of January 1, 2006.

No compensation expense for stock option grants is reflected in the Company’s reported net loss for the years ended December 31, 2005, 2004 and 2003. The following information regarding net loss and net loss per share has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method prescribed by SFAS 123 (in thousands, except per share amounts).

	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>From Inception (May 1, 1994) to December 31, 2005</u>
Reported net loss .....	<b>\$(18,041)</b>	\$(16,055)	\$(11,838)	\$(131,062)
Add: Stock-based employee compensation expense included in reported net loss .....	—	—	—	768
Deduct: Stock-based employee compensation expense determined under the fair value based method for all awards .....	<b>(1,678)</b>	(1,888)	(3,009)	(22,680)
Pro forma net loss .....	<b>(19,719)</b>	(17,943)	(14,847)	(152,974)
Pro forma preferred stock dividend and accretion .....	—	—	—	(18,489)
Pro forma loss applicable to common shareholders .....	<b>\$(19,719)</b>	\$(17,943)	\$(14,847)	\$(171,463)
Reported basic and diluted loss applicable to common shareholders per share .....	<b>\$ (0.28)</b>	\$ (0.30)	\$ (0.36)	
Pro forma basic and diluted loss applicable to common shareholders per share .....	<b>\$ (0.30)</b>	\$ (0.34)	\$ (0.45)	

The fair value of stock options was estimated at the date of grant using a Black-Scholes option valuation model with the following weighted-average assumptions:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Interest rate .....	<b>3.91%</b>	3.75%	3.73%
Volatility .....	<b>54.12%</b>	72%	146%
Expected life (in years) .....	<b>5.80</b>	5.95	5.88
Dividend yield .....	—	—	—
Weighted-average grant date fair value of options granted during the year .....	<b>\$ 1.22</b>	\$2.97	\$0.33

The stock-based compensation for grants of stock options as presented above does not include restricted stock expense of \$26,000, which was reported as part of the net loss for the year ended December 31, 2005.

### Recently Issued Accounting Standards

In December 2004, the Financial Accounting Standards Board issued SFAS 123R, which replaces SFAS 123 and supersedes APB 25. SFAS123R requires the recognition of the fair value of stock-based compensation to employees and non-employees in net earnings. The Company currently accounts for stock-based compensation expense for restricted stock, grants of stock options and purchases under the employee stock purchase plan under APB 25 and provides pro forma disclosures required by SFAS 123, as amended by SFAS 148. The Company will adopt SFAS 123R and will recognize an expense for share-based compensation in its consolidated financial statements beginning January 1, 2006. The pro forma net loss and net loss per share amounts shown in the above table were determined as if the Company had used a fair-value-based method similar to the methods required under SFAS 123R to measure compensation expense for share-based payments. We expect the adoption of SFAS 123R to have a significant adverse impact on our consolidated statements of operations and net loss per share. We estimate the maximum expense to be recognized for options granted prior to January 1, 2006 will be \$620,000 for 2006, \$330,000 for 2007, \$320,000 for 2008 and \$5,000 for 2009. In addition, we will recognize an expense each year beginning in 2006 for compensation expense associated with restricted stock awards, purchases under the employee stock purchase plan and option grants on or after January 1, 2006, if any.

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS 154), which applies to all voluntary changes in accounting principle, and changes the requirements for

accounting for and reporting of a change in accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements of a voluntary change in accounting principle unless it is impracticable. Previously, most voluntary changes in accounting principle were recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors made occurring in fiscal years beginning after June 1, 2005.

### **3. License Agreements**

#### **License Agreements with Yale University**

Since 1988, the Company or its predecessor companies have entered into a series of agreements under which the Company has licensed inventions from Yale University ("Yale"). The license agreements with Yale grant the Company exclusive licenses to make, use, sell and practice the inventions covered by various patents and patent applications. Each license agreement requires the Company to pay royalties and, in some cases, milestone payments to Yale. Certain licenses are terminable in the event the Company does not exercise due diligence in commercializing the licensed technology.

***License Agreement with Yale University – September 1990.*** Pursuant to a license agreement entered into in September 1990 between the Company and Yale, the Company has a license to a synthetic form of melanin, which the Company has named MELASYN<sup>®</sup>. Under the terms of the amended license agreement, the Company pays a license fee to Yale based on a percentage of net sales and sublicensing revenues. Through December 31, 2005, the Company has paid royalties to Yale of \$81,000 on sublicensing revenues under this agreement.

In 1998, the Company agreed to be the exclusive selling agent for MELASYN<sup>®</sup> and entered into a non-exclusive sublicense for the MELASYN<sup>®</sup> technology with San-Mar Laboratories ("San-Mar"). Under the terms of the amended sublicense agreement, the Company received a sublicense fee for products sold by San-Mar with guaranteed minimum annual royalties of \$50,000 per year. This amended sublicense agreement expired on February 28, 2003. In March 2004, the Company entered into a non-exclusive sublicense agreement for MELASYN<sup>®</sup> with Johnson and Johnson Consumer Companies, Inc. The terms of the agreement do not include any upfront or milestone payments. If products including the Company's technology are developed, the Company will receive a royalty based on sales in countries where it has issued patents.

***License Agreement with Yale University – August 1994.*** The Company is a party to a license agreement with Yale entered into in August 1994 and subsequently amended in five amendments. Under this amended license, Yale granted to the Company a non-transferable worldwide exclusive license to make, have made, use, sell and practice inventions under certain patents and patent applications for therapeutic and diagnostic purposes. The Company also has a non-exclusive license to two patents under this amended license. The patents and patent applications under this license and its amendments cover Cloretazine<sup>®</sup>, KS119W, and B-L-Fd4C. The term of the license is the expiration of any patents relating to any inventions or, with respect to non-patented inventions or research, 17 years. Yale is entitled to royalties on sales, if any, of resulting products and sublicensing revenues and, with regard to several patents related to sulfonylhydrazine prodrugs (including Cloretazine<sup>®</sup> and KS119W) and Triapine<sup>®</sup>, potential milestone payments totaling \$850,000 based on the completion of Phase II clinical trials, regulatory filings and regulatory approvals. No milestone payments have been paid or are due under the amended license agreement through December 31, 2005.

Pursuant to the original agreement, the Company issued to Yale 159,304 shares of the Company's common stock and made a payment of \$50,000. In June 1997, this license agreement and another license agreement dated December 1995 were amended pursuant to which the Company issued 150,000 shares of its common stock to Yale valued at \$600,000. Through December 31, 2005, the Company has paid royalties to Yale of \$107,000 on sublicensing revenues under this agreement.

***License Agreements with Yale University – December 1995.*** In December 1995, the Company and Yale entered into a license agreement pursuant to which the Company received a non-transferable

worldwide exclusive license, expiring over the lives of the patents, to three inventions relating to gene therapy for melanoma. Technology licensed under this agreement relates to TAPET<sup>®</sup>. In June 1997, pursuant to the license agreement, the Company paid Yale a \$100,000 initial fixed royalty fee.

In December 1995, the Company and Yale entered into another license agreement pursuant to which the Company received a non-transferable worldwide exclusive license, expiring over the lives of the patents, to an invention relating to whitening skin.

Under the licensing agreements, Yale is entitled to potential milestone payments totaling \$1,000,000 based on the completion of Phase II clinical trials, regulatory filings and regulatory approvals. In addition, Yale is entitled to royalties on sales, if any, of resulting products and sublicense revenues. There are no amounts due under these agreements as of December 31, 2005.

#### **Other License Agreements**

**License Agreement with Beijing Pason Pharmaceuticals, Inc. – September 2003.** In September 2003, the Company entered into a license agreement with Beijing Pason Pharmaceuticals, Inc. (“Pason”) whereby the Company granted Pason the exclusive rights to develop, manufacture and market Triapine<sup>®</sup> in the People’s Republic of China, Taiwan, Hong Kong and Macao (the “Territory”). Under the terms of the agreement, the Company received an initial payment in November 2003 of \$500,000 and may receive \$4.75 million in potential additional milestone payments and potential royalty payments of 11% of any Triapine<sup>®</sup> revenues in the Pason Territory. In accordance with the Securities and Exchange Commission’s Staff Accounting Bulletin No. 104, *Revenue Recognition*, the Company will recognize revenue of approximately \$400,000, which represents the initial payment received from Pason net of royalties paid to Yale, over the life of the agreement. The Company recognized revenue related to this agreement of approximately \$18,000, \$18,000, \$4,000 and \$40,000 for the years ended December 31, 2005, 2004 and 2003, and for the period from May 1, 1994 (inception) through December 31, 2005, respectively.

**License Agreement with Austrian Inventors and Austria Wirtschaftsservice Gesellschaft m.b.H.– June 2005.** In November 2003, the Company entered into a research collaboration and option agreement for certain novel anticancer compounds, heterocyclic compounds, with a group of inventors from the Institute of Pharmacy and the Institute of Medical Chemistry and Biochemistry at the University of Innsbruck, and Austria Wirtschaftsservice Gesellschaft m.b.H. In June 2005, the Company entered into an exclusive worldwide license agreement for the compounds. The Company recorded as research and development expense an initial payment of \$25,000 in 2003 to enter into the option agreement and an additional payment of \$37,500 in 2005 to enter into the license agreement. The terms of the license agreement call for potential milestone payments totaling \$775,000 for each licensed product based on regulatory filings, commencement of a Phase III clinical trial or pivotal registration study, and regulatory approvals, as well as royalties based on product revenues.

#### **4. Accrued Expenses**

The following is a summary of accrued expenses as of December 31 (in thousands):

	<u>2005</u>	<u>2004</u>
Clinical trials .....	<b>\$2,553</b>	\$4,326
Gifts .....	<b>250</b>	250
Professional fees .....	<b>217</b>	289
Other .....	<b>285</b>	265
Total Accrued Expenses .....	<u><b>\$3,305</b></u>	<u>\$5,130</u>

#### **5. Shareholders’ Equity**

In April 1995, 2,000,000 shares of common stock valued at \$2.16 per share were issued in conjunction with the merger with MelaRx resulting in net proceeds to the Company of \$4.3 million (refer to Note 1). Shortly prior to the consummation of the merger, the Company issued 76,349 shares of common stock for net proceeds of \$0.2 million.

In August 1995, the Company completed an initial public offering (“IPO”) of 2,875,000 Unit Purchase Options (“UPOs”), consisting of an aggregate of 2,875,000 shares of common stock, 2,875,000 redeemable Class A Warrants and 2,875,000 redeemable Class B Warrants at \$4.00 per UPO. The net proceeds to the Company from the IPO were \$9.7 million before repayment of certain bridge financing. In addition, the Company granted to the underwriter an option to purchase up to 250,000 UPOs at \$5.20 per UPO, subsequently adjusted due to antidilution provisions. Each Class A Warrant entitled the holder to purchase one share of common stock and one Class B Warrant. Each Class B Warrant entitled the holder to purchase one share of common stock. The Class A and Class B Warrants were exercisable through August 14, 2000, and were exchanged, exercised or redeemed prior to that date, resulting in aggregate net proceeds to the Company of \$23.2 million.

Commencing with its IPO through December 31, 2005, the Company has raised gross proceeds of \$171.2 million through the issuance of common stock, preferred stock and warrants.

#### **Issuance and Extension of Placement Agent Warrants**

In connection with two private financings of the Company’s predecessor, MelaRx, Inc., the placement agent was issued warrants to purchase 202,486 shares of common stock at prices ranging from \$3.56 to \$4.44 per share, expiring on July 5, 1998 (the “Expiration Date”). Through the Expiration Date, holders of warrants to purchase 94,336 shares elected a cashless exercise into 13,949 shares of common stock and the remaining warrants to purchase 108,150 shares of common stock expired.

#### **Class A Convertible Preferred Stock**

In May 1996, the Company completed a private placement of 1,250,000 shares of Class A Convertible Preferred Stock (“Class A Stock”), at \$10.00 per share, resulting in net proceeds to the Company of \$11.5 million. Each share of Class A Stock was convertible at the option of the holder into 2.777777 shares of the Company’s common stock. The Company recorded an imputed one-time non-cash dividend of approximately \$11.4 million as a result of the difference between the conversion price and the quoted market price of the Company’s common stock as of the date of issuance as required by the Financial Accounting Standards Board Emerging Issues Task Force D-60, *Accounting for the Issuance of Convertible Preferred Stock and Debt Securities with a Nondetachable Conversion Feature* (EITF D-60). The shares of Class A Stock paid semi-annual dividends of 5% per annum, payable in additional shares of Class A Stock. The Company recorded non-cash dividends from 1996 through 2000 totaling \$1.8 million based on the quoted market price of the common stock as of the dividend date. All non-cash dividends have been recognized as a charge against the accumulated deficit with a corresponding increase in additional paid-in capital. The non-cash dividends have been included in the loss applicable to common shareholders.

In connection with the foregoing transaction, the Company issued warrants to the placement agent, expiring May 22, 2001 (the “Expiration Date”), to purchase an aggregate of 546,875 shares of the Company’s common stock at prices ranging from \$3.96 to \$12.00. As of the Expiration Date, holders of warrants to purchase 257,321 shares elected cash or cashless exercises into 174,572 shares of common stock and the remaining warrants to purchase 289,554 shares expired. The issuance of the Class A Stock at closing also triggered certain antidilution adjustment provisions of the Company’s other outstanding warrants, resulting in the issuance of additional warrants.

In accordance with the terms of the Class A Stock, the Company notified the holders of outstanding shares of its intention to redeem their Class A stock on December 26, 2000 (the “Redemption Date”) at a redemption price of \$10.00 per share. All outstanding shares of Class A Stock were converted by the holders into shares of common stock with the exception of 545 shares of Class A Stock that were redeemed for an aggregate of \$5,450 and cancelled as of the Redemption Date.

#### **Class B Convertible Preferred Stock**

In August 1997, the Company completed a private placement of 4,850 shares of non-voting Class B Convertible Preferred Stock (“Class B Stock”) at \$1,000 per share, resulting in net proceeds to the Company of \$4.5 million. Shares of Class B Stock were immediately convertible into shares of

common stock including an accretion of 8% per annum. The Company recorded an imputed one-time charge of \$0.4 million as a result of the difference between the conversion price and the quoted market price of the Company's common stock at the date of issuance. Shares of the Class B Stock were eligible to receive dividends paid in Class C Convertible Preferred Stock ("Class C Stock") which were immediately convertible into shares of the Company's common stock. Conversions of Class B Stock in 1998 resulted in the issuance of 180,141 shares of common stock valued at \$0.6 million. In addition, the Company recorded accretion of 37,168 shares of common stock valued at \$0.1 million in 1997 and 61,078 shares of common stock valued at \$0.3 million in 1998. All non-cash dividends were recorded as a charge against the accumulated deficit with a corresponding increase in additional paid-in capital. The non-cash dividends have been included in the loss applicable to common shareholders.

In August 1998, the Company reached agreement with the holders of its Class B Stock to convert an aggregate of 2,892 shares of Class B Stock, constituting all of the outstanding Class B Stock, into an aggregate of 1,070,423 shares of common stock. The conversions of Class B Stock resulted in the issuance of 304,188 shares of common stock valued at \$1.1 million, and accretion of 6,553 shares of common stock valued at \$23,000. As part of this agreement, an additional 101,569 common shares were issued to holders of the Class B Stock. In accordance with Financial Accounting Standards Board Emerging Issues Task Force D-42, *The Effect on the Calculation of Earnings Per Share for the Redemption or Induced Conversion of Preferred Stock*, the excess of \$0.4 million of the fair value of the common stock issued upon conversion over the fair value of the common stock issuable pursuant to the original conversion terms was included in the loss applicable to common shareholders. Holders of the Class B Stock waived their antidilution rights arising from the issuance of the 5% Redeemable Convertible Preferred Stock Series 1998.

#### **5% Redeemable Convertible Preferred Stock Series 1998**

In June 1998, the Company completed a private placement of 5,000 shares of non-voting 5% Redeemable Convertible Preferred Stock Series 1998 ("Series 1998 Preferred Stock"). The Series 1998 Preferred Stock was issued at \$1,000 per share, resulting in net proceeds to the Company of \$4.7 million. The shares of Series 1998 Preferred Stock accrued dividends of 5% per annum payable in-kind. Each share of Series 1998 Preferred Stock was convertible into common stock based on the formula of issued price plus accrued dividends divided by \$3.60. In connection with the sale of the Series 1998 Preferred Stock, the Company imputed a one-time non-cash dividend of approximately \$1.6 million as a result of the difference between the conversion price and the quoted market price of the Company's common stock at the date of issuance as required by EITF D-60. Such amount was recognized upon issuance of the Series 1998 Preferred Stock as a charge against the accumulated deficit with a corresponding increase to additional paid-in capital. The imputed non-cash dividend was included in the loss applicable to common shareholders. The dividend requirement on Preferred Stock also reflects the amortization of the costs of completing the offering and the accretion of the 5% per annum dividend. The 5% accretion resulted in a charge against the accumulated deficit with a corresponding increase to additional paid-in-capital from 1998 through 2000 of \$0.8 million. The issuance of the Series 1998 Preferred Stock at closing also triggered certain antidilution adjustment provisions of the Company's outstanding warrants, resulting in the issuance of additional warrants.

In accordance with the terms of the Series 1998 Preferred Stock, all of the outstanding preferred shares having a redemption value of \$5.4 million were automatically converted into 1,507,024 common shares at the \$3.60 conversion price, effective February 22, 2000.

#### **Antidilution Adjustment to Class A and Class B Warrants**

As a result of the sale in May 1996 of Class A Stock, an antidilution adjustment was made to the exercise price of the Class A Warrants and the Class B Warrants and there was a corresponding distribution of additional Class A Warrants and Class B Warrants. Each holder of a Class A Warrant was issued an additional 0.1 Class A Warrant and the exercise price of the Class A Warrants was reduced from \$5.20 to \$4.73. Each holder of a Class B Warrant was issued an additional 0.1 Class B Warrant and the exercise price of the Class B Warrants was reduced from \$7.00 to \$6.37.

Subsequently, as a result of the sale in June 1998 of Series 1998 Preferred Stock, an additional antidilution adjustment was made to the exercise price of the Class A Warrants and the Class B Warrants with a corresponding distribution of additional Class A Warrants and Class B Warrants. Each holder of a Class A Warrant was issued an additional 0.02 Class A Warrant and the exercise price of the Class A Warrants was reduced from \$4.73 to \$4.63. Each holder of a Class B Warrant was issued an additional 0.02 Class B Warrant and the exercise price of the Class B Warrant was reduced from \$6.37 to \$6.23.

#### **Class A and Class B Warrant Exchange Offers**

In 1998, the Company offered to exchange each outstanding Class A Warrant, at the holder's option, for either 0.438 shares of common stock or 0.254 shares of common stock and \$0.66 in cash. The Company simultaneously offered to exchange each outstanding Class B Warrant, at the holder's option, for either 0.212 shares of common stock or 0.123 shares of common stock and \$0.32 in cash. As a result of the exchange offers, 3,209,806 Class A Warrants and 1,881,835 Class B Warrants were exchanged for 1,395,027 and 397,925 shares of the Company's common stock, and \$39,000 and \$3,700 in cash, respectively.

#### **Redemption of Class A Warrants**

The Class A Warrants entitled the holder to purchase one share of common stock and one Class B Warrant for an exercise price of \$4.63. In February 2000, the Company notified holders of its outstanding Class A Warrants of its intention to redeem the warrants on March 13, 2000 (the "Redemption Date"). The Company received net proceeds of \$5.7 million from the exercise of 1.3 million Class A Warrants.

#### **Redemption of Class B Warrants**

The Class B Warrants entitled the holder to purchase one share of common stock at an exercise price of \$6.23. In March 2000, the Company notified holders of its outstanding Class B Warrants of its intention to redeem the warrants on April 27, 2000 (the "Redemption Date"). The Company received net proceeds of \$17.5 million from the exercise of 2.9 million Class B Warrants.

#### **Private Placement of Common Stock – April 1999**

In April 1999, the Company completed a private placement of 893,915 shares of its common stock at \$4.47 per share resulting in net proceeds of approximately \$4 million.

#### **Public Offering of Common Stock – October 1999**

In October and November 1999, the Company completed the sale of 2,530,000 shares of common stock at \$5.00 per share, in an underwritten public offering. The net proceeds from this offering were approximately \$11.1 million. In conjunction with the offering, the underwriter was granted warrants to purchase 220,000 shares of common stock at \$6.00 per share, expiring October 25, 2004. Through the expiration date, holders of warrants to purchase 12,000 shares elected cashless exercises into 6,786 shares of common stock and the remaining warrants to purchase 208,000 shares of common stock expired.

#### **Public Offering of Common Stock – August 2001**

In August 2001, the Company completed the sale of 2,500,000 shares of common stock at \$5.00 per share, in an underwritten public offering. The net proceeds from this offering were approximately \$11.4 million.

#### **Private Placement of Common Stock – June 2003**

In June 2003, the Company completed a private placement of 3,846,150 shares of its common stock at \$1.30 per share and warrants to purchase 1,923,075 shares of common stock at \$2.20 per share. The warrants expire on June 23, 2008. The net proceeds from this offering were approximately \$4.5 million.



### **Private Placement of Common Stock – September 2003**

In September 2003, the Company completed a private placement of 6,475,000 shares of its common stock at \$1.75 per share and warrants to purchase 6,475,000 shares of common stock at \$2.50 per share. A warrant to purchase an additional 100,000 shares of common stock at \$2.50 per share was issued to the placement agent and valued at approximately \$172,000. All of these warrants expire on September 19, 2008. Beginning April 9, 2005, if the volume weighted average price of the common stock is at or above \$3.50 per share for a period of 20 consecutive trading days, then the warrants shall become callable by the Company upon written notice within 3 trading days of such period. The net proceeds, after consideration of cash offering costs, were approximately \$10.4 million.

### **Private Placement of Common Stock – February 2004**

In February 2004, the Company completed a private placement of 13,553,845 shares of its common stock at \$2.60 per share and warrants to purchase 3,388,463 shares of common stock at \$3.25 per share. A warrant to purchase an additional 300,000 shares of common stock at \$3.25 per share was issued to the placement agent and valued at approximately 667,000. All of these warrants expire on February 11, 2009. Beginning May 27, 2005, if the volume weighted average price of the common stock is at or above \$4.875 per share for a period of 20 consecutive trading days, then the warrants shall become callable by the Company upon written notice within 10 trading days of such period. The net proceeds, after consideration of cash offering costs, were approximately \$33 million.

### **Registered Direct Offering of Common Stock – January 2005**

In January 2005, the Company received net proceeds of \$30.2 million from a registered direct offering of 10 million shares of its common stock at \$3.25 per share.

### **Reserved Shares**

As of December 31, 2005, the Company has reserved 21,872,078 shares of its common stock for issuances related to potential future exercises of warrants outstanding, stock options outstanding and stock available for grant (see Note 6), as well as potential future purchases of common stock under the employee stock purchase plan (see Note 7). In addition, shares are reserved for the following but the number of reserved shares is not fixed. The Company may from time to time sell up to an aggregate of \$75 million of its common stock or warrants under an effective Form S-3 shelf registration statement including 10 million shares of common stock issued in a direct registered offering in January 2005. The Company also has a stockholder rights plan whereby each share of its outstanding common stock has the right to purchase one share of common stock as set forth in the rights agreement.

### **Warrants Outstanding**

A summary of the outstanding warrants to purchase shares of the Company's common stock, as described above, as of December 31, 2005 is as follows:

<u>Warrants issued in connection with</u>	<u>Number of Shares of Common Stock to be Issued Upon Exercise of Outstanding Warrants</u>	<u>Exercise Price Per Share of Outstanding Warrants</u>	<u>Expiration Date</u>
Private placement – June 2003 .....	1,192,349	\$2.20	6/23/2008
Private placement – September 2003 .....	4,439,313	\$2.50	9/19/2008
Private placement – February 2004 .....	<u>3,567,309</u>	\$3.25	2/11/2009
Total .....	<u>9,198,971</u>		

## **6. Stock Options and Restricted Stock**

### **Stock Options**

The Company's 2003 Stock Option Plan (the "2003 Plan") was terminated in October 2005 in connection with the adoption of the Company's 2005 Stock Incentive Plan (the "2005 Plan"). The

Company's Amended and Restated 1993 Stock Option Plan (the "1993 Plan") expired on April 15, 2003. As such, the Company no longer grants options under the 1993 Plan and 2003 Plan (the "Option Plans"). Stock options previously granted remain outstanding under the Option Plans and will continue to vest according to schedule. Options outstanding outside the Option Plans represent stock options granted in 1999 to purchase 980,000 shares of common stock to the Company's Chief Executive Officer under the Senior Executive Stock Option Plan. There are no additional shares available for issuance under this plan.

Incentive options granted to employees and officers under the Option Plans vest in equal annual installments over periods ranging from one to four years commencing no earlier than the first anniversary of the date of grant, or earlier on a change of control. Incentive options expire the earlier of: (i) ten years after the date of grant, or (ii) three months after termination of service. Incentive options which are not vested expire immediately upon termination of service. The exercise price for incentive options granted was equal to the fair market value of the common stock on the date of grant.

The Option Plans provided for the automatic grant of non-qualified stock options to purchase shares of common stock to directors of the Company who are not employees or principal stockholders. The exercise price for each share subject to a director option was equal to the fair market value of the common stock on the date of grant. Director options vest after one year under the 2003 Plan and two years under the 1993 Plan, or earlier on a change of control. Generally, director options will expire the earlier of: (i) 10 years after the date of grant, or (i) one year after termination of service as a director under the 2003 Plan or 90 days after termination of service as a director under the 1993 Plan. Director options which are not vested expire immediately upon termination of service as a director. Options granted to directors totaled 0, 115,000 and 135,694 in 2005, 2004 and 2003, respectively.

A summary of the Company's stock option activity under all option plans and related information is as follows:

	2005		2004		2003	
	Options (in 000's)	Weighted- Average Exercise Price	Options (in 000's)	Weighted- Average Exercise Price	Options (in 000's)	Weighted- Average Exercise Price
Outstanding at beginning of year . . . .	5,174	\$4.68	4,497	\$4.68	4,127	\$5.08
Granted . . . . .	82	2.24	746	4.53	518	1.51
Exercised . . . . .	(218)	0.94	(35)	2.21	(6)	0.55
Forfeited . . . . .	(17)	4.62	(24)	2.85	(142)	4.83
Expired . . . . .	(89)	—	(10)	5.98	—	—
Outstanding at end of year . . . . .	<u>4,932</u>	<u>\$4.81</u>	<u>5,174</u>	<u>\$4.68</u>	<u>4,497</u>	<u>\$4.68</u>
Exercisable at end of year . . . . .	<u>4,306</u>	<u>\$4.97</u>	<u>3,955</u>	<u>\$4.93</u>	<u>3,390</u>	<u>\$5.00</u>

The following table presents weighted-average price and life information about significant option groups outstanding as of December 31, 2005:

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number Outstanding (in 000's)</u>	<u>Weighted-Average Remaining Life (Years)</u>	<u>Weighted-Average Exercise Price</u>	<u>Number Exercisable (in 000's)</u>	<u>Weighted-Average Exercise Price</u>
\$0.36 - \$1.79 .....	1,138	6.8	\$ 0.93	1,042	\$ 0.87
\$1.80 - \$3.57 .....	162	5.9	2.51	82	2.78
\$3.58 - \$5.36 .....	2,047	6.0	4.57	1,597	4.61
\$5.37 - \$7.15 .....	890	3.1	5.84	890	5.84
\$7.16 - \$8.94 .....	328	4.3	7.40	328	7.40
\$8.95 - \$10.72 .....	10	4.4	9.88	10	9.88
\$10.73 - \$14.30 .....	65	2.6	12.25	65	12.25
\$14.31 - \$16.09 .....	282	4.2	14.88	282	14.88
\$16.10 - \$17.88 .....	10	4.8	17.88	10	17.88
	<u>4,932</u>	<u>5.4</u>	<u>\$ 4.81</u>	<u>4,306</u>	<u>\$ 4.97</u>

### **Restricted Stock**

In October 2005, the Company's shareholders approved the 2005 Plan. The 2005 Plan provides for a range of awards, including restricted stock, stock appreciation rights, deferred stock, other awards based on shares of common stock, and performance awards. Under the 2005 Plan, 7,441,907 shares of common stock are available for new awards to directors, officers, employees and consultants on the date of the plan's adoption. The amount of shares authorized for granting included 716,907 shares transferred from the 2003 Plan. No award may be made under the 2005 Plan after October 25, 2015.

The 2005 Plan provides an initial restricted stock grant on the first trading day following a non-employee director's initial appointment or election to the board for the number of shares of common stock determined by dividing \$100,000 by the fair market value of the common stock on such date (providing that, if the price per share of the common stock is less than \$2.00 on such date, the number of restricted shares is fixed at 34,700), which shares will vest in three equal annual installments on the anniversary of the grant date or upon a change in control. Further, on the first trading day following each annual meeting, each eligible director will receive an automatic grant of restricted stock for the number of shares of common stock determined by dividing \$28,200 by the fair market value of the common stock on such date (provided that, if the price per share of the common stock is less than \$2.00 on such date, the number of shares of restricted stock is fixed at 11,300), such shares will fully vest one year after the date of each grant or upon a change in control.

For the year ended December 31, 2005, the Company issued 77,610 shares of restricted stock at a fair value of \$2.05 per share and recorded compensation expense of \$26,000 for the restricted shares. As of December 31, 2005, there was \$133,000 of deferred compensation expense recorded related to non-vested restricted stock. The expense will be recognized over the vesting period ending in November 2006.

### **7. Stock Purchase Plan**

A total of 450,000 shares of common stock are authorized for issuance under the Company's employee stock purchase plan (the "Stock Purchase Plan"). The Stock Purchase Plan permits eligible employees to purchase up to 2,000 shares of common stock at the lower of 85% of the fair market value of the common stock at the beginning or at the end of each six-month offering period. 22,171 shares, 6,692 shares and 31,782 shares were issued in 2005, 2004 and 2003, respectively, under the Stock Purchase Plan.

### **8. 401(k) Savings Plan**

The Company makes matching contributions in cash under a 401(k) Savings Plan up to an annual maximum match of \$1,000 per employee or, prior to January 1, 2004, its common stock at the election

of the employee. The expense for the matching contribution was \$24,000, \$23,000 and \$25,000 for the years ended December 31, 2005, 2004 and 2003, respectively, and \$221,000 for the period from May 1, 1994 (inception) through December 31, 2005. 9,399 shares were issued in 2003 for the stock matching contribution.

## 9. Income Taxes

At December 31, 2005, the Company has available for federal income tax purposes net operating loss carryforwards, subject to review by the Internal Revenue Service, totaling \$115 million and a general business tax credit of \$3.7 million expiring in 2010 through 2025. The difference between the deficit accumulated during the development stage for financial reporting purposes and the net operating loss carryforwards for tax purposes is primarily due to certain costs which are not currently deductible for tax purposes and differences in accounting and tax basis resulting from the merger described in Note 1. The ability of the Company to realize a future tax benefit from a portion of its net operating loss carryforwards and general business credits may be limited due to changes in ownership of the Company.

Significant components of the deferred income taxes are as follows (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Operating loss carryforwards .....	<b>\$ 44,845</b>	\$ 39,129
General business tax credit carryforwards .....	<b>3,662</b>	3,072
AMT tax credit carryforwards .....	<b>10</b>	10
Contributions .....	<b>786</b>	1,241
Compensation related .....	<b>243</b>	168
Other .....	<b>311</b>	375
Total deferred income tax asset .....	<b>49,857</b>	43,995
Valuation allowance .....	<b>(49,857)</b>	(43,995)
Deferred income tax asset, net .....	<b>\$ —</b>	\$ —

The valuation allowance increased by \$5.9 million and \$7.1 million during 2005 and 2004, respectively.

For the year ended December 31, 2005, the Company recorded approximately \$40,000 related to minimum state capital taxes paid.

## 10. Commitments and Contingencies

### Leases

The Company has non-cancelable operating leases for its facility and its laboratory and office equipment expiring through 2010. Rental expense under the facility lease is recognized on a straight-line basis. Rental expense under the operating leases was approximately \$344,000, \$298,000 and \$284,000 for the years ended December 31, 2005, 2004 and 2003, respectively, and \$2.7 million for the period from May 1, 1994 (inception) through December 31, 2005. As of December 31, 2005, future minimum lease payments due under non-cancelable operating lease agreements with initial terms in excess of one year are \$248,000 for 2006, \$224,000 for 2007, \$217,000 for 2008, \$217,000 for 2009 and \$217,000 for 2010.

In January 2006, the Company extended its facility lease through December 31, 2010. Rental expenses for 2006 to 2010 under the extended lease are reflected in the above future minimum lease payment amounts.

### Agreements

Under the terms of an employment agreement, the Company is obligated to pay its Chief Executive Officer (“CEO”) a minimum annual salary of \$412,000 through December 31, 2008. The CEO is also eligible for a bonus of up to 50% of his base salary based on the achievement of specified objectives.

In the event the CEO's employment is terminated by the Company for any reason other than cause or disability, or if the CEO terminates for good reason as defined in the agreement, the Company is obligated to pay him two times the sum of his base salary plus his average annual bonus for the prior two years and to continue payment of certain insurance costs on his behalf.

The Company has entered into severance agreements with its officers pursuant to which each of these officers would be entitled to certain payments in the event such officer loses his employment during the twelve-month period following a "change of control", as defined in the agreement, and additionally, in the case of the Company's President, following a change in the Company's CEO. Specifically, the officer would be entitled to a lump sum severance payment equal to the sum of twelve months of the officer's monthly base salary plus the average of the last two cash bonus payments made to the officer, and to the continuation of group health insurance benefits for up to eighteen months. The foregoing amounts are not payable if termination of the officer is because of his death, by the Company for cause, or by the officer other than for good reason.

A former director of the Company is a party to a Consulting and Finder's Agreement with the Company dated June 4, 1992, and amended February 17, 1995. This agreement entitles him to receive an annual fee equal to 10% of the net after-tax profits of the Company attributable to the sale or licensing of products or technology related to TAPET<sup>®</sup> licensed pursuant to the Company's December 1995 license agreement with Yale (refer to Note 3), until the cumulative total of such fees equals \$3 million. Such fee continues to be payable notwithstanding the director's death until the \$3 million has been paid. Through December 31, 2005, no amounts are due or have been paid under this agreement.

The Company has various commitments relating to its research and license agreements (refer to Note 3).

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, typically clinical sites, suppliers and business partners. Pursuant to these agreements, we generally indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of our product candidates, or with any U.S patent or any copyright or other intellectual property infringement claim by any third party with respect to products. The term of these indemnification agreements is generally perpetual. The potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have not incurred any costs to defend lawsuits or settle claims related to these indemnification agreements. We have no liabilities recorded for costs associated with these agreements as of December 31, 2005.

## 11. Related Party Transactions

The Company recorded research and development expense of \$200,000, \$200,000 and \$400,000 for the years ended December 31, 2005, 2004 and 2003, respectively, related to gifts to fund research through March 31, 2007 at the laboratory headed by one of its directors, an affiliate of Yale. Included in the Company's current liabilities at December 31, 2005, is \$250,000 for the balance of the gifts to be paid in five equal quarterly installments through the first quarter of 2007.

## 12. Selected Quarterly Financial Data (Unaudited)

The following is a summary of unaudited selected quarterly financial data for the years ended December 31, 2005 and 2004 (in thousands, except per share amounts):

2005	Quarter				Year
	First	Second	Third	Fourth	2005
Revenues .....	\$ 5	\$ 7	\$ 6	\$ 5	\$ 23
Net loss .....	(4,552)	(5,107)	(3,727)	(4,655)	(18,041)
Basic and diluted loss per share .....	(0.07)	(0.08)	(0.06)	(0.07)	(0.28)

<u>2004</u>	<u>Quarter</u>				<u>Year</u>
	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>	<u>2004</u>
Revenues .....	\$ 96	\$ 125	\$ 50	\$ 4	\$ 275
Net loss .....	(3,258)	(3,669)	(3,906)	(5,222)	(16,055)
Basic and diluted loss per share ..	(0.07)	(0.07)	(0.07)	(0.09)	(0.30)

**ITEM 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

**ITEM 9A. *Controls and Procedures***

**Controls and Procedures**

Based on their evaluation as of December 31, 2005, our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure that the information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

**Management’s Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2005, our internal control over financial reporting is effective based on these criteria. Our independent registered public accounting firm, Ernst & Young LLP, have issued an audit report on our assessment of our internal control over financial reporting, which is included herein.

There was no change in our internal control over financial reporting during the quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

**ITEM 9B. *Other Information***

None.

## **PART III**

### **ITEM 10. *Directors and Executive Officers of the Registrant***

#### **Executive Officers and Directors**

See “Part I – Executive Officers and Directors.”

#### **Audit Committee Financial Expert**

Our board of directors has determined that Mr. Bickerstaff who serves on its audit committee qualifies as “audit committee financial expert” (as that term is defined in the rules promulgated by the United States Securities and Exchange Commission (SEC) pursuant to the Sarbanes-Oxley Act of 2002). Our board of directors has a separately-designated standing audit committee established in accordance with Section 3(a)(58)A of the Securities Exchange Act of 1934 and has also determined that all members of the audit committee are “independent”, as that term is used in Item 7(d)(3)(iv) of Schedule 14A under the Securities Exchange Act of 1934.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors, and persons who beneficially own more than ten percent of our Common Stock, to file initial reports of ownership and reports of changes in ownership with the SEC and the NASDAQ Stock Market. Executive officers, directors and greater than ten percent beneficial owners are required by the SEC to furnish us with copies of all Section 16(a) forms they file.

Based upon a review of the forms furnished to us and written representations from our executive officers and directors, we believe that during fiscal 2005 all Section 16(a) filing requirements applicable to our executive officers, directors and greater than ten percent beneficial owners were complied with.

#### **Code of Ethics**

We have adopted a Code of Ethics and Business Conduct applying to our directors, officers and employees, as well as a Code of Ethics that applies to our chief executive officer and senior financial officers. The codes have been posted on our website, [www.vionpharm.com](http://www.vionpharm.com).

## ITEM 11. Executive Compensation

The following table sets forth information concerning all cash and non-cash compensation awarded to, earned by or paid to our Chief Executive Officer and to our four most highly compensated executive officers, other than the Chief Executive Officer, who were serving as executive officers at December 31, 2005, for services rendered to us in all capacities during the three fiscal years ended December 31, 2005.

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation		
		Salary (\$)	Bonus (\$)	Other Annual Compensation	Restricted Stock Awards <sup>(5)</sup>	Securities Underlying Options/SARs (#)	All Other Compensation (\$)
Alan Kessman . . . . .	2005	\$428,480	\$ 80,000	(4)	—	—	\$ 1,000 <sup>(6)</sup>
— Chief Executive Officer <sup>(1)</sup>	2004	\$412,000 <sup>(2)</sup>	\$100,000	(4)	—	150,000	\$ 1,000 <sup>(6)</sup>
	2003	\$412,000 <sup>(3)</sup>	—	(4)	—	80,000	\$14,200 <sup>(7)</sup>
Howard B. Johnson . . . . .	2005	\$275,000	\$ 80,053	(4)	—	—	—
— President and Chief Financial Officer	2004	\$250,000 <sup>(2)</sup>	\$ 25,001	(4)	—	100,000	—
	2003	\$200,000 <sup>(3)</sup>	—	(4)	—	60,000	—
Ann Lee Cahill . . . . .	2005	\$200,000	\$ 65,000	(4)	—	—	\$ 1,000 <sup>(6)</sup>
— Vice President, Clinical Development <sup>(8)</sup>	2004	\$184,800	\$ 15,400	(4)	—	105,000	\$ 1,000 <sup>(6)</sup>
	2003	—	—	(4)	—	—	—
Ivan King, Ph.D. . . . .	2005	\$220,000	\$ 35,035	(4)	—	—	\$ 1,000 <sup>(6)</sup>
— Vice President, Research and Development	2004	\$208,000 <sup>(2)</sup>	\$ 20,800	(4)	—	50,000	\$ 1,000 <sup>(6)</sup>
	2003	\$200,000 <sup>(3)</sup>	—	(4)	—	40,000	\$ 1,000 <sup>(6)</sup>
Terrence W. Doyle, Ph.D. . . . .	2005	\$224,973	\$ —	(4)	—	—	\$ 1,000 <sup>(6)</sup>
— Vice President, Chief Scientific Officer <sup>(9)</sup>	2004	\$224,973 <sup>(2)</sup>	\$ 4,500	(4)	—	—	\$ 1,000 <sup>(6)</sup>
	2003	\$216,320 <sup>(3)</sup>	—	(4)	—	10,000	\$ 1,500 <sup>(6)</sup>

- (1) We are a party to an employment agreement with Mr. Kessman. See “— Employment Agreements.”
- (2) Excludes 2004 payments of salary deferrals in 2002-2003 to conserve cash resources as follows: Mr. Kessman — \$114,607; Mr. Johnson — \$27,222; Dr. King — \$27,222; Dr. Doyle — \$29,440; and Dr. Sznol — \$30,704.
- (3) Includes 2003 salary deferrals to conserve cash resources, net of payments of salary deferrals beginning August 2003, as follows: Mr. Kessman — \$14,274; Mr. Johnson — \$3,889; Dr. King — \$3,889; Dr. Doyle — \$4,203; and Dr. Sznol — \$4,387.
- (4) Aggregate amount of such compensation is less than the lesser of \$50,000 or 10% of the total salary and bonus reported for the indicated person.
- (5) On January 5, 2006, Messrs. Kessman, Johnson, King and Ms. Cahill were granted 466,667 shares, 221,667 shares, 138,889 shares and 186,667 shares of restricted stock, respectively, for their performance in 2005. The shares will vest upon the earliest of (A) December 31, 2008; (B) the approval of an NDA to market Cloretazine<sup>®</sup>; or (C) the occurrence of a Change of Control, as defined in our 2005 Stock Incentive Plan. There were no restricted shares held by our executive officers as of December 31, 2005.
- (6) Consists of matching contribution to the Company’s 401(k) Savings Plan.
- (7) Consists of life and disability insurance payments.
- (8) Ms. Cahill was named an executive officer on October 15, 2004.
- (9) In January 2004, we entered into a consulting agreement with Gemin X, Inc. (Gemin X), under which Dr. Doyle renders consulting services to Gemin X. Gemin X paid us \$207,000 and \$213,325 for Dr. Doyle’s consulting for the years ended December 31, 2005 and 2004, respectively. Dr. Doyle has informed us of his intent to retire on March 31, 2006. It is intended that our agreement with Gemin X will terminate as of that date.



## Option Grants in Last Fiscal Year

The following table sets forth the grant of stock options made during the year ended December 31, 2005 to the persons named in the Summary Compensation Table:

Name (a)	Number of Securities Underlying Options Granted (b)	% of Total Options Granted to Employees in Fiscal Period (c)	Exercise of Base Price (\$/Sh) (d)	Expiration Date (e)	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
					5% (\$) (f)	10% (\$) (g)
Alan Kessman . . . . .	—	—	—	—	—	—
Howard B. Johnson . . . . .	—	—	—	—	—	—
Ann Lee Cahill . . . . .	—	—	—	—	—	—
Ivan King, Ph.D. . . . .	—	—	—	—	—	—
Terrence W. Doyle, Ph.D. . .	—	—	—	—	—	—

## Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table sets forth information with respect to stock options exercised in 2005 and unexercised stock options held by the persons named in the Summary Compensation Table at December 31, 2005.

Name (a)	Shares Acquired on Exercise (#) (b)	Value Realized (\$) (c)	Number of Securities Underlying Unexercised Options at Fiscal Year-End (#)		Value of Unexercised In-the-Money Options at Fiscal Year-End (\$) <sup>(1)</sup>	
			Exercisable (d)	Unexercisable (e)	Exercisable (f)	Unexercisable (g)
Alan Kessman . . . . .	—	\$ —	1,542,927	—	\$171,400	\$ —
Howard B. Johnson . . . . .	—	\$ —	399,999	182,500	\$ 82,949	\$1,600
Ann Lee Cahill . . . . .	—	\$ —	64,166	85,834	\$ 22,533	\$ 267
Ivan King, Ph.D. . . . .	—	\$ —	312,048	50,834	\$ 73,633	\$1,067
Terrence W. Doyle, Ph.D. . .	—	\$ —	230,533	3,334	\$ 42,790	\$ 267

<sup>(1)</sup> Computed based upon the difference between the closing price of the Company's common stock on December 30, 2005 (\$1.65) and the exercise price.

## Employment and Change in Control Agreements

In November 2003, we entered into an employment agreement effective January 1, 2004 with Alan Kessman, our Chief Executive Officer. Pursuant to this agreement, Mr. Kessman receives a minimum base salary of \$412,000 per year and is eligible for a bonus of up to 50% of his base salary based on the achievement of specified objectives. In the event Mr. Kessman's employment is terminated by us for any reason other than cause or disability, or if Mr. Kessman terminates for good reason, we are obligated to pay him two times the sum of his base salary plus his average annual bonus for the prior two years and to continue payment of certain insurance costs on his behalf. Under Mr. Kessman's employment agreement, it shall constitute "good reason" for Mr. Kessman to terminate his employment and receive the amounts described above if there is a change in control and the Company or its successors, as the case may be, fails to agree in writing to extend the expiration date of the employment agreement to the two-year anniversary of the change of control. In September 2005 and January 2006 we negotiated extensions of Mr. Kessman's employment agreement, and the termination date of Mr. Kessman's employment agreement is now December 31, 2008.

We entered into severance agreements with Howard B. Johnson, our President and Chief Financial Officer, Ann Lee Cahill, our Vice President of Clinical Development, Meghan Fitzgerald, our Vice President and Chief Business Officer, Dr. Ivan King, our Vice President of Research and Development, Karen Schmedlin our Vice President of Finance, Chief Accounting Officer and

Corporate Secretary, and Dr. Terrence W. Doyle, our Vice President and Chief Scientific Officer, pursuant to which each of these officers would be entitled to certain payments in the event such officer loses his employment during the twelve-month period following a “change in control,” as defined in the agreement. Specifically, if a “change in control” occurs, the officer shall be entitled to a lump sum severance payment equal to the sum of twelve months of the officer’s monthly base salary as in effect as of the date of termination or immediately prior to the change in control, whichever is greater, plus the average of the last two cash bonus payments made to the officer prior to the change in control. The officer would also be entitled to all payments necessary to provide him with group health insurance benefits substantially similar to those which he was receiving immediately prior to the date of termination until the earlier of 18 months after such termination or the date he has obtained new full-time employment. The foregoing amounts are not payable if termination of the officer is because of his death, by us for cause, or by the officer other than for good reason.

On September 13, 2005, we entered into an additional agreement with Howard B. Johnson, our President and Chief Financial Officer, pursuant to which Mr. Johnson would be entitled to certain payments in the event his employment is terminated after Alan Kessman’s retirement, resignation or termination as our Chief Executive Officer (“CEO”). Specifically, if at any time within one year after the earlier of (i) the date of a public announcement by the Company of the hiring of a new CEO and (ii) the date of hiring of such new CEO as set forth in such public announcement (the “CEO Hiring Date”) Mr. Johnson is terminated by the Company without cause (as defined in the agreement), he shall be entitled to a lump sum payment equal to the sum of twelve months of his monthly base salary as in effect as of the date of termination or immediately prior to such termination, whichever is greater, plus the average of the last two cash bonus payments made to Mr. Johnson prior to his termination. Mr. Johnson would also be entitled to all payments necessary to provide him with group health insurance benefits substantially similar to those which he was receiving immediately prior to the date of termination until the earlier of 12 months after such termination or the date he obtains new full-time employment. Also, if Mr. Johnson voluntarily resigns from his position as President and Chief Financial Officer of the Company within the first 90 days following the CEO Hiring Date, he shall be entitled to receive his full base salary, at the rate as in effect at the date of resignation, at such time as such payments would have been due pursuant to his previous salary arrangement, until the earlier of 12 months after the date of such resignation or the date he obtains new full-time employment (the “Transition Period”), provided that Mr. Johnson advises and consults by telephone, in writing or, at a mutually agreeable time, in person regarding the affairs of the Company with the officers and directors of the Company upon requests for such services by such officers and directors during the Transition Period. In the event of such resignation, Mr. Johnson would also be entitled to all payments necessary to provide him with group health insurance benefits substantially similar to those which he was receiving immediately prior to the date of termination until the earlier of 12 months after such termination or the date he obtains new full-time employment. The foregoing amounts are not payable if the termination of Mr. Johnson is due to his death, is a result of a termination by us for cause or if Mr. Johnson is offered the position of CEO.

### **Compensation of Directors**

Through September 12, 2005, our non-employee directors received \$1,000 for each board meeting attended and the chairman of the board received \$4,000 for each board meeting attended. Directors were also reimbursed for expenses actually incurred in attending board or committee meetings.

Our 2003 Stock Option Plan provided for, among other things, the automatic grant of 20,000 stock options to each person who is initially elected or appointed to the Board of Directors as a non-employee director. The exercise price for each share subject to such options is equal to the fair market value of the common stock on the date of grant. These options vest after one year (or earlier on a change of control) and, generally, expire upon the earlier of ten years after the date of grant or one year after termination of service as a director. Upon their initial appointment to the Board on June 8, 2005, Mr. Bickerstaff and Mr. Willis were each granted 20,000 options at an exercise price of \$2.09 per share. Due to shareholder approval of the 2005 Stock Incentive Plan on October 25, 2005, no additional option grants will be made under our 2003 Stock Option Plan.

Upon the advice and recommendation of outside compensation consultants retained by the Compensation Committee, which advice and recommendation was based upon a detailed analysis of the practices of companies within our peer group as well as emerging trends occurring within director compensation arena, and other factors considered by the Compensation Committee and the Board, the Compensation Committee recommended and the Board of Directors approved the following changes, effective September 13, 2005, to the cash compensation payable to our non-employee directors:

- payment of a \$15,000 annual retainer to each director other than the chairman of the board;
- payment of a \$40,000 annual retainer to the chairman of the board;
- payment of a \$5,000 annual retainer to the chair of each committee of the board other than the chair of the audit committee;
- payment of a \$10,000 annual retainer to the chair of the audit committee;
- the increase of the meeting fee payable for each board meeting attended from \$1,000 to \$1,500 and the elimination of the \$4,000 meeting fee payable to the chairman of the board; and
- payment of \$1,000 meeting fee for each committee meeting attended in person and \$500 for each committee meeting attended by teleconference that exceeds one hour.

Directors will also continue to be reimbursed for expenses actually incurred in attending board and committee meetings.

Also upon the advice and recommendation of outside compensation consultants retained by the Compensation Committee, and other factors considered by the Compensation Committee and the Board, effective September 13, 2005, the Compensation Committee recommended and the Board of Directors approved changing the form in which equity compensation is provided to our non-employee directors from stock option awards to restricted stock awards, on the following terms:

- annual restricted stock grants to each non-employee director on the first trading day following each annual meeting for the number of shares of our common stock determined by dividing \$28,200 by the fair market value of our common stock on such date (provided that, if the price per share of our common stock is less than \$2.00 on such date, the number of shares of restricted stock shall be fixed at 11,300), which shares shall fully vest one year after the date of each grant or upon a change in control; and
- an initial restricted stock grant on the first trading day following a non-employee director's initial appointment or election to the board for the number of shares of our common stock determined by dividing \$100,000 by the fair market value of our common stock on such date (provided that, if the price per share of our common stock is less than \$2.00 on such date, the number of shares of restricted stock shall be fixed at 34,700), which shares shall vest in three equal annual installments or upon a change in control.

Pursuant to our 2005 Stock Incentive Plan approved by our stockholders on October 25, 2005, a grant of 12,935 shares of restricted stock was made to each of our non-employee directors (Messrs. Bickerstaff, Miller and Willis and Drs. Carter, Sartorelli and Sznol) following our 2005 annual meeting of stockholders. These shares vest one year after the date of grant (or earlier upon a change of control) and are subject to forfeiture upon termination of service as a director prior to the vesting date.

### **Compensation Committee Interlocks and Insider Participation**

The compensation committee consists of Gary Willis, George Bickerstaff and William Miller. No member of the compensation committee was an officer or employee of the Company during 2005 or was formerly an officer of the Company. In addition, no executive officer at the Company served as a member of another entity's Board of Directors or as a member of the compensation committee of

another entity (or other board committee performing equivalent functions) during 2005, which entity had an executive officer serving on the Board of Directors of the Company.

### **Compensation Committee Report on Executive Compensation**

This Executive Compensation Report discusses the Company's executive compensation policies and the basis for the compensation paid to the Executive Officers during the year ended December 31, 2005.

*Compensation Policy.* The Committee's policy with respect to executive compensation has been designed to:

- Adequately and fairly compensate executive officers in relation to responsibilities, capabilities and contributions to the Company and in a manner that is commensurate with compensation paid by companies of comparable size and at a comparable stage of development within the Company's industry;
- Reward executive officers for the achievement of short-term goals and for the enhancement of the long-term value of the Company; and
- Align the interests of the executive officers with those of the stockholders with respect to short-term operating goals and long-term increases in the value of the Company's Common Stock.

The components of compensation generally paid to executive officers consist of: (a) base salary and (b) incentive compensation in the form of annual bonus payments and equity-based incentive compensation awards by the Company under the Company's 2005 Stock Incentive Plan. The Company's Compensation Committee is responsible for reviewing and approving cash compensation paid by the Company to its executive officers and members of the Company's senior management team, including annual bonuses and stock-based awards, selecting the individual executives and members of senior management who will be awarded bonuses and stock-based awards, and for determining the timing, pricing and amount of all stock-based awards granted to executives and members of senior management under the Company's 2005 Stock Incentive Plan.

The Company's executive compensation program emphasizes the use of incentive-based compensation to reward the Company's executive officers and members of senior management for individual contributions to the achievement of the Company's business, research and product development objectives recommended by the CEO and approved by the Compensation Committee. The Company uses stock-based awards to provide an incentive for a substantial number of its officers and employees, including members of management, and to reward such officers and employees for achieving the Company's business objectives. The Company believes its incentive compensation plan rewards management when the Company and its stockholders have benefited from achieving the Company's business objectives and targeted clinical, research and development objectives, all of which the Compensation Committee feels will dictate, in large part, the Company's future operating results. The Compensation Committee believes that its policy of compensating officers and employees with incentive-based compensation fairly and adequately compensates those individuals in relation to their responsibilities, capabilities and contribution to the Company, and in a manner that is commensurate with compensation paid by companies of comparable size and at a comparable stage of development within the Company's industry.

*Components of Compensation.* The primary components of compensation paid by the Company to its executive officers and senior management personnel, and the relationship of such components of compensation to the Company's performance, are discussed below:

- *Base Salary.* The Compensation Committee periodically reviews the base salary paid by the Company to its executive officers and members of the senior management team. Adjustments to base salaries are determined based upon a number of factors, including the Company's performance (to the extent such can fairly be attributed or related to each executive's

performance), as well as the nature of each executive's responsibilities, capabilities and contributions. The Compensation Committee attempts to ascertain whether salaries fairly reflect job responsibilities and prevailing market conditions and rates of pay. Generally, salary increases, if any, are given annually at the beginning of each year. The Compensation Committee believes that base salaries for the Company's executive officers have historically been reasonable in relation to the Company's size and performance in comparison with the compensation paid by similarly sized companies or companies within the Company's industry.

- *Incentive Compensation.* As discussed above, a substantial portion of each executive officer's compensation package is in the form of incentive compensation designed to reward the achievement of short-term operating goals and long-term increases in stockholder value. Annually, the CEO recommends, and the Compensation Committee considers and adopts performance criteria for the Company's executive officers on which to base bonuses for the year. Typically, the cash bonus to be paid based upon the achievement of the performance criteria will be between 25% and 50% of the executive's base salary. The performance criteria are generally the achievement of certain targets relating to the Company's clinical trials, registrational requirements of the Company's drug products, business development objectives, increases in stockholder value and financial objectives. The Company's 2005 Stock Incentive Plan allows the Board of Directors or the Compensation Committee to grant stock-based awards of the Company's Common Stock to executive officers and employees. Under the terms of the 2005 Stock Incentive Plan, the Board of Directors and the Compensation Committee have authority to select the executive officers and employees who will be granted stock-based awards and to determine the timing, pricing and number of shares of stock to be awarded. Typically, these awards vest upon the earliest of (A) approximately three years after the date of grant, (B) the approval of an NDA to market Cloretazine<sup>®</sup>, or (C) the occurrence of a Change of Control, as defined in our 2005 Stock Incentive Plan, although the Compensation Committee may adopt other or additional vesting criteria. The Compensation Committee believes that the stock-based awards with the forgoing vesting criteria reward executive officers only to the extent that stockholders have benefited from increases in the value of the Company's Common Stock.

*Compensation of the Chief Executive Officer.* The Company has entered into an executive employment agreement as amended with Mr. Kessman. For material terms of this executive employment agreement see "*Employment Agreements*". The Compensation Committee believes that the monthly compensation under the agreement adequately and fairly compensates Mr. Kessman in relation to his responsibilities, capabilities, contributions and dedication to the Company and secures for the Company the benefit of his leadership, management and financial skills and capabilities. Moreover, the Compensation Committee believes that the salary and other benefits are reasonable in relation to the responsibilities, capabilities, contributions and dedication of Mr. Kessman to the Company and are in line with the compensation earned by chief executive officers employed by companies of comparable size and stage of development within the Company's industry.

*Tax Deductibility.* Section 162(m) of the Internal Revenue Code of 1986, as amended, generally denies publicly-held corporations a federal income tax deduction for compensation exceeding \$1,000,000 paid to Named Executive Officers, excluding performance-based compensation. Through December 31, 2005, this provision has not limited our ability to deduct executive compensation, but the Compensation Committee will continue to monitor the potential impact of Section 162(m) on our ability to deduct executive compensation.

*Conclusion.* The Compensation Committee believes that the concepts discussed above further the stockholder interests because a significant part of executive compensation is based upon the Company achieving its product development and other specific goals set by the Board of Directors. At the same time, the Compensation Committee believes that the program encourages responsible management of the Company in the short-term. The Compensation Committee regularly considers plan design so that the total program is as effective as possible in furthering stockholder interests.

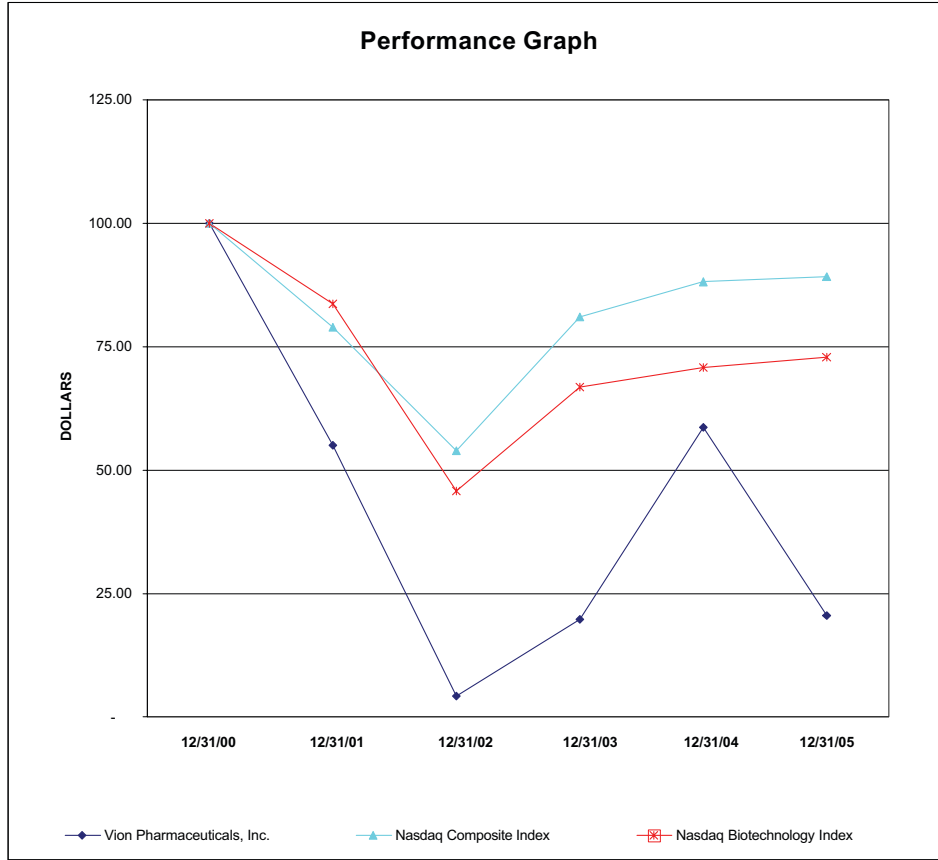
The Compensation Committee bases its review on the experience of its own members, on information requested from management personnel, and on discussions with and information compiled by various independent consultants retained by the Company.

Submitted by the Compensation Committee:

GARY WILLIS, CHAIRMAN  
GEORGE BICKERSTAFF  
WILLIAM R. MILLER

**Performance Graph**

The following line graph compares the five-year cumulative total stockholder's return on our Common Stock to: (i) the change in the cumulative total return on the Nasdaq Composite Index for U.S. Companies and (ii) the change in the cumulative total return on the Nasdaq Biotechnology Index, which includes biotechnology companies, assuming an investment of \$100 made in each and assuming the reinvestment of any dividends.



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

The following table sets forth information as of March 1, 2006 (except as otherwise noted in the footnotes) regarding the beneficial ownership (as defined by the Securities and Exchange Commission (the “SEC”)) of our Common Stock: (i) each person known by us to own beneficially more than five percent of our outstanding Common Stock; (ii) each of our current directors; (iii) each executive officer named in the Summary Compensation Table; and (iv) all of our current directors and executive officers as a group. Except as otherwise specified, the named beneficial owner has the sole voting and investment power over the shares listed and the address of each beneficial owner is c/o Vion Pharmaceuticals, Inc., 4 Science Park, New Haven, Connecticut 06511.

<u>Directors and Officers</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percent of Outstanding Shares of Common Stock</u>
George Bickerstaff .....	12,935	*
Stephen K. Carter, M.D. ....	94,986 <sup>(1)</sup>	*
William R. Miller .....	394,294 <sup>(2)</sup>	*
Alan C. Sartorelli, Ph.D. ....	534,648 <sup>(3)</sup>	*
Mario Sznol, M.D. ....	455,521 <sup>(4)</sup>	*
Gary Willis .....	12,935	*
Alan Kessman .....	2,059,450 <sup>(5,6)</sup>	3.0%
Howard B. Johnson .....	709,166 <sup>(6,7)</sup>	1.0%
Ann Lee Cahill .....	258,636 <sup>(6,8)</sup>	*
Ivan King, Ph.D. ....	460,437 <sup>(6,9)</sup>	*
Terrence W. Doyle, Ph.D. ....	463,057 <sup>(10)</sup>	*
All directors and executive officers as a group (13 persons). ....	5,768,069 <sup>(11)</sup>	8.1%
<u>Other Beneficial Owners</u>		
Raj Rajaratnam Galleon Management, L.L.C. Galleon Management, L.P. Galleon Advisors, L.L.C. Galleon Captains Partners, L.P. Galleon Captains Offshore, Ltd. Galleon Healthcare Partners, L.P. Galleon Healthcare Offshore, Ltd. 135 East 57th Street, 16th Floor New York, NY 10022 .....	5,702,948 <sup>(12)</sup>	8.4%
OrbiMed Advisors LLC OrbiMed Capital LLC Samuel D. Isaly 767 Third Avenue, 30 <sup>th</sup> Floor New York, NY 10017 .....	3,362,100 <sup>(13)</sup>	5.0%

\* Less than one percent

<sup>(1)</sup> Includes 82,051 shares issuable upon exercise of options.

<sup>(2)</sup> Includes 88,472 shares issuable upon exercise of options.

<sup>(3)</sup> Includes 190,874 shares beneficially owned by Dr. Sartorelli’s wife, as to which Dr. Sartorelli disclaims beneficial ownership. Also includes 121,508 shares issuable upon exercise of options.

<sup>(4)</sup> Includes 437,586 shares issuable upon exercise of options.

<sup>(5)</sup> Includes 12,756 shares held by a family trust of which Mr. Kessman is a controlling member. Also includes 1,542,927 shares issuable upon exercise of options.



- (6) On January 5, 2006, Messrs. Kessman, Johnson, King and Ms. Cahill were granted 466,667 shares, 221,667 shares, 138,889 shares and 186,667 shares of restricted stock, respectively, for their performance in 2005. The shares will vest upon the earliest of (A) December 31, 2008; (B) the approval of an NDA to market Cloretazine<sup>®</sup>; or (C) the occurrence of a Change of Control, as defined in our 2005 Stock Incentive Plan.
- (7) Includes 487,499 shares issuable upon exercise of options.
- (8) Includes 67,916 shares issuable upon exercise of options.
- (9) Includes 312,048 shares issuable upon exercise of options.
- (10) Includes 43,400 shares held by Dr. Doyle's wife, as to which Dr. Doyle disclaims beneficial ownership. Also includes 230,533 shares issuable upon exercise of options.
- (11) Includes 3,430,256 shares issuable upon exercise of options.
- (12) Based on data set forth in an Amendment No. 1 to Schedule 13G filed with the SEC on February 15, 2006, of the 5,702,948 shares reported in such Schedule 13G: (i) 811,356 are held by Galleon Captains Partners, L.P.; (ii) 209,000 are held by Galleon Healthcare Partners, L.P.; (iii) 3,267,944 are held by Galleon Captains Offshore, Ltd.; and (iv) 1,414,648 are held by Galleon Healthcare Offshore, Ltd. Galleon Management, L.P. and Galleon Advisors, L.L.C. share dispositive and voting power over the shares held by Galleon Captains Partners, L.P. and Galleon Healthcare Partners, L.P. pursuant to a partnership agreement by and between Galleon Captains Partners, L.P. and Galleon Healthcare Partners, L.P. Galleon Management, L.P. acts as investment manager to Galleon Captains Offshore, Ltd. and Galleon Healthcare Offshore, Ltd. and has dispositive and voting power with respect to the shares held by them. Raj Rajaratnam is the managing member of Galleon Management, L.L.C., which, as the general partner of Galleon Management, L.P., controls Galleon Management, L.P. Mr. Rajaratnam is also the managing member of Galleon Management, L.L.C. and Galleon Advisors L.L.C. As managing member of Galleon Management, L.L.C. and Galleon Advisors L.L.C., Mr. Rajaratnam holds sole dispositive and voting power over the securities held by Galleon Captains Partners L.P., Galleon Healthcare Partners, L.P., Galleon Captains Offshore, Ltd. and Galleon Healthcare Offshore, Ltd. The shares reported as owned in the Schedule 13G by Raj Rajaratnam, Galleon Management, L.P., Galleon Management, L.L.C., and Galleon Advisors, L.L.C. may be deemed beneficially owned as a result of the purchase of such shares by Galleon Captains Partners, L.P., Galleon Captains Offshore, Ltd., Galleon Healthcare Partners, L.P., and Galleon Healthcare Offshore, Ltd., as the case may be. Each of Raj Rajaratnam, Galleon Management, L.P., Galleon Management, L.L.C., and Galleon Advisors, L.L.C. disclaims any beneficial ownership of the shares reported in the Schedule 13G, except to the extent of any pecuniary interest therein.
- (13) Based on data set forth in Schedule 13G filed with the SEC on February 6, 2006, of the 3,362,100 shares reported in such Schedule 13G: (i) 1,725,100 are held by OrbiMed Advisors LLC; and (ii) 1,637,000 are held by OrbiMed Capital LLC. OrbiMed Advisors LLC and OrbiMed Capital LLC are investment advisors. Samuel D. Isaly is a control person OrbiMed Advisors LLC and OrbiMed Capital LLC and shares dispositive and voting power over the shares held by OrbiMed Advisors LLC and OrbiMed Capital LLC. OrbiMed Advisors LLC and OrbiMed Capital LLC hold shares on behalf of Caduceus Capital Master Fund Limited (560,000 shares), Caduceus Capital II, L.P. (268,000 shares), UBS Eucalyptus Fund, LLC (438,000 shares), PaineWebber Eucalyptus Fund, LLC (53,000 shares), HFR SHC Aggressive Fund (106,000 shares), Knightsbridge Post Venture IV L.P. (210,800 shares), Knightsbridge Integrated Holdings, V, LP (225,200 shares), Knightsbridge Netherlands II, LP (56,600 shares), Knightsbridge Integrated Holdings IV Post Venture, LP (88,200 shares), Knightsbridge Post Venture III, LP (40,200 shares), Knightsbridge Netherlands I LP (38,300 shares), Knightsbridge Netherlands III LP (58,500 shares), Knightsbridge Integrated Holdings II Limited (53,400 shares), Knightsbridge Venture Completion 2005 LP (26,100 shares), Knightsbridge Venture Capital VI, L.P. (73,400 shares), Knightsbridge Venture Capital IV LP (54,600 shares), Knightsbridge Venture Capital III LP (40,800 shares), and Finsbury Emerging Biotechnology plc (971,000 shares).

## Equity Compensation Plan Information

The following table provides information about shares of our common stock that may be issued upon the exercise of options and rights under all of the Company's existing equity compensation plans as of December 31, 2005.

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights(\$)</u>	<u>Number of Securities Available for Future Issuance Under Equity Compensation Plans</u>
Equity compensation plans approved by security holders .....	3,983,686 <sup>(1)(2)</sup>	\$4.61	7,741,277 <sup>(3)</sup>
Equity compensation plans not approved by security holders .....	948,144 <sup>(4)</sup>	(4)	—
<b>Total</b> .....	<b>4,931,830</b>		<b>7,741,277</b>

(1) Reflects the following:

- (a) Outstanding options to purchase 1,222,833 shares of our common stock granted under our 2003 Stock Option Plan. We no longer grant stock options under our 2003 Stock Option Plan due to the adoption of our 2005 Stock Incentive Plan, and

- (b) Outstanding options to purchase 2,760,853 shares of our common stock granted under our 1993 Stock Option Plan. We no longer grant stock options under our 1993 Stock Option Plan, which expired on April 15, 2003.
- (2) Under our 2000 Employee Stock Purchase Plan, participants are permitted to purchase our common stock during the stock offering period. Accordingly, the number of shares of common stock to be issued under our 2000 Employee Stock Purchase Plan is not determinable and is not included.
- (3) Reflects 7,364,297 shares of our common stock available for future issuance at December 31, 2005 under our 2005 Stock Incentive Plan and 376,980 shares of our common stock available for future issuance under our 2000 Employee Stock Purchase Plan.
- (4) Reflects outstanding options to purchase 948,144 shares of our common stock granted under our Senior Executive Stock Option Plan (the "Senior Plan") to Mr. Kessman in January 1999 at exercise prices ranging from \$5.25 to \$5.775 in connection with his employment agreement. The shares of common stock issuable upon exercise of the options granted to Mr. Kessman under the Senior Plan have not been registered. The following summarizes the principal terms of the Senior Plan, which was adopted by our Board of Directors on January 11, 1999. Options may be granted under the Senior Plan to our Chief Executive Officer and to a director or officers who are considered a Reporting Persons under Rule 16b-3. The Board has appointed its Compensation Committee to administer the plan. Subject to the limitations of the Senior Plan, the Compensation Committee has broad authority under the Senior Plan. The maximum number of shares of common stock that may be issued under the Senior Plan is 980,000, subject to customary antidilution and other adjustments provided for in the Senior Plan, and the maximum number of shares of common stock with respect to such options that may be granted to any individual in any calendar year is 980,000 shares. Shares of common stock available for issuance under the Senior Plan may be authorized and unissued or held by the Company in its treasury. All options expire not more than 10 years after the date of grant. The exercise price for each share of common stock covered by an option will be determined by the Committee at the time of grant. The Committee may establish vesting and other conditions or restrictions on the exercise of an option and/or upon the issuance of common stock in connection with the exercise of an option as it deems appropriate. No option will be exercisable during the first 6 months after the date of grant. If an optionee's employment or service terminates, the portion of an option not exercisable on the date of termination shall immediately terminate and the portion of an option that is exercisable on the date of termination shall remain exercisable for a period of time following the termination date, as follows: (i) if due to death or disability, for one year; (ii) if due to cause, immediately terminates; and (iii) for any other termination, for 3 months. The Senior Plan will terminate on September 9, 2013, unless sooner terminated by the Board. The Board may amend or terminate the Senior Plan at any time.

### ITEM 13. *Certain Relationships and Related Transactions*

We recorded research and development expense of \$200,000 during 2005 related to a gift to fund research through March 31, 2007 at the laboratory headed by one of our directors, Dr. Sartorelli, at Yale University. The balance of gifts of \$250,000 at December 31, 2005 will be paid in five equal quarterly installments through the first quarter of 2007.

### ITEM 14. *Principal Accountant Fees and Services*

The following table presents the aggregate fees for professional audit services and other services rendered by Ernst & Young LLP, our independent registered public accountants, in 2005 and 2004:

	Years ended December 31,			
	2005		2004	
	Fees	% Approved by the Audit Committee	Fees	% Approved by the Audit Committee
Audit fees	\$180,993	100%	\$166,195	100%
Audit related fees	—	—	—	—
Tax fees	29,554	100%	28,000	100%
All other fees	1,515	100%	1,590	100%
Total	<u>\$212,062</u>		<u>\$195,785</u>	

*Audit Fees* consist of fees billed for the annual audit of our financial statements and other audit services including the provision of consents and the review of documents filed with the SEC. The fees for 2005 include \$60,000 of accrued audit fees for the 2005 year-end audit that were not billed until 2006. The fees for 2004 include \$73,000 of accrued audit fees for the third-quarter 2004 review and the 2004 year-end audit that were not billed until 2005.

*Audit Related Fees* consist of fees billed for transaction consultations.

*Tax Fees* consist of fees billed for tax compliance services.

*All Other Fees* consist of a subscription fee for an online accounting research database.

## **Audit Committee Pre-approval Policies and Procedures**

The Audit Committee of our Board of Directors is responsible, among other matters, for the oversight of the external auditor. The Audit Committee has adopted a policy regarding pre-approval of audit and permissible non-audit services provided by our independent registered public accountants (the “Policy”).

Under the Policy, proposed services either (i) may be pre-approved by the Audit Committee without consideration of specific case-by-case services as “general pre-approval”; or (ii) require the specific pre-approval of the Audit Committee as “specific pre-approval”. The Audit Committee may delegate either type of pre-approval authority to one or more of its members. The Policy sets out the audit, audit-related, tax and other services that have received the general pre-approval of the Audit Committee, including those described in the footnotes to the table, above; these services are subject to annual review by the Audit Committee. All other audit, audit-related, tax and other services must receive a specific pre-approval from the Audit Committee.

The Audit Committee establishes budgeted fee levels annually for each of the four categories of audit and non-audit services that are pre-approved under the Policy, namely, audit, audit-related, tax and other services. Requests or applications to provide services that require specific approval by the Audit Committee are submitted to the Audit Committee by both the external auditor and the chief financial officer. At each regular meeting of the Audit Committee, the external auditor provides a report in order for the Audit Committee to review the services that the external auditor is providing, as well as the status and cost of those services.

## PART IV

### ITEM 15. Exhibits, Financial Statement Schedules

#### (a) 1. Financial Statements

The following is a list of the Financial Statements included in Item 8 of Part II of this Report:

	<u>Page</u>
Reports of Independent Registered Public Accounting Firm .....	34
Consolidated Balance Sheets as of December 31, 2005 and 2004 .....	36
Consolidated Statements of Operations for the Years Ended December 31, 2005, 2004 and 2003 and for the Period from May 1, 1994 (Inception) through December 31, 2005. ....	37
Consolidated Statement of Changes in Shareholders' Equity for the Period from May 1, 1994 (Inception) Through December 31, 2005 .....	38
Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2004 and 2003 and for the Period from May 1, 1994 (Inception) through December 31, 2005 .....	44
Notes to Consolidated Financial Statements .....	45

#### 2. Financial Statement Schedules

Schedules not included herein are omitted because they are inapplicable or not required or because the required information is given in the financial statements and notes thereto.

#### 3. Exhibits

The exhibits required by this item and included in this report or incorporated herein by reference are as follows:

<u>Exhibit No.</u>	<u>Description</u>
2.1 —	Agreement and Plan of Merger among MelaRx Pharmaceuticals, Inc., OncoRx Research Corp. and OncoRx, Inc. dated as of April 19, 1995 <sup>(1)</sup>
2.2 —	Certificate of Merger, dated April 20, 1995 <sup>(1)</sup>
3.1 —	Restated Certificate of Incorporation, as amended <sup>(2)</sup>
3.2 —	By-laws, as amended <sup>(2)</sup>
3.3 —	Certificate of Amendment to the Certificate of Incorporation of Vion Pharmaceuticals, Inc. dated as of July 26, 2001 <sup>(13)</sup>
3.4 —	Certificate of Amendment to the Certificate of Incorporation of Vion Pharmaceuticals, Inc. dated as of June 10, 2004 <sup>(22)</sup>
4.1 —	Rights Agreement dated as of October 26, 1998 between Vion Pharmaceuticals, Inc. and American Stock Transfer & Trust Company (includes form of Right Certificate attached as Exhibit A and a Summary of Rights to Purchase Common Shares attached as Exhibit B thereto) <sup>(3)</sup>
4.2 —	Revised form of Warrant Agreement by and between Vion Pharmaceuticals, Inc. and Brean Murray & Co., Inc. <sup>(4)</sup>
4.3 —	Form of Underwriter's Warrant (included as Exhibit A to Exhibit 4.2 above) <sup>(4)</sup>
4.4 —	Amendment No. 1 to Rights Agreement between Vion Pharmaceuticals, Inc. and American Stock Transfer & Trust Company dated as of August 16, 2004 <sup>(23)</sup>

Exhibit No.	Description
10.1	— License Agreement between Yale University and OncoRx, Inc. dated as of August 31, 1994 <sup>(1,16)</sup>
10.2	— Letter Agreement between Yale University and OncoRx, Inc. dated August 19, 1994 <sup>(1)</sup>
10.3	— Extension Agreement between Yale University and MelaRx Pharmaceuticals, Inc., dated as of July 1, 1992 <sup>(1)</sup>
10.4	— License Agreement between Yale University and OncoRx Corporation dated as of November 15, 1995 <sup>(15)</sup>
10.5	— Letter Agreement between Yale University and MelaRx Pharmaceuticals, Inc., dated as of February 2, 1995 <sup>(1)</sup>
10.6	— Reserved
10.7	— Reserved
10.8	— License Agreement between Yale University and OncoRx, Inc. dated as of December 15, 1995 <sup>(15)</sup>
10.9	— Reserved
10.10	— Reserved
10.11	— Reserved
10.12	— Consulting and Finder's Agreement between MelaRx Pharmaceuticals, Inc. and Jacob A. Melnick, dated June 4, 1992, as amended by Agreement dated February 17, 1995 <sup>(1)</sup>
10.13	— Clinical Trials Agreement between Vion Pharmaceuticals, Inc. and the Division of Cancer Treatment and Diagnosis, NCI, dated January 9, 2003 <sup>(15)</sup>
10.14	— Letter Agreement between Yale University and OncoRx, Inc. (formerly MelaRx Pharmaceuticals, Inc.), dated July 5, 1995 <sup>(1)</sup>
10.15	— Reserved
10.16	— Reserved
10.17	— Reserved
10.18	— Reserved
10.19	— Amendment No. 1 to License Agreement between Yale University and Vion Pharmaceuticals, Inc. (f/k/a OncoRx, Inc.) dated as of June 12, 1997 <sup>(9)</sup>
10.20	— Amendment No. 2 to License Agreement between Yale University and Vion Pharmaceuticals, Inc. (f/k/a OncoRx, Inc.) dated as of June 12, 1997 <sup>(9)</sup>
10.21	— Collaborative Development and Distribution Agreement between Boehringer Ingelheim International GmbH and Vion Pharmaceuticals, Inc. dated November 24, 1997 <sup>(6,32)</sup>
10.22	— Reserved
10.23	— Amendment No. 5 to a License Agreement between Yale University and Vion Pharmaceuticals, Inc. (f/k/a OncoRx, Inc.) dated as of March 3, 2003 <sup>(16,32)</sup>
10.24	— Amendment No. 3 to a License Agreement between Yale University and Vion Pharmaceuticals, Inc. (f/k/a OncoRx, Inc.) dated as of September 25, 1998 <sup>(10)</sup>

Exhibit No.	Description
10.25	— Form of Severance Agreement between the Company and Ann Lee Cahill, Terrence W. Doyle, Meghan Fitzgerald, Howard B. Johnson, Ivan King, Karen Schmedlin and Mario Sznol <sup>(11)</sup>
10.26	— Reserved
10.27	— Senior Executive Stock Option Plan <sup>(11)</sup>
10.28	— Reserved
10.29	— Development and License Agreement dated December 1, 1999 between the Company and Boehringer Ingelheim International GmbH <sup>(12,32)</sup>
10.30	— Reserved
10.31	— Amendment No. 4 to a License Agreement between Yale University and Vion Pharmaceuticals, Inc. (f/k/a OncoRx, Inc.) dated as of January 31, 2000 <sup>(13, 32)</sup>
10.32	— Lease between Science Park Development Corporation and Vion Pharmaceuticals, Inc. dated November 1, 2001 <sup>(14)</sup>
10.33	— Vion Pharmaceuticals, Inc. Amended and Restated 1993 Stock Option Plan, as Amended <sup>(14)</sup>
10.34	— Securities Purchase Agreement as of June 19, 2003 <sup>(17)</sup>
10.35	— Registration Rights Agreement as of June 19, 2003 <sup>(17)</sup>
10.36	— Form of Warrant <sup>(17)</sup>
10.37	— Securities Purchase Agreement as of September 8, 2003 <sup>(18)</sup>
10.38	— Registration Rights Agreement as of September 8, 2003 <sup>(18)</sup>
10.39	— Form of Warrant <sup>(18)</sup>
10.40	— Research Services Agreement between Vion Pharmaceuticals, Inc. and Eli Lilly and Company as of September 8, 2003 <sup>(19,32)</sup>
10.41	— License Agreement between Vion Pharmaceuticals, Inc. and Beijing Pason Pharmaceuticals, Inc. dated September 12, 2003 <sup>(19,32)</sup>
10.42	— Employment Agreement between Vion Pharmaceuticals, Inc. and Alan Kessman dated as of November 3, 2003 <sup>(19)</sup>
10.43	— Research Collaboration and Option Agreement with a group of inventors from the Institute of Pharmacy and the Institute of Medical Chemistry and Biochemistry at the University of Innsbruck, and Austria Wirtschaftsservice Gesellschaft m.b.H. and Vion Pharmaceuticals, Inc. dated November 24, 2003 <sup>(31,32)</sup>
10.44	— Securities Purchase Agreement as of February 9, 2004 <sup>(20)</sup>
10.45	— Registration Rights Agreement as of February 9, 2004 <sup>(20)</sup>
10.46	— Form of Warrant <sup>(20)</sup>
10.47	— License Agreement between Johnson & Johnson Consumer Companies, Inc. and Vion Pharmaceuticals, Inc. dated March 1, 2004 <sup>(21,33)</sup>
10.48	— Vion Pharmaceuticals, Inc. 2003 Stock Option Plan, as amended (through June 2004) <sup>(22)</sup>
10.49	— Form of Stock Option Agreement for Executive Officers <sup>(22)</sup>

Exhibit No.	Description
10.50	— Amendment to Option Agreements with Mario Sznol <sup>(22)</sup>
10.51	— Consulting Agreement between Vion Pharmaceuticals, Inc. and Mario Sznol dated October 15, 2004 <sup>(24)</sup>
10.52	— Placement Agency Agreement by and among Vion Pharmaceuticals, Inc., CIBC World Markets Corp. and Leerink Swann & Company, dated January 25, 2005 <sup>(25)</sup>
10.53	— Escrow Agreement by and between Vion Pharmaceuticals, Inc., JPMorgan Chase Bank, N.A. and CIBC World Markets Corp., dated January 25, 2005 <sup>(25)</sup>
10.54	— Agreement by and between Howard B. Johnson and Vion Pharmaceuticals, Inc., dated September 13, 2005 <sup>(26)</sup>
10.55	— Amendment No. 1, dated September 13, 2005, to the Employment Agreement with Alan Kessman dated November 3, 2003 <sup>(26)</sup>
10.56	— Amended Exclusive License Agreement, by and among Dr. Johnny Easmon, Prof. Dr. Gottfried Heinisch, Dr. Gerhard Pustinger, Prof. Dr. Heinz-Herbert Fiebig, Prof. Dr. Johann-Hofmann, Austria Wirtschaftsservice Gesellschaft M.B.H. and the Company, dated as of June 30, 2005 <sup>(27, 32)</sup>
10.57	— Vion Pharmaceuticals, Inc. 2005 Stock Incentive Plan <sup>(28)</sup>
10.58	— Form of Restricted Stock Agreement for Non- Employee Directors Under the 2005 Stock Incentive Plan <sup>(28)</sup>
10.59	— Form of Restricted Stock Agreement under 2005 Stock Incentive Plan for Executive Officers <sup>(29)</sup>
10.60	— Amendment No. 2 of Employment Agreement of Alan Kessman, dated as of January 3, 2006 <sup>(29)</sup>
10.61	— First Amendment to Lease, dated January 25, 2006, by and between Vion Pharmaceuticals, Inc. and Science Park Development Corporation <sup>(30)</sup>
21.1	— Subsidiaries of the Registrant
23.1	— Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	— Power of Attorney (included on signature page)
31.1	— Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	— Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	— Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	— Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

<sup>(1)</sup> Incorporated by reference to the Company's Registration Statement on Form SB-2 (File No. 33-93468), effective August 14, 1995.

<sup>(2)</sup> Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarterly period ended June 30, 1998.

- (3) Incorporated by reference to the Company's Current Report on Form 8-K filed on October 26, 1998.
- (4) Incorporated by reference to the Company's Registration Statement on Form S-1 (File No. 333-83837), effective October 26, 1999.
- (5) Reserved
- (6) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997.
- (7) Reserved
- (8) Reserved
- (9) Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 1997.
- (10) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1998.
- (11) Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 1999.
- (12) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999.
- (13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
- (14) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
- (15) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.
- (16) Incorporated by reference to the Company's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002.
- (17) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 20, 2003.
- (18) Incorporated by reference to the Company's Current Report on Form 8-K filed on September 10, 2003.
- (19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.
- (20) Incorporated by reference to the Company's Current Report on Form 8-K filed on February 11, 2004.
- (21) Incorporated by reference to the Company's Current Report on Form 8-K/A filed on March 18, 2004.
- (22) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
- (23) Incorporated by reference to the Company's Current Report on Form 8-K filed on August 16, 2004.
- (24) Incorporated by reference to the Company's Current Report on Form 8-K/A filed on November 9, 2004.
- (25) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 26, 2005.



- (26) Incorporated by reference to the Company's Current Report on Form 8-K filed on September 13, 2005.
- (27) Incorporated by reference to the Company's Current Report on Form 8-K filed on September 28, 2005.
- (28) Incorporated by reference to the Company's Current Report on Form 8-K filed on October 31, 2005.
- (29) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 9, 2006.
- (30) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 31, 2006.
- (31) Incorporated by reference to the Company's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2003.
- (32) Certain portions of this exhibit have been omitted pursuant to an order granting confidential treatment by the Securities and Exchange Commission.
- (33) Certain portions of this exhibit have been omitted pursuant to a request for an order granting confidential treatment by the Securities and Exchange Commission. The omitted non-public information has been filed with the Securities and Exchange Commission.

## SIGNATURES

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

### VION PHARMACEUTICALS, INC

Date: March 16, 2006

By: /s/ Alan Kessman

Alan Kessman  
Chief Executive Officer

## POWER OF ATTORNEY

KNOWN ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alan Kessman and Howard B. Johnson, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting to said attorneys-in-fact and agents, and each of them, full power and authority to do and perform such and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ William R. Miller</u> William R. Miller	Chairman of the Board	March 16, 2006
<u>/s/ Alan Kessman</u> Alan Kessman	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2006
<u>/s/ Howard B. Johnson</u> Howard B. Johnson	President and Chief Financial Officer (Principal Financial Officer)	March 16, 2006
<u>/s/ Karen Schmedlin</u> Karen Schmedlin	VP Finance and Chief Accounting Officer (Principal Accounting Officer)	March 16, 2006
<u>/s/ George Bickerstaff</u> George Bickerstaff	Director	March 16, 2006
<u>/s/ Stephen K. Carter, M.D.</u> Stephen K. Carter, M.D.	Director	March 16, 2006
<u>/s/ Alan C. Sartorelli, Ph.D.</u> Alan C. Sartorelli, Ph.D.	Director	March 16, 2006
<u>/s/ Mario Sznol, M.D.</u> Mario Sznol M.D.	Director	March 16, 2006
<u>/s/ Gary K. Willis.</u> Gary K. Willis.	Director	March 16, 2006

**EXHIBIT 21.1            SUBSIDIARIES OF THE REGISTRANT**

**Name of Subsidiary**

**Incorporated In**

VION (UK) LIMITED

UNITED KINGDOM

### **Consent of Independent Registered Public Accounting Firm**

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

- (1) Registration Statement (Form S-8 No. 333-129746, No. 333-98738, No. 333-39407, No. 333-38730 and No. 333-67050) pertaining to the Vion Pharmaceuticals, Inc. 2005 Stock Incentive Plan, the Vion Pharmaceuticals, Inc. 2003 Stock Option Plan, the Vion Pharmaceuticals, Inc. Amended and Restated 1993 Stock Option Plan, as amended and in the Registration Statement (Form S-8 No. 333-53772) pertaining to the Vion Pharmaceuticals, Inc. 2000 Employee Stock Purchase Plan, and
- (2) Registration Statement (Form S-3 No. 333-37941, No. 333-61477, No. 333-79939, No. 333-95671 and No. 333-58206) of Vion Pharmaceuticals, Inc. and in the related Prospectus;

of our reports dated March 8, 2006, with respect to the consolidated financial statements of Vion Pharmaceuticals, Inc., Vion Pharmaceuticals, Inc.'s management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Vion Pharmaceuticals, Inc., included in this Form 10-K for the year ended December 31, 2005.

/s/ Ernst & Young LLP

Hartford, Connecticut  
March 13, 2006

## EXHIBIT 31.1

### CERTIFICATION

I, Alan Kessman, Chief Executive Officer of Vion Pharmaceuticals, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Vion Pharmaceuticals, Inc. (the "Registrant");
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this annual report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - d) Disclosed in this annual report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting;
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 16, 2006

/s/ Alan Kessman

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Alan Kessman  
Chief Executive Officer

## EXHIBIT 31.2

### CERTIFICATION

I, Howard B. Johnson, Chief Financial Officer of Vion Pharmaceuticals, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Vion Pharmaceuticals, Inc. (the "Registrant");
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - d) Disclosed in this annual report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting;
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 16, 2006

/s/ Howard B. Johnson

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Howard B. Johnson  
Chief Financial Officer

**EXHIBIT 32.1**

**WRITTEN STATEMENT OF THE CHIEF EXECUTIVE OFFICER**

Pursuant to 18 U.S.C. Section 1350, I, the undersigned Chief Executive Officer of Vion Pharmaceuticals, Inc. (the "Company"), hereby certify that the Annual Report on Form 10-K of the Company for the year ended December 31, 2005 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2006

/s/ Alan Kessman

Alan Kessman  
Chief Executive Officer

**EXHIBIT 32.2**

**WRITTEN STATEMENT OF THE CHIEF FINANCIAL OFFICER**

Pursuant to 18 U.S.C. Section 1350, I, the undersigned Chief Financial Officer of Vion Pharmaceuticals, Inc. (the "Company"), hereby certify that the Annual Report on Form 10-K of the Company for the year ended December 31, 2005 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2006

/s/ Howard B. Johnson

Howard B. Johnson  
Chief Financial Officer



# DIRECTORS AND OFFICERS

## BOARD OF DIRECTORS

### **William R. Miller**

Chairman of the Board; former Vice Chairman of the Board of Directors of Bristol-Myers Squibb Company

### **George Bickerstaff**

Managing Director of CRT Capital Group LLC

### **Stephen K. Carter, M.D.**

Former Senior Vice President, Clinical and Regulatory Affairs of SUGEN, Inc.

### **Alan Kessman**

Chief Executive Officer

### **Alan C. Sartorelli, Ph.D.**

Founder and Chairman, Scientific Advisory Board; Alfred Gilman Professor of Pharmacology, Yale University School of Medicine

### **Mario Sznol, M.D.**

Associate Professor of Medicine, Yale University School of Medicine

### **Gary Willis**

Former Chairman, President and Chief Executive Officer of Zygo Corporation

## OFFICERS

### **Alan Kessman**

Chief Executive Officer

### **Howard B. Johnson**

President and Chief Financial Officer

### **Ann Cahill**

Vice President, Clinical Development

### **Meghan Fitzgerald**

Vice President and Chief Business Officer

### **Ivan King, Ph.D.**

Vice President, Research and Development

### **Karen Schmedlin**

Vice President of Finance, Chief Accounting Officer and Secretary

# SHAREHOLDER INFORMATION

## CORPORATE WEBSITE

For further information, the Company's website provides current and historical information on Vion Pharmaceuticals, Inc., its product development programs, its clinical trials, investor relations and career opportunities. This site is located at: [www.vionpharm.com](http://www.vionpharm.com).

## INVESTOR RELATIONS

Copies of the Company's 2005 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K to the Securities and Exchange Commission are available online at [www.vionpharm.com](http://www.vionpharm.com) or to shareholders without charge upon written request. General stockholder inquiries, including requests for the Company's Annual Report on Form 10-K, should be directed to the Company's investor relations department at the address on the back cover.

## TRANSFER AGENT AND REGISTRAR

Questions regarding stock holdings, certificate transfers/replacements and address changes should be directed to: American Stock Transfer & Trust Company  
59 Maiden Lane  
New York, New York 10038  
(800) 937-5449

## CORPORATE COUNSEL

Fulbright and Jaworski L.L.P.  
New York, New York

## INDEPENDENT AUDITORS

Ernst & Young LLP  
Hartford, Connecticut

## STOCK LISTING

The Nasdaq Capital Market<sup>SM</sup>  
Symbol: VION

## CORPORATE PROFILE

Vion Pharmaceuticals, Inc. is developing cancer therapeutics. Vion has two agents in clinical trials: Cloretazine® (VNP40101M), a unique alkylating agent, and Triapine®, a potent inhibitor of a key step in DNA synthesis. Cloretazine® (VNP40101M) is being evaluated in a Phase III trial in combination with cytarabine in relapsed acute myelogenous leukemia. Trials of Cloretazine® (VNP40101M) as a single agent in previously untreated elderly acute myelogenous leukemia and high-risk myelodysplastic syndrome, adult and pediatric brain tumors, small-cell lung cancer and chronic lymphocytic leukemia, and in combination with temozolomide in hematologic malignancies, are also underway. Triapine® is being evaluated in trials sponsored by the National Cancer Institute. In preclinical studies, Vion is also evaluating VNP40541, a hypoxia-selective compound, and hydrazone compounds. For additional information on Vion and its product development programs, visit the Company's Internet web site at [www.vionpharm.com](http://www.vionpharm.com).



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