

VIROPHARMA INC
Form 10-K
March 19, 2004
Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

Annual report pursuant to section 13 or 15(d) of

the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2003

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: 0-21699

VIROPHARMA INCORPORATED

(Exact name of registrant as specified in our charter)

Delaware
(State or other jurisdiction of

23-2789550
(I.R.S. Employer Identification No.)

incorporation or organization)

405 Eagleview Boulevard,

19341

Exton, Pennsylvania
(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: 610-458-7300

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

Title of each class:

Name of each exchange on which registered:

None

None

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

Common Stock, par value \$.002

Edgar Filing: VIROPHARMA INC - Form 10-K

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 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.

The approximate aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$56,515,912 as of June 30, 2003, based upon the closing sale price per share of the Common Stock as quoted on the Nasdaq National Market on that date.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

The number of shares of the registrant's Common Stock outstanding as of March 1, 2004 was 26,491,413.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

VIROPHARMA INCORPORATED

FORM 10-K ANNUAL REPORT

For Fiscal Year Ended December 31, 2003

TABLE OF CONTENTS

	Page
<u>PART I</u>	
Item 1. <u>Business</u>	1
Item 2. <u>Properties</u>	27
Item 3. <u>Legal Proceedings</u>	27
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	28
<u>PART II</u>	
Item 5. <u>Market for the Registrant's Common Equity and Related Stockholder Matters</u>	29
Item 6. <u>Selected Financial Data</u>	30
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	31
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	41
Item 8. <u>Financial Statements and Supplementary Data</u>	41
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	41
Item 9A. <u>Control and Procedures</u>	41
<u>PART III</u>	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	42
Item 11. <u>Executive Compensation</u>	47
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	51
Item 13. <u>Certain Relationships and Related Transactions</u>	52
Item 14. <u>Principal Accountant Fees and Services</u>	53
<u>PART IV</u>	
Item 15. <u>Exhibits, Financial Statement Schedules and Reports on Form 8-K</u>	54
<u>Index to Financial Statements and Schedules</u>	59

ViroPharma, ViroPharma plus the design and Picovir are trademarks and service marks of ViroPharma or its licensors. We have obtained trademark registration in the United States for the marks in connection with certain products and services. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of others.

Table of Contents

PART I

Business

We are a pharmaceutical company dedicated to the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings. We are focusing our current product development activities on viral diseases, including cytomegalovirus (CMV) infection and hepatitis C (HCV). The status of our current product development activities is described under the heading Product Pipeline.

We intend to build franchises within narrowly focused prescribing groups. Initially we will focus on the transplant, hepatology and gastroenterology areas, using our clinical programs in CMV infections related to hematopoietic stem cell (bone marrow) transplantation, and HCV, as foundations for that effort. We intend to pursue aggressively products in late stage clinical development, and marketed products that are under-promoted or not currently promoted, to expand our current portfolio. Such products may be intended to treat, or are currently used to treat, the patient populations in which we hope our CMV and HCV product candidates will be used, or may be products to treat other diseases for which patients are treated by physician specialists or in hospital settings.

We were incorporated in Delaware in September 1994 and commenced operations in December 1994. Our executive offices are located at 405 Eagleview Boulevard, Exton, PA 19341, our telephone number is 610-458-7300 and our website is at www.viropharma.com. Information contained on our website is not incorporated into this annual report on Form 10-K.

Overview of Recent Developments

In January 2004, we announced that we had made the strategic decision to focus on later stage opportunities, and restructured our operations to substantially discontinue our early stage activities, including discovery research and most internal preclinical development activities. We will complete certain discrete efforts related to our early stage programs in order to finalize the transition. Upon completion of these activities in mid-2004, we will have reduced our workforce by approximately 70% overall. As a result of this restructuring, we expect to have sufficient cash available at the beginning of 2004 to fund our current business operations and debt service requirements until at least the end of 2006. We believe that the reduction in expenses resulting from this restructuring should provide us with the flexibility to execute the planned development of our pipeline of antiviral programs, and consider new opportunities to expand our product portfolio.

The discontinuation of our early stage activities requires us to wind down our biodefense program in the coming months as part of the transition. We have ceased efforts to develop pleconaril for the treatment of serious or life-threatening diseases as part of our restructuring. We also agreed with Wyeth to cease screening compounds against HCV under our collaboration. The development portion of our HCV collaboration with Wyeth will continue, and is not effected by our restructuring.

We initiated phase 1 studies with maribavir, our most advanced product candidate, in January 2004, and we expect to initiate phase 2 studies in the second quarter of 2004. We intend to advance maribavir initially for the prevention of CMV infections related to hematopoietic stem cell (bone marrow) transplantation.

Edgar Filing: VIROPHARMA INC - Form 10-K

We have a co-development and co-promotion collaboration with Wyeth for hepatitis C, or HCV. Together with Wyeth, we initiated Phase I clinical trials of our lead product candidate for the treatment of hepatitis C in February 2004.

2003 Events

In November 2003, we entered into an option agreement with Schering Corporation to license our intranasal formulation of the antiviral compound pleconaril for the treatment of the common cold in the United States and Canada. Schering paid us an upfront option fee of \$3 million, and we are conducting a series of clinical studies to evaluate the antiviral activity, safety and other performance characteristics of the new intranasal pleconaril

Table of Contents

formulation. After assessing data on the product's performance from these characterization studies, Schering has the option to enter into a full license agreement with us under which Schering would assume responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada.

In August 2003, we entered into a license agreement with GlaxoSmithKline (GSK) under which we acquired worldwide rights (excluding Japan) from GSK to an antiviral compound, maribavir (VP41263), for the prevention and treatment of CMV infections related to transplant (including solid organ and hematopoietic stem cell transplantation), congenital transmission, and in patients with HIV infection. Maribavir is a benzimidazole compound that was in development by GSK for the treatment of CMV retinitis in HIV+ patients.

In July 2003, we announced that we had discovered a compound that demonstrated potent antiviral activity against the smallpox virus. We also announced in July 2003 that we discontinued further development of our previous HCV product candidate, HCV371.

In March 2003, we announced that we submitted an application for Orphan Drug designation for oral Picovir® (pleconaril) for the treatment of life-threatening chronic enteroviral meningoencephalitis in patients with agammaglobulinemia or hypogammaglobulinemia caused by primary immune deficiency (CEMA).

In January 2003, we announced that we decided to discontinue the development of our respiratory syncytial virus, or RSV, compounds. We are seeking to outlicense the RSV program, as well as certain other assets related to our early stage programs that we discontinued as part of our restructuring in January 2004.

Product Pipeline

We are focusing our current product development activities on viral diseases, including cytomegalovirus, hepatitis C and the common cold. The following chart describes our product candidates:

Product Candidate	Disease Indication	Development Status	ViroPharma
			Commercialization Rights
Maribavir	CMV in transplant patients	Phase 1 in allogenic stem cell transplant patients	Worldwide, other than Japan
HCV-086	Hepatitis C	Phase 1	Co-promotion rights in the United States and Canada with Wyeth
Follow-On to HCV-086	Hepatitis C	Preclinical	Co-promotion rights in the United States and Canada with Wyeth
Pleconaril-Intranasal	Common Cold	Proof-of-concept studies	United States and Canada, subject to an option granted to Schering Corporation

Cytomegalovirus

We initiated phase 1 clinical studies with maribavir in January 2004. We expect to advance maribavir into phase 2 clinical trials in patients who have undergone allogeneic stem cell (e.g. bone marrow) transplantation in the second quarter of 2004.

Table of Contents

Human cytomegalovirus, or HCMV, is a member of the herpes virus group which includes the viruses that cause chicken pox, mononucleosis, herpes labialis (cold sores) and genitalis (genital herpes). Like other herpes viruses, HCMV has the ability to remain dormant in the body for long periods of time. Human CMV infection rates average between 50% and 85% of adults in the U.S. by 40 years of age. In most individuals with intact immune systems, CMV causes little to no apparent illness. However, in immunocompromised individuals, CMV can lead to serious disease or death. Before the availability of potent anti-HIV therapy, CMV associated retinitis was commonly seen in patients with HIV/AIDS. Currently, patients who are immunosuppressed following hematopoietic stem cell (e.g., bone marrow) or solid organ transplantation remain at high risk of CMV infection. In these patients, CMV can lead to severe conditions such as pneumonitis or hepatitis, or to complications such as acute or chronic rejection of a transplanted organ.

Hepatitis C

We initiated Phase 1 clinical trials of our lead product candidate for the treatment of hepatitis C in February 2004 with Wyeth, our HCV collaborator. Our Wyeth collaboration is a co-development and co-promotion effort.

Hepatitis is an inflammation of the liver that is often caused by viruses, such as hepatitis A, B, or C. Hepatitis C virus is recognized as a major cause of chronic hepatitis worldwide. According to the World Health Organization and U.S. Centers for Disease Control and Prevention (CDC), about 4 million Americans and 170 million people worldwide are infected with HCV. Approximately 3 to 4 million people are newly infected with HCV each year, with the highest prevalence of HCV infection occurring among males and those between the ages of 30 to 49.

The acute stage, which occurs 2 weeks to 6 months after infection, usually is so mild that most people do not know they have been infected. About 75% of people that are newly infected with HCV progress to develop chronic infection. Liver damage (cirrhosis) develops in about 10% to 20% of persons with chronic infection, and liver cancer develops in 1% to 3% of persons with chronic infection over a period of 20 to 30 years. Liver damage caused by HCV infection is the most common reason for liver transplantation in the United States.

There currently are no approved antiviral agents directed specifically against HCV and no vaccine for prevention of HCV infection, although some companies, in addition to ViroPharma and Wyeth, are working on developing such products. Approximately 50% of patients who receive full courses of currently available therapies achieve a sustained virologic response. There are several interferon products available worldwide, but there are substantial limitations to the use of these products when given as monotherapy or in conjunction with ribavirin in the treatment of chronic HCV infection. These include poor treatment response in patients infected with particular genotypes of the virus and significant side effects that can lead to discontinuation of therapy in approximately 20% of patients. We believe that this is an underserved market and are working with Wyeth toward advancing specific antiviral product candidates for treatment of hepatitis C.

Picornaviruses

Pleconaril is a proprietary, small molecule inhibitor of picornaviruses. In preclinical studies, pleconaril has demonstrated the ability to inhibit picornavirus replication *in vitro* by a novel, virus-specific mode of action. Pleconaril works by inhibiting the function of the viral protein coat, also known as the viral capsid, which is essential for virus infectivity and transmission. Preclinical studies have shown that pleconaril integrates within the picornavirus capsid at a specific site that is common to a majority of picornaviruses and disrupts several stages of the virus infection cycle. In July 2002, the United States Food and Drug Administration, or FDA, issued a not-approvable letter in response to our new drug application for an oral formulation of pleconaril for the treatment of the common cold in adults.

Edgar Filing: VIROPHARMA INC - Form 10-K

In November 2003, we entered into an option agreement with Schering Corporation regarding our intranasal formulation of pleconaril for the treatment of the common cold in the United States and Canada. Under terms of

Table of Contents

the agreement, Schering paid us an up-front option fee of \$3 million. ViroPharma is conducting a series of clinical studies designed to evaluate the antiviral activity, safety and other performance characteristics of the new intranasal pleconaril formulation. We expect results from these studies to be available in mid-2004.

After assessing data on the product's performance from these characterization studies, Schering has the option to enter into a full license agreement with us under which Schering would assume responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. If Schering chooses to exercise its option, we expect to receive an initial license fee of \$10 million and Schering will purchase our existing inventory of bulk drug substance for an additional pre-determined fee. We would also be eligible to receive additional milestone payments upon achievement of certain targeted events as well as royalties on Schering's sales of intranasal pleconaril in the United States and Canada.

Business Development

We intend to pursue aggressively in-licensing or other means of acquiring products in a late stage of clinical development, and marketed products that are under-promoted or not currently promoted, in order to expand our current portfolio. Such products may be intended to treat, or are currently used to treat, the patient populations in which we hope our CMV and HCV product candidates will be used, or may be products to treat other diseases for which patients are treated by physician specialists or in hospital settings.

Competition for products in late stage clinical development, or that are currently on the market but are under-promoted or not currently promoted, is intense and may require significant resources. There is no assurance that we will be successful in acquiring such products, or that such products can be acquired on terms acceptable to us. Additionally, if we are successful in acquiring a marketed product, we will have to build marketing and sales forces. There is no assurance that we would be successful in developing a sales and marketing force, that we would be able to penetrate the markets for any such products or that we could achieve market acceptance of our products.

Strategic Relationships

GlaxoSmithKline

In August 2003 we entered into a license agreement with GlaxoSmithKline (GSK) under which we acquired worldwide rights (excluding Japan) to an antiviral compound, maribavir (VP41263), for the treatment of human cytomegalovirus (HCMV) disease. Maribavir is a benzimidazole compound that was in development by GSK for the treatment of CMV retinitis in HIV+ patients. We initiated phase 1 clinical studies with maribavir in January 2004. We expect to advance maribavir into phase 2 clinical trials in patients that have undergone allogeneic stem cell (e.g., bone marrow) transplantation in the second quarter of 2004.

Under the terms of the agreement, we have exclusive worldwide rights (excluding Japan) to develop and commercialize maribavir for the prevention and treatment of cytomegalovirus infections related to transplant (including solid organ and hematopoietic stem cell transplantation), congenital transmission, and in patients with HIV infection. The patents covering maribavir expire in 2015. We paid GSK a \$3.5 million up-front licensing fee and will pay additional milestones based upon defined clinical development and regulatory events. We also will pay royalties to GSK and its licensor on product sales in the United States and rest of world (excluding Japan). We will be dependent on GSK to prosecute and maintain the patents related to maribavir, and to file any applications for patent term extension. We also may be dependent on

Edgar Filing: VIROPHARMA INC - Form 10-K

GSK to protect such patent rights. We have the right to sublicense our rights under the agreement, which under certain circumstances requires GSK's consent. Our agreement with GSK terminates when we are no longer obligated to pay royalties to GSK on sales of products developed under the agreement.

Wyeth

In December 1999, we entered into a collaboration and license agreement with Wyeth (formerly American Home Products Corporation) to jointly develop products for use in treating hepatitis C due to the hepatitis C virus

Table of Contents

in humans. Under the agreement, we licensed to Wyeth worldwide rights under certain patents and know-how owned by us or created under the agreement. We have the right to co-promote these products in the United States and Canada and Wyeth will promote the products elsewhere in the world. Wyeth has the right to manufacture any commercial products developed under the agreement.

In June 2003, we amended our collaboration agreement with Wyeth to, among other things, focus the parties' screening activity on one target, to allocate more of the collaboration's pre-development efforts to ViroPharma (subject to our cost sharing arrangement with Wyeth for this work), and to clarify certain of the reconciliation and reimbursement provisions of the collaboration agreement. In addition, under the amended agreement both companies are permitted to work outside the collaboration on screening against targets other than the target being addressed together under the collaboration. In connection with our restructuring in January 2004, we agreed with Wyeth to cease screening compounds against HCV under our collaboration. During the term of the agreement, the two parties will work exclusively with each other on any promising compounds against the collaboration's HCV target.

Wyeth paid us \$5.0 million on the effective date of the original agreement, and is obligated to make milestone payments to us, and purchase additional shares of our common stock at a premium to the market price, upon the achievement of certain development milestones. Through December 31, 2003, Wyeth has purchased an aggregate of 200,993 shares of our common stock for \$6,000,000 upon the achievement of two milestones. The remaining milestone events generally include successful completion of steps in the clinical development of an HCV product and the submission for, and receipt of, marketing approval for the product in the United States and abroad. These milestones, however, may never be attained. Wyeth will provide significant financial support for the development of HCV therapeutic compounds developed under the agreement.

Until the expiration or termination of the agreement, any profits from the sale of products developed under the agreement and sold in the United States and Canada will be shared equally between us and Wyeth, subject to adjustment under certain circumstances. For sales of these products outside the United States and Canada, Wyeth will make royalty payments to us. These royalty payments will be reduced upon the expiration of the last of our patents covering those products.

Our agreement with Wyeth terminates, country-by-country, in the United States and Canada, if the parties are no longer co-promoting any product developed under the agreement, and outside the United States and Canada, when Wyeth is no longer obligated to pay us royalties on sales of products developed under the agreement.

Schering Corporation

In November 2003, we entered into an agreement granting Schering Corporation the option to license our intranasal formulation of pleconaril for the treatment of the common cold in the United States and Canada.

Under terms of the agreement, Schering paid us an up-front option fee of \$3 million. We are conducting a series of clinical studies designed to evaluate the antiviral activity, safety and other performance characteristics of the new intranasal pleconaril formulation. We expect results from these studies to be available in mid-2004.

After assessing data from these characterization studies, Schering has the option to enter into a full license agreement with us under which Schering would assume responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. If Schering chooses to exercise its option, we expect to receive an initial license fee of \$10 million and Schering will purchase our existing

Edgar Filing: VIROPHARMA INC - Form 10-K

inventory of bulk drug substance for an additional pre-determined fee. We would also be eligible to receive additional milestone payments upon achievement of certain targeted events as well as royalties on Schering's sales of intranasal pleconaril in the licensed territory.

Table of Contents

Sanofi-Synthelabo

In our agreement with Sanofi-Synthelabo, originally entered into in December 1995 and amended and restated in February 2001, we received exclusive rights under patents owned by Sanofi-Synthelabo to develop and market all products relating to pleconaril and related compounds for use in picornavirus disease indications in the United States and Canada, as well as a right of first refusal for any other indications in the United States and Canada. We further amended our agreement with Sanofi in November 2003 in connection with our entry into the option agreement with Schering Corporation in respect of intranasal pleconaril. If Schering exercises its option to continue the development and commercialization of pleconaril, the November 2003 amendment, among other things, reduces the royalty rate payable to Sanofi-Synthelabo. Pleconaril is covered by one of the licensed United States patents, which expires in 2012, and one of the licensed Canadian patents, which expires in 2013. We will be dependent on Sanofi-Synthelabo to prosecute and maintain certain of these patents, and to file any applications for patent term extension. We also may be dependent on Sanofi-Synthelabo to protect such patent rights. We have the right to sublicense our rights under the agreement, which under certain circumstances requires Sanofi-Synthelabo's consent, such consent not to be unreasonably withheld.

Under our agreement with Sanofi-Synthelabo, until the expiration or termination of the agreement, we must make royalty payments on any sales of products in the United States and Canada developed under the agreement, which royalty payments will be reduced upon the expiration of the last patent on pleconaril or any related drug, except for reduced royalty payments on Schering's sales of the drug, which extends indefinitely. We are entitled to royalties from Sanofi-Synthelabo on sales of products by Sanofi-Synthelabo outside the United States and Canada. Sanofi-Synthelabo will make a milestone payment to us upon submission of pleconaril for regulatory approval in Japan.

Our patent licenses under the amended and restated agreement with Sanofi-Synthelabo terminate on the later of expiration of the last patent licensed to us under the agreement or ten years following our first sale of a product in the United States or Canada containing a compound licensed to us under the agreement, or earlier under certain circumstances. In the event that our rights to use Sanofi-Synthelabo's patents and trademarks terminate, under certain circumstances the agreement may restrict our ability to market pleconaril and compete with Sanofi-Synthelabo. In addition, Sanofi-Synthelabo has the right to terminate the agreement if we are subject to a change of control that would materially and adversely affect the development, manufacturing and marketing of the products under the agreement. The term automatically renews for successive five-year terms unless either party gives six months' prior written notice of termination. We also have the right to manufacture, or contract with third parties to manufacture, any drug product derived from the pleconaril drug substance.

Manufacturing

We currently do not have capabilities to manufacture commercial or clinical trial supplies of drugs, and do not intend to develop such capabilities for any product in the near future. Our commercialization plans are to rely on the infrastructure of third parties for the manufacture and distribution of our product candidates.

We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce drug substance and product in accordance with the Food and Drug Administration's (or the FDA) current Good Manufacturing Practices and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our drug candidates.

For the preparation of compounds for preclinical development and for the manufacture of limited quantities of drug substances for clinical development, we have used both in-house capabilities and the capabilities of our collaborators, and we contract with third-party manufacturers. In the future, we expect to rely solely on third-party manufacturers to manufacture drug substance and final drug products for both clinical

development and commercial sale.

Table of Contents

Marketing and Sales

Under our agreement with GlaxoSmithKline, we have the exclusive right to market and sell maribavir throughout the world (other than Japan). Under our agreement with Wyeth, we have the right to copromote in the United States and Canada hepatitis C products arising from our collaboration. Under our agreement with Sanofi-Synthelabo, we have the exclusive right to market and sell pleconaril for all picornavirus indications in the United States and Canada. If Schering Corporation exercises its option to further develop and commercialize pleconaril, Schering will be solely responsible for the marketing, promotion and sale of pleconaril following its approval.

We currently do not have a marketing or sales staff. The success and commercialization of our hepatitis C product candidates depend in part on the performance of Wyeth. If Schering exercises its option to undertake the exclusive right to develop and commercialize pleconaril in the United States and Canada, then the success and commercialization of pleconaril in those territories will depend entirely on the performance of Schering. If we are successful in acquiring FDA approval of maribavir or any other product candidate that we may acquire as a result of our business development efforts, we will need to build a commercial capability. There is no assurance that any of our collaboration partners will be successful in commercializing the products that we have licensed to them, that they will perform adequately their obligations as expected, or that any revenue would be derived from such arrangements. There is no assurance that we will be able to build our own commercial organization.

Patents and Proprietary Technology

We believe that patent protection and trade secret protection are important to our business and that our future will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the United States and abroad. We currently have received five issued United States patents and three non-United States patents describing compounds, compositions and methods for treating hepatitis C, one non-United States patents describing technology and methods for identifying inhibitors of HCV, two issued United States patents and three non-United States issued patents describing methods for treating pestivirus disease (a disease caused by viruses related to HCV) and related technology and four issued United States patents for compounds, compositions or methods for treating influenza. We have one issued United States patent and two non-United States patents describing compounds, compositions and methods for treating RSV diseases. We have two pending United States patent applications describing compounds, compositions and methods of treating and preventing picornavirus disease and related technology. We have nineteen United States patent applications describing compounds and methods for treating hepatitis C and related virus diseases, as well as compounds active against pestivirus diseases. We have three pending United States patent applications describing technology and methods for identifying inhibitors of HCV. We have one pending United States patent application describing compounds and methods of treating orthopoxvirus infection. We also have filed related patent applications under the Patent Cooperation Treaty (PCT) as well as other non-United States national and/or regional patent applications. These patent applications describe compounds and methods for treating hepatitis C and related virus diseases, pestivirus diseases, RSV diseases and rotavirus and technology, compositions and methods for identifying inhibitors of HCV and related technology. We intend to seek patent protection on these inventions in countries having significant market potential around the world on the basis of our PCT and related foreign filings.

As patent applications in the United States are maintained in secrecy until patents issue (unless earlier publication is required under applicable law or in connection with patents filed under the PCT) and as publication of discoveries in the scientific or patent literature often lags behind the actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions described in each of these pending patent applications or that we or our licensors were the first to file patent applications for such inventions. Furthermore, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions, and, therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that any patents will issue from any of these patent applications or, should any patents issue, that we will be provided with adequate protection against

Table of Contents

potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge these patents or circumvent our patent position in the United States or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

Pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of filing, irrespective of the period of time it may take for the patent to ultimately issue. This may shorten the period of patent protection afforded to our products as patent applications in the biopharmaceutical sector often take considerable time to issue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a period of time following Food and Drug Administration approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were used to support the marketing application for the drug. Pursuant to the FDA Modernization Act of 1997, this period of exclusivity can be extended if the applicant performs certain studies in pediatric patients. This marketing exclusivity prevents a third party from obtaining FDA approval for a similar or identical drug under an Abbreviated New Drug Application or a 505(b)(2) New Drug Application.

The Drug Price Competition and Patent Term Restoration Act of 1984 also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an Investigational New Drug Application and the filing of the corresponding New Drug Application plus the period of time between the filing of the New Drug Application and FDA approval, with a five year maximum patent extension. We cannot be sure that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of this law.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also oblige our employees, and to the extent practicable, our consultants, advisors and collaborators, to assign to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with those being developed by us. Therefore, our product candidates may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future. Furthermore, to the extent that we, or our consultants or research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in related or resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that we are prevented from the development, manufacture or sale of products requiring such licenses. In addition, we could incur substantial costs in defending ourselves in legal proceedings instituted before the United States Patent and Trademark Office or in a suit brought against us by a private party based on such patents or proprietary rights, or in a suit by us asserting our patent or proprietary rights against another party, even if the outcome is not adverse to us.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements on the clinical development, manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and

Table of Contents

the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval and promotion of our products. All of our products will require regulatory approval before commercialization. In particular, therapeutic products for human use are subject to rigorous preclinical and clinical testing and other requirements of the Federal Food, Drug, and Cosmetic Act, implemented by the FDA, as well as similar statutory and regulatory requirements of foreign countries. Obtaining these marketing approvals and subsequently complying with ongoing statutory and regulatory requirements is costly and time consuming. Any failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining, regulatory approval or in complying with other requirements, could adversely affect the commercialization of products then being developed by us and our ability to receive product or royalty revenues.

The steps required before a new drug product may be distributed commercially in the United States generally include:

- conducting appropriate preclinical laboratory evaluations of the product's chemistry, formulation and stability, and animal studies to assess the potential safety and efficacy of the product;
- submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an Investigational New Drug Application, or IND;
- making the Investigational New Drug Application effective after the resolution of any safety or regulatory concerns of FDA;
- obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the drug product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:
 - *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion;
 - *Phase 2:* The drug is studied in patients to identify possible adverse effects and safety risks, to determine dose tolerance and the optimal dosage, and to collect initial efficacy data;
 - *Phase 3:* The drug is studied in an expanded patient population at multiple clinical study sites to confirm efficacy and safety at the optimized dose by measuring a primary endpoint established at the outset of the study;
- submitting the results of preliminary research, preclinical studies, and clinical studies as well as chemistry, manufacturing and controls information on the drug to the FDA in a New Drug Application, or NDA; and
- obtaining FDA approval of the New Drug Application prior to any commercial sale or shipment of the drug product.

This process can take a number of years and typically requires substantial financial resources. The results of preclinical studies and initial clinical trials are not necessarily predictive of the results from large-scale clinical trials, and all clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including the difficulty in obtaining enough patients, clinical investigators, drug supply, or financial support, or because of unforeseen adverse effects. The FDA has issued regulations intended to accelerate the approval process for the development, evaluation and marketing of new therapeutic products intended to treat life-threatening or severely debilitating diseases, especially

Edgar Filing: VIROPHARMA INC - Form 10-K

where no alternative therapies exist. If applicable, these provisions may shorten the traditional product development process in the United States. Similarly, products that represent a substantial improvement over existing therapies may be eligible for priority review with a target review and approval time of six months. Nonetheless, even if a product is eligible for these programs, or for priority review, approval may be denied or delayed by FDA or additional trials may be required. As a condition of approval FDA

Table of Contents

also can require further testing of the product and monitoring of the effect of commercialized products, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Upon approval, a drug product may be marketed only in those dosage forms and for those indications approved in the New Drug Application, although information may be distributed about off-label indications in certain circumstances and physicians are permitted to prescribe drugs for such off-label uses.

In addition to obtaining FDA approval for each indication to be treated with each product, each domestic drug product manufacturing establishment must register with the FDA, list its drug products with the FDA, comply with current Good Manufacturing Practices and pass inspections by the FDA. Moreover, the submission of applications for approval may require additional time to complete manufacturing stability studies. Foreign establishments manufacturing drug products for distribution in the United States also must list their products with the FDA and comply with current Good Manufacturing Practices. They also are subject to periodic inspection by the FDA or by local authorities under agreement with the FDA.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to extensive continuing regulation by the FDA, including record-keeping requirements and a requirement to analyze and report adverse experiences with the drug. In addition to continued compliance with standard regulatory requirements, the FDA also may require post-marketing testing and surveillance to monitor the safety and efficacy of the marketed product. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product are discovered following approval.

The Federal Food, Drug, and Cosmetic Act also mandates that drug products be manufactured consistent with current Good Manufacturing Practices. In complying with the FDA's regulations on current Good Manufacturing Practices, manufacturers must continue to spend time, money and effort in production, recordkeeping, quality control, and auditing to ensure that the marketed product meets applicable specifications and other requirements. The FDA periodically inspects drug product manufacturing facilities to ensure compliance with current Good Manufacturing Practices. Failure to comply subjects the manufacturer to possible FDA action, such as warning letters, suspension of manufacturing, seizure of the product, voluntary recall of a product or injunctive action, as well as possible civil penalties. We currently rely on, and intend to continue to rely on, third parties to manufacture our compounds and products. Such third parties will be required to comply with current Good Manufacturing Practices.

Even after FDA approval has been obtained, and often as a condition to expedited approval, further studies, including post-marketing studies, may be required. Results of post-marketing studies may limit or expand the further marketing of the products. If we propose any modifications to a product, including changes in indication, manufacturing process, manufacturing facility or labeling, we may need to submit a New Drug Application supplement to the FDA.

Products manufactured in the United States for distribution abroad will be subject to FDA regulations regarding export, as well as to the requirements of the country to which they are shipped. These latter requirements are likely to cover the conduct of clinical trials, the submission of marketing applications, and all aspects of product manufacture and marketing. Such requirements can vary significantly from country to country. As part of our strategic relationships our collaborators may be responsible for the foreign regulatory approval process of our products, although we may be legally liable for noncompliance.

We are also subject to various federal, state and local laws, rules, regulations and policies relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, previously used in connection with our research work. Although we believe that our safety procedures for handling and disposing of such materials comply with current federal, state and local laws, rules,

Table of Contents

regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated.

The extent of government regulation which might result from future legislation or administrative action cannot be accurately predicted. In this regard, although the Food and Drug Administration Modernization Act of 1997 modified and created requirements and standards under the Federal Food, Drug, and Cosmetic Act with the intent of facilitating product development and marketing, the FDA is still in the process of developing regulations implementing the Food and Drug Administration Modernization Act of 1997. Consequently, the actual effect of these developments on our business is uncertain and unpredictable.

Moreover, we anticipate that Congress, state legislatures and the private sector will continue to review and assess controls on health care spending. Any such proposed or actual changes could cause us or our collaborators to limit or eliminate spending on development projects and may otherwise affect us. We cannot predict the likelihood, nature, or extent of adverse governmental regulation that might result from future legislative or administrative action, either in the United States or abroad. Additionally, in both domestic and foreign markets, sales of our proposed products will depend, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. Significant uncertainty often exists as to the reimbursement status of newly approved health care products. In addition, third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development.

Competition

We intend to pursue aggressively in-licensing or other means of acquiring products in a late stage of clinical development, or those that are currently on the market but are under-promoted or not currently promoted. We plan to seek products for diseases treated by physician specialists and in hospital settings to complement the markets that we hope our CMV and HCV programs will serve. We will face intense competition in acquiring products to expand our product portfolio. Many of the companies and institutions that we will compete with in acquiring products to expand our product portfolio have substantially greater capital resources, research and development staffs and facilities than we have, and substantially greater experience in conducting business development activities.

Stem cell and solid organ transplant patients at risk for CMV infection or with active CMV disease are most likely to receive ganciclovir or valganciclovir (prodrug of ganciclovir), each of which were developed and are marketed by F. Hoffmann-La Roche. Ganciclovir and valganciclovir, however, are limited by a neutropenia side effect. A patient with neutropenia has a low level of neutrophils in his or her blood. Neutrophils are very important in defending the body against various infections, and therefore, a patient with too few neutrophils is more susceptible to these infections. Foscarnet (AstraZeneca) and cidofovir (Gilead Sciences) may also be used to treat active CMV infections in certain patient populations such as neutropenic patients, patients with ganciclovir-resistant CMV infection, or patients for whom ganciclovir is otherwise contraindicated. However, use of either foscarnet or cidofovir is limited by the side effect of renal impairment. Valaciclovir, a broad-spectrum antiviral agent marketed in several countries, is in late-phase development in the U.S. for CMV infections. Additionally, we believe that two vaccine products are in early-phase clinical trials that there are several preclinical drug development initiatives targeted for this indication.

Non-specific medications are also available to treat HCV. Interferon products, alone or in combination with ribavirin, are used to treat hepatitis C.

Edgar Filing: VIROPHARMA INC - Form 10-K

In addition to approved products, other companies are developing treatments for viral diseases, including compounds in preclinical and clinical development for CMV, HCV and rhinovirus infections. These companies

Table of Contents

include both public and private entities, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions. For example, Eli Lilly, Merck & Co. and Boehringer Ingelheim, among several other companies, are developing compounds to treat hepatitis C. Pfizer, Inc. may be developing a compound to treat infections caused by rhinoviruses, which are viruses included in the picornavirus family. Developments by these or other entities may render our products under development non-competitive or obsolete. Our ability to compete successfully will be based on our ability to:

- develop proprietary products;
- attract and retain scientific personnel;
- obtain patent or other protection for our products;
- obtain required regulatory approvals; and
- manufacture and successfully market our products either alone or through outside parties.

Some of our competitors have substantially greater financial, research and development, manufacturing, marketing and human resources and greater experience in product discovery, development, clinical trial management, FDA regulatory review, manufacturing and marketing than we do.

Human Resources

As of January 31, 2004, we had 88 full-time employees. Of these employees, 53 are engaged in completing certain discrete activities relating to our early stage programs in order to finalize the transition in connection with our restructuring in January 2004. After the completion of these activities in mid-2004, we estimate that we will have approximately 35 full-time employees, and we are currently seeking to fill certain additional positions. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical products companies. None of our employees is covered by collective bargaining agreements. We believe that we have been successful in attracting skilled and experienced personnel; however, competition for such personnel is intense. We believe that our relations with our employees are good.

Available Information

Our Internet website is www.viropharma.com and you may find our SEC filings on the Investors page of that website. We provide access to all of our filings with the United States Securities and Exchange Commission, or SEC, free of charge, as soon as reasonably practicable after filing with the SEC on such site. Our Internet website and the information contained on that website, or accessible from our website, is not intended to be incorporated into this Annual Report on Form 10-K.

Table of Contents

RISK FACTORS

Our disclosure and analysis in this report contains some forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as anticipate, estimate, expect, project, intend, plan, believe, and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to present or anticipated scientific progress, development and regulatory approval of potential pharmaceutical products, business development plans and initiatives, future revenues, capital expenditures, research and development expenditures, future financings and collaborations, personnel, manufacturing requirements and capabilities, and other statements regarding matters that are not historical facts or statements of current condition.

Any or all of our forward-looking statements in this report may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in the discussion below will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially. The risks described below are not the only ones facing our company. Additional risks not presently known to us, or that we currently deem immaterial, may also impair our business operations. We do not intend to update our forward-looking statements to reflect future events or developments.

Our success depends on our ability to enhance our existing pipeline of product candidates through the in-license or other acquisition of late stage clinical development candidates or marketed products, and if our business development efforts are not successful, our ability to achieve profitability will depend on the successful development of our earlier stage product candidates and our ability to finance the development of such product candidates.

Our current product portfolio consists of early stage compounds. For example, our most advanced product candidate is maribavir, which we expect will enter phase 2 clinical trials in the second quarter of 2004. We intend to pursue aggressively the in-license or the acquisition of products in late stage clinical development and marketed products that are under-promoted or not currently promoted, to expand our current portfolio. Such products may be intended to treat, or are currently used to treat, the patient populations in which we hope our cytomegalovirus, or CMV, and hepatitis C product candidates will be used, or may be products to treat other diseases for which patients are treated by physician specialists and in hospital settings. If we are not successful in acquiring products in late stage clinical development, or marketed products that are under-promoted or not currently promoted, then we will be dependent upon our ability to raise financing for, and the successful development and commercialization of, our product candidates in our CMV and hepatitis C programs.

Many other large and small companies within the pharmaceutical and biotechnology industry seek to establish collaborative arrangements for product research and development, or otherwise acquire products, in competition with us. We face additional competition from public and private research organizations, academic institutions and governmental agencies in establishing collaborative arrangements for product development. Many of the companies and institutions that compete against us have substantially greater capital resources, research and development staffs and facilities than we have, and substantially greater experience in conducting business development activities. These entities represent significant competition to us as we seek to expand our pipeline through the in-license or acquisition of products in a late stage of clinical development, or that are currently on the market but are under-promoted or not currently promoted. Moreover, while it is not feasible to predict the actual cost of acquiring additional product candidates, that cost could be substantial and we may need additional financing in order to acquire new products. Furthermore, our convertible notes may make it difficult for us to raise additional funding.

We have a history of losses and our future profitability is uncertain.

Edgar Filing: VIROPHARMA INC - Form 10-K

We are a development stage company with no current source of product revenue. We have incurred losses in each year since our inception in 1994. As of December 31, 2003, we had an accumulated deficit of approximately

Table of Contents

\$257.6 million. Our ability to achieve profitability is dependent on a number of factors, including our ability to acquire additional product candidates to expand our product portfolio, develop and obtain regulatory approvals for our product candidates, successfully commercialize those product candidates, generate revenues from the sale of products from existing and potential future collaborative agreements, and secure contract manufacturing, distribution and logistics services. We do not know when or if we will acquire additional products to expand our product portfolio, complete our product development efforts, receive regulatory approval of any of our product candidates or successfully commercialize any approved products. As a result, we are unable to accurately predict the extent of any future losses or the time required to achieve profitability, if at all. Moreover, we expect to incur additional operating losses over the next several years, primarily due to development activities with our CMV and hepatitis C programs, and business development activities seeking new opportunities to expand our product pipeline.

Our restructuring plan may not achieve the intended benefits.

We restructured our company in January 2004, and we had previously restructured our company in August 2002 following the termination of our pleconaril copromotion agreement with Aventis Pharmaceuticals Inc. Our restructuring efforts have placed and may continue to place a significant strain on our managerial, operational, financial and other resources. Additionally, the restructuring may negatively affect our employee turnover, recruitment and retention of employees. We cannot assure you that our restructuring efforts will make us more efficient, or will provide sufficient resources to enable us to in-license or otherwise acquire additional product opportunities to expand our product portfolio as a result of our business development efforts.

None of our product candidates is approved for commercial use and if our product candidates do not receive regulatory approval, or if we are unable to comply with applicable regulations and maintain our products regulatory approval, we will be limited in our ability to commercialize these products and may never achieve profitability.

We have not received regulatory approval to commercialize any of our product candidates. In May 2002, we received a not approvable letter from the FDA in connection with an oral formulation of pleconaril to treat the common cold. Our other product candidates are at early stages of development and may not be shown to be safe or effective. We may never receive regulatory approvals for these product candidates. We will need to complete preclinical and clinical testing of each of our product candidates before submitting marketing applications. Negative, inconclusive or inconsistent clinical trial results could prevent regulatory approval, increase the cost and timing of regulatory approval or cause us to perform additional studies or to file for a narrower indication than planned. In 2001, the FDA enacted new regulations requiring the development and submission of pediatric use data for new drug products. Our failure to obtain these data, or to obtain a deferral of, or exemption from, this requirement could adversely affect our chances of receiving regulatory approval, or could result in regulatory or legal enforcement actions.

The development any of our product candidates is subject to many risks, including that:

- the product candidate is found to be ineffective or unsafe;
- the clinical test results for a product candidate delay or prevent regulatory approval;
- the FDA forbids us to initiate or continue testing of our product candidates in human clinical trials;

Edgar Filing: VIROPHARMA INC - Form 10-K

- the product candidate cannot be developed into a commercially viable product;
- the product candidate is difficult or costly to manufacture;
- the product candidate later is discovered to cause adverse effects that prevent widespread use, require withdrawal from the market, or serve as the basis for product liability claims;

Table of Contents

- third party competitors hold proprietary rights that preclude us from marketing the product; and
- third party competitors market a more clinically effective or more cost-effective product.

Even if we believe that the clinical data demonstrates the safety and efficacy of our product candidate, regulators may disagree with us, which could delay, limit or prevent the approval of our product candidates. As a result, we may not obtain regulatory approval, or even if a product is approved, we may not obtain the labeling claims we believe are necessary or desirable for the promotion of the product. In addition, regulatory approval may take longer than we expect as a result of a number of factors, including failure to qualify for priority review of our application. All statutes and regulations governing the approval of our product candidates are subject to change in the future. These changes may increase the time or cost of regulatory approval, limit approval, or prevent it completely.

Even if we receive regulatory approval for our product candidates, or acquire an already approved product, the later discovery of previously unknown problems with a product, manufacturer or facility may result in adverse consequences, including withdrawal of the product from the market. Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and may be subject to continuous review.

If we are unable to commercialize our product candidates as anticipated, we will not have a source of continuing revenue and we will be unable to achieve profitability and be able to service our debt requirements.

Our long-term success depends upon our ability to develop and commercialize drug product candidates and if our drug development programs are not successful, we may not be able to achieve profitability.

We have not completed the development of any of our product candidates. Our failure to develop and commercialize product candidates successfully may cause us to cease operations. We are performing clinical research on a product candidate for the prevention and treatment of CMV, preclinical and clinical research on product candidates for the treatment of hepatitis C and clinical research on an intranasal product for the treatment of the common cold. Our potential therapies under development for the treatment of CMV and hepatitis C will require significant additional development efforts by us and regulatory approvals prior to any commercializations. We cannot be certain that our efforts in this regard will lead to commercially viable products. We may abandon further development efforts of the follow-on compound in our hepatitis C program even before such compound enters clinical trials. We do not know what the final cost to manufacture our CMV and hepatitis C product candidates in commercial quantities will be, or the dose required to treat patients and consequently, what the total cost of goods for a treatment regimen will be.

We are performing proof-of-concept studies with an intranasal formulation of pleconaril to treat the common cold. In November 2003, we entered into an option agreement with Schering Corporation regarding this formulation. Based on its assessment of the product's performance in these proof-of-concept studies, Schering has the option to enter into a full license agreement with us under which Schering would assume responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. Schering's failure to exercise this option may cause us to abandon development work on this indication.

We do not know whether any of our development products ultimately will be shown to be safe and effective. Moreover, governmental authorities may enact new legislation or regulations that could limit or restrict our development efforts. We may receive unfavorable results from ongoing clinical trials of these product candidates in clinical development, which may cause us to abandon further development efforts. If we are unable to successfully develop our product candidates, and if we are unable to acquire marketed products through our business development

efforts, we will not have a source of revenue and will not achieve profitability and be able to service our debt requirements.

Table of Contents

We may need substantial additional funding and may not have access to capital. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our clinical development and business development activities, which would delay the achievement of profitability.

We will need to raise substantial additional funds to continue our business activities and fund our debt service obligations. We have incurred losses from operations since inception and we expect to incur additional operating losses over at least the next several years. We expect to continue to incur losses due primarily from limited revenues and costs associated with our CMV and hepatitis C programs, and business development activities seeking new opportunities to expand our product pipeline. We believe that we may require additional capital by 2007. In addition, the amount and timing of our actual capital requirements as well as our ability to finance such requirements will depend upon numerous factors, including:

- the cost of acquiring products in late stage clinical development;
- the cost of acquiring commercialized products;
- the cost of commercializing our products;
- our ability to generate revenue and positive cash flow through our collaboration agreement with Wyeth;
- the cost and progress of our development programs;
- the cost of milestone payments that may be due to GlaxoSmithKline under our license agreement with them for maribavir, if defined clinical and regulatory events are achieved;
- the time and cost involved in obtaining regulatory approvals;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the cost of reducing the principal amount of our debt;
- the effect of competing technological and market developments;
- whether Schering exercises its options to continue the development and commercialization of intranasal-pleconaril for the treatment of the common cold;
- if Schering does exercise its option, whether we receive the milestone payments and royalties associated with certain events along the development and commercialization lifecycle of that program;

Edgar Filing: VIROPHARMA INC - Form 10-K

- our ability to license our early stage and other non-core assets to a third party;
- the effect of changes and developments in our existing collaborative, licensing and other relationships; and
- the outcome of our ongoing securities class action litigation.

We may be unable to raise sufficient funds to complete our development, marketing and sales activities for any of our product candidates. Potential funding sources include:

- public and private securities offerings;
- debt financing, such as bank loans; and
- expectation that we will sell additional collaborative, licensing and other arrangements with third parties.

We may not be able to find sufficient debt or equity funding on acceptable terms. If we cannot, we may need to delay, reduce or eliminate development programs, as well as other aspects of our business. The sale by us of additional equity securities or the equity securities may have an adverse effect on the price of our common stock. In addition, collaborative arrangements may require us to grant product development programs or licenses to third parties for products that we might otherwise seek to develop or commercialize ourselves.

Table of Contents

We have significant indebtedness and debt service payments which could negatively impact our liquidity.

We are highly leveraged and have significant debt service requirements. We currently have \$127.9 million in principal amount of indebtedness outstanding in the form of our 6.0% Subordinated Convertible Notes due 2007. The level of our indebtedness, among other things, could:

- make it difficult for us to obtain any necessary future financing for working capital, capital expenditures, debt service requirements or other purposes;
- limit our flexibility in planning for, or reacting to changes in, our business; and
- make us more vulnerable in the event of a downturn in our business.

Currently, we are not generating sufficient cash flow from operations to satisfy the annual debt service payments for our outstanding subordinated convertible notes due in March 2007. This will require us to use a portion of our working capital to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, which would negatively impact our future prospects.

Our ability to meet our debt service obligations and to reduce our total indebtedness depends on our future operating performance and on economic, financial, competitive, regulatory and other factors affecting our operations. Many of these factors are beyond our control and our future operating performance could be adversely affected by some or all of these factors. We historically have been unable to generate sufficient cash flow from operations to meet our operating needs and have relied on equity, debt and capital lease financings to fund our operations.

We may not be able to pay our debt and other obligations.

There can be no assurance that we will be able to meet our debt service obligations, including our obligations to pay principal and interest under the existing notes. If our cash, cash equivalents, short-term investments and operating cash flows are inadequate to meet our obligations, we could face substantial liquidity problems. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our convertible notes or our other obligations, we would be in default under the terms thereof, which would permit the holders of our convertible notes to accelerate their maturities and which could also cause defaults under any future indebtedness we may incur. Any such default would have a material adverse effect on our business, prospects, financial condition and operating results. In addition, we cannot be sure that we would be able to repay amounts due in respect of our convertible notes if payment of the notes were to be accelerated following the occurrence of an event of default as defined in the indenture of our convertible notes.

We depend on collaborations with third parties, which may reduce our product revenues or restrict our ability to commercialize products, and also ties our success to the success of certain of our collaborators.

Edgar Filing: VIROPHARMA INC - Form 10-K

We have entered into, and may in the future enter into additional, sales and marketing, distribution, manufacturing, development, licensing and other strategic arrangements with third parties. For example, in November 2003, we entered into an option agreement with Schering Corporation regarding our intranasal formulation of pleconaril for the treatment of the common cold in the United States and Canada. ViroPharma is conducting a series of clinical studies designed to evaluate the antiviral activity, safety and other performance characteristics of the new intranasal pleconaril formulation. Based on Schering's assessment of the product's performance in these characterization studies, Schering has the option to enter into a full license agreement with us. If Schering chooses to exercise its option, we expect to receive an initial license fee of \$10 million, payments for our existing inventory of bulk drug substance, milestone payments upon achievement of certain targeted events and royalties on products sales, if any. However, Schering would thereafter have responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. Sanofi-Synthelabo also has exclusive rights to market and sell pleconaril in countries other than the United States and Canada for which we will receive a royalty.

Table of Contents

In August 2003, we entered into a license agreement with GlaxoSmithKline under which we acquired worldwide rights, excluding Japan, from GlaxoSmithKline to an antiviral compound, maribavir (VP41263), for the prevention and treatment of cytomegalovirus infections related to transplant (including solid organ and hematopoietic stem cell transplantation), congenital transmission, and in patients with HIV infection. GlaxoSmithKline has the exclusive right to market and sell products covered by these patents and patent applications in Japan.

In December 1999, we entered into an agreement with Wyeth to develop jointly products for use in treating the effects of hepatitis C virus in humans. Under the agreement, we licensed to Wyeth worldwide rights under patents and know-how owned by us or created under the agreement. While we have the right to co-promote these products in the United States and Canada, Wyeth will promote the products elsewhere in the world. Wyeth also has the right to manufacture any commercial products developed under the agreement.

If our partners do not successfully market and sell products in their territories, we will not receive revenue from royalties on their sales of products.

We are currently engaged in additional discussions relating to other arrangements. We cannot be sure that we will be able to enter into any such arrangements with third parties on terms acceptable to us or at all. Third party arrangements may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, or may have other terms that are burdensome to us, and may involve the acquisition of our equity securities.

Our ultimate success may depend upon the success of our collaborators. We have obtained, and will attempt to obtain in the future, licensed rights to certain proprietary technologies and compounds from other entities, individuals and research institutions, for which we may be obligated to pay license fees, make milestone payments and pay royalties. In addition, we may in the future enter into collaborative arrangements for the marketing, sales and distribution of our product candidates, which may require us to share profits or revenues. We may be unable to enter into additional collaborative licensing or other arrangements that we need to develop and commercialize our drug candidates. Moreover, we may not realize the contemplated benefits from such collaborative licensing or other arrangements. These arrangements may place responsibility on our collaborative partners for preclinical testing, human clinical trials, the preparation and submission of applications for regulatory approval, or for marketing, sales and distribution support for product commercialization. We cannot be certain that any of these parties will fulfill their obligations in a manner consistent with our best interests. These arrangements may also require us to transfer certain material rights or issue our equity securities to corporate partners, licensees and others. Any license or sublicense of our commercial rights may reduce our future potential product revenue. Moreover, we may not derive any revenues or profits from these arrangements. In addition, our current strategic arrangements may not continue and we may be unable to enter into future collaborations. Collaborators may also pursue alternative technologies or drug candidates, either on their own or in collaboration with others, that are in direct competition with us.

If our licensors do not protect our rights under our license agreements with them or do not reasonably consent to our sublicense of rights or if these license agreements are terminated, we may lose revenue and expend significant resources defending our rights.

We have licensed from GlaxoSmithKline worldwide rights, excluding Japan, to an antiviral compound, maribavir (VP41263), for the prevention and treatment of cytomegalovirus infections related to transplant (including solid organ and hematopoietic stem cell transplantation), congenital transmission, and in patients with HIV infection. This compound, and a related compound, are subject to patents and patent applications in a variety of countries throughout the world. We have licensed from Sanofi-Synthelabo the exclusive United States and Canadian rights to certain antiviral agents for use in picornavirus indications, which are the subject of U.S. and Canadian patents and patent applications owned by Sanofi-Synthelabo, certain of which describe pleconaril and others of which describe compounds that are either related to pleconaril or have antiviral activity. We depend on

Table of Contents

GlaxoSmithKline and Sanofi-Synthelabo to prosecute and maintain many of these patents and patent applications and protect such patent rights. Failure by GlaxoSmithKline or Sanofi-Synthelabo to prosecute or maintain such patents or patent applications and protect such patent rights could lead to our loss of revenue. Under certain circumstances, our ability to sublicense our rights under these license agreements is subject to the licensor's consent. If our license agreements with GlaxoSmithKline and Sanofi-Synthelabo are terminated, our ability to manufacture, develop, market and sell products under those agreements would terminate.

Many potential competitors who have greater resources and experience than we do may develop products and technologies that make ours non-competitive or obsolete.

There are many entities, both public and private, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions, engaged in developing pharmaceuticals for applications similar to those targeted by us. For example, there are products already marketed by F. Hoffman La-Roche for CMV and Schering Corporation for hepatitis C. In addition, Eli Lilly, Merck & Co. and Boehringer Ingelheim, among several other companies, are developing compounds to treat hepatitis C. Pfizer, Inc. may be developing a compound to treat infections caused by rhinoviruses, which are viruses included in the picornavirus family. Developments by these or other entities may render our products under development non-competitive or obsolete. Furthermore, many of our competitors are more experienced than we are in drug development and commercialization, obtaining regulatory approvals and product manufacturing and marketing. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly and more effectively than we do. Competitors may succeed in developing products that are more effective and less costly than any that we develop and also may prove to be more successful in the manufacturing and marketing of products.

Any product that we successfully develop and for which we gain regulatory approval must then compete for market acceptance and market share. Accordingly, important competitive factors, in addition to completion of clinical testing and the receipt of regulatory approval, will include product efficacy, safety, timing and scope of regulatory approvals, availability of supply, marketing and sales capacity, reimbursement coverage, pricing and patent protection.

Any of our future products may not be accepted by the market, which would harm our business and results of operations.

Even if approved by the FDA and other regulatory authorities, our product candidates may not achieve market acceptance by patients, prescribers or third-party payors. As a result, we may not receive revenues from these products as anticipated. The degree of market acceptance will depend upon a number of factors, including:

- the receipt and timing of regulatory approvals, and the scope of marketing and promotion activities permitted by such approvals (e.g., the label for the product approved by the FDA);
- the availability of third-party reimbursement including government health administration authorities and private health insurers;
- the establishment and demonstration in the medical community, such as doctors and hospital administrators, of the clinical safety, efficacy and cost-effectiveness of drug candidates, as well as their advantages over existing treatment alternatives, if any;
- the effectiveness of the sales and marketing force that may be promoting our products; and

- the effectiveness of our contract manufacturers.

Legal proceedings could require us to spend substantial amounts of money and impair our operations.

In March and May 2002, complaints were filed in the United States District Court for the Eastern District of Pennsylvania against us seeking an unspecified amount of damages on behalf of an alleged class of persons who purchased shares of our common stock at various times between July 13, 1999 and March 19, 2002. In July 2002,

Table of Contents

the complaints were consolidated into a single action. The consolidated complaint names us, as well as certain of our directors and officers, as defendants. The consolidated complaint alleges that we and/or such directors and officers violated federal securities laws by misrepresenting and failing to disclose certain information regarding Picovir[®] (pleconaril). In August 2002, we filed a motion to dismiss the consolidated complaint. In April 2003, the court granted in part and denied in part the Company's motion to dismiss the consolidated complaint. In December 2003, we filed a motion for partial summary judgment of this action and a memorandum opposing the certification of the plaintiffs' class action status. In March 2004, we entered into an agreement in principle with plaintiffs' counsel to settle this litigation. The proposed settlement will be paid from our insurance coverage and will not result in the payment of any funds by us. However, the proposed settlement is subject to the approval of the court. If the proposed settlement is not approved by the court, then the range of possible resolutions of these proceedings could include judgments against us or our directors or officers or settlements that could require substantial payments by us, which could have a material adverse impact on our financial position, results of operations and cash flows. These proceedings might require substantial attention of our management team and therefore divert time and attention from our business and operations.

The regulatory process is expensive, time consuming and uncertain and may prevent us from obtaining required approvals for the commercialization of our product candidates.

We have product candidates for the treatment of CMV in clinical development and hepatitis C in preclinical and clinical development. We must complete significant development, laboratory testing, and clinical testing on these product candidates before we submit marketing applications in the United States and abroad.

The rate of completion of clinical trials depends upon many factors, including the rate of enrollment of patients. Our ability to enroll patients in certain clinical trials for maribavir depends on our ability to identify a sufficient number of patients who have undergone allogeneic hematopoietic stem cell (e.g., bone marrow) transplantation. If we are unable to accrue sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. In addition, the FDA or Institutional Review Boards may require us to delay, restrict, or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Moreover, we may be unable to submit a NDA to the FDA for our product candidates within the timeframe we currently expect. Once an NDA is submitted, an NDA must be approved by the FDA before we can commercialize the product described in the application. The cost of human clinical trials varies dramatically based on a number of factors, including:

- the order and timing of clinical indications pursued;
- the extent of development and financial support from corporate collaborators;
- the number of patients required for enrollment;
- the difficulty of obtaining clinical supplies of the product candidate; and
- the difficulty in obtaining sufficient patient populations and clinicians.

All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of our clinical trials. Any unanticipated costs or delays in our clinical studies could delay the commercialization of the product and harm our ability to achieve

profitability.

Even if we obtain positive preclinical or clinical trial results in initial studies, future clinical trial results may not be similarly positive. As a result, ongoing and contemplated clinical testing, if permitted by governmental authorities, may not demonstrate that a product candidate is safe and effective in the patient population and for the disease indications for which we believe it will be commercially advantageous to market the product. The failure of our clinical trials to demonstrate the safety and efficacy of our desired indications could delay the commercialization of the product and harm our ability to raise capital and achieve profitability and be able to service our debt requirements.

Table of Contents

If we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, our products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval from the FDA, along with the manufacturing processes, post-approval clinical data collection and promotional activities for such product, will be subject to continual review and periodic inspection by the FDA and other regulatory bodies. After approval of a product, we will have significant ongoing regulatory compliance obligations. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in penalties or other actions, including:

- warning letters;
- fines;
- product recalls;
- withdrawal of regulatory approval;
- operating restrictions, including restrictions on such products or manufacturing processes;
- disgorgement of profits;
- injunctions; and
- criminal prosecution.

We depend on patents and proprietary rights, which may offer only limited protection against potential infringement and if we are unable to protect our patents and proprietary rights, we may lose the right to develop, manufacture, market or sell products and lose sources of revenue.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong patent position for our products and technologies both in the United States and in other countries. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to us and diversion of our efforts. We intend to file applications as appropriate for patents describing the composition of matter of our drug candidates, the proprietary processes for producing such compositions, and the uses of our drug candidates. We own twelve issued United States patents, nine non-United States patents and have twenty-five pending United States patent applications. We also have filed international, regional and non-United States national patent applications in order to pursue patent protection in major foreign countries.

Edgar Filing: VIROPHARMA INC - Form 10-K

We also rely on trade secrets, know-how and continuing technological advancements to protect our proprietary technology. We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and we may not be able to successfully protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how.

Many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

To facilitate development of our proprietary technology base, we may need to obtain licenses to patents or other proprietary rights from other parties. If we are unable to obtain such licenses, our product development efforts may be delayed. We may collaborate with universities and governmental research organizations which, as a result, may acquire certain rights to any inventions or technical information derived from such collaboration.

Table of Contents

We may incur substantial costs in asserting any patent rights and in defending suits against us related to intellectual property rights, even if we are ultimately successful. If we are unsuccessful in defending a claim that we have infringed or misappropriated the intellectual property of a third party, we could be required to pay substantial damages, stop using the disputed technology, develop new non-infringing technologies, or obtain one or more licenses from third parties. If we or our licensors assert our patents, a court may determine that our patents or our licensors' patents are invalid or unenforceable, or that the defendant's activity is not covered by the scope of our patents or our licensors' patents. The United States Patent and Trademark Office or a private party could institute an interference proceeding relating to our patents or patent applications. An opposition or revocation proceeding could be instituted in the patent offices of foreign jurisdictions. An adverse decision in any such proceeding could result in the loss of our rights to a patent or invention.

We may not receive third party reimbursement for any of our future products, which would cause us to lose anticipated revenues and delay achievement of profitability.

Even if we receive regulatory approval to sell any of our product candidates, our future revenues, profitability and access to capital will be determined in part by the price at which we and our distribution partners can sell such approved products. There are continuing efforts by governmental and private third-party payors to contain or reduce the costs of health care through various means. We expect a number of federal, state and foreign proposals to control the cost of drugs through governmental regulation. We are unsure of the form that any health care reform legislation may take or what actions federal, state, foreign, and private payors may take in response to the proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance and we could lose anticipated revenues and experience delayed achievement of profitability and be unable to service our debt requirements.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our ability to compete.

We are highly dependent upon qualified scientific, technical, and managerial personnel, including our president and CEO, Michel de Rosen, and our vice president and chief financial officer, Vincent J. Milano. We are currently seeking to fill certain key positions, including a person to lead our development and regulatory efforts. Our anticipated growth and expansion into new areas and activities will require additional expertise and the addition of new qualified personnel. There is intense competition for qualified personnel in the pharmaceutical field. Therefore, we may not be able to attract and retain the qualified personnel necessary for the development of our business. Furthermore, we have not entered into non-competition agreements with our key employees. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, would harm our development programs, and our ability to manage day-to-day operations, attract collaboration partners, attract and retain other employees, and generate revenues. We do not maintain key man life insurance on any of our employees.

We may be subject to product liability claims, which can be expensive, difficult to defend and may result in large judgments or settlements against us.

The administration of drugs to humans, whether in clinical trials or after marketing clearance is obtained, can result in product liability claims. Product liability claims can be expensive, difficult to defend and may result in large judgments or settlements against us. In addition, third party collaborators and licensees and may not

Table of Contents

protect us from product liability claims. We currently only maintain product liability insurance for human clinical trials per claim and in the aggregate amount of \$6 million. We may not be able to obtain or maintain adequate protection against potential liabilities arising from product sales. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to product liability claims. A successful product liability claim in excess of our insurance coverage could harm our financial condition, results of operations and prevent or interfere with our product commercialization efforts. In addition, any successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms. Even if a claim is not successful, defending such a claim may be time-consuming and expensive.

We have limited sales and marketing experience and if we are unable to develop our own sales and marketing capability we may be unsuccessful in commercializing our products.

Under our agreement with GlaxoSmithKline, we have the exclusive right to market and sell maribavir throughout the world, other than Japan. Under our agreement with Wyeth, we have the right to co-promote hepatitis C products arising from our collaboration in the United States and Canada. If Schering Corporation exercises its option to further develop and commercialize intranasal pleconaril, Schering will be solely responsible for the marketing, promotion and sale of intranasal pleconaril following its approval. We intend to pursue aggressively in-licensing or other means of acquiring products in a late stage of clinical development, or that are currently on the market but are under-promoted or not currently promoted.

We currently do not have a marketing or sales staff. If we are successful in acquiring the FDA's approval of any product candidate, including any product that we may acquire as a result of our business development efforts, we will need to build a commercial capability. The development of a marketing and sales capability will require significant expenditures, management resources and time. We may be unable to build such a sales force, the cost of establishing such a sales force may exceed any product revenues, or our marketing and sales efforts may be unsuccessful. We may not be able to find a suitable sales and marketing partner for our products. If we are unable to successfully establish a sales and marketing capability in a timely manner or find suitable sales and marketing partners, our business and results of operations will be harmed. Even if we are able to develop a sales force or find a suitable marketing partner, we may not successfully penetrate the markets for any of our proposed products.

We currently depend, and will in the future depend, on third parties to manufacture our products and product candidates. If these manufacturers fail to meet our requirements and the requirements of regulatory authorities, our business, financial condition and results of operations will be harmed.

We do not have the internal capability to manufacture commercial quantities of pharmaceutical products following the FDA's cGMP. In order to continue to develop products, apply for regulatory approvals and commercialize our products, we will need to contract for or otherwise arrange for the necessary manufacturing capabilities.

There are a limited number of manufacturers that operate under the FDA's cGMP capable of manufacturing our products. If we are unable to enter into supply and processing contracts with any of these manufacturers or processors, there may be additional costs and delay in the development and commercialization of our products. Even if we are able to enter into supply and processing contracts with any of these manufacturers or processors, but such manufacturers or processors are unable to satisfy our requirements, there may be additional cost and delay in the development or commercialization of our products. If we are required to find an additional or alternative source of supply, there may be additional cost and delay in the development or commercialization of our products. Additionally, the FDA inspects all commercial manufacturing facilities before approving an NDA for a drug manufactured at those sites. If any of our manufacturers or processors fails to pass this the FDA inspection, the approval and eventual commercialization of our products may be delayed.

Table of Contents

If our product manufacturers fail to comply with regulatory requirements, our product commercialization could be delayed or subject to restrictions.

Any contract manufacturers that we use must adhere to the FDA's regulations on cGMP, which are enforced by the FDA through its facilities inspection program. These facilities must pass a plant inspection before the FDA will issue an approval of the product. The manufacture of product at these facilities will be subject to strict quality control, testing and recordkeeping requirements. Moreover, while we may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the product, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

If we encounter delays or difficulties with contract manufacturers, packagers or distributors, market introduction and subsequent sales of our products could be delayed. If we change the source or location of supply or modify the manufacturing process, regulatory authorities will require us to demonstrate that the product produced by the new source or from the modified process is equivalent to the product used in any clinical trials that were conducted. If we are unable to demonstrate this equivalence, we will be unable to manufacture products from the new source or location of supply, or use the modified process, we may incur substantial expenses in order to ensure equivalence, and it may harm our ability to generate revenues.

If we, or our manufacturers, are unable to obtain raw and intermediate materials needed to manufacture our products in sufficient amounts or on acceptable terms, we will incur significant costs and sales of our products would be delayed or reduced.

We, or our manufacturers with whom we contract, may not be able to maintain adequate relationships with current or future suppliers of raw or intermediate materials for use in manufacturing our products or product candidates. If our current manufacturing sources and suppliers are unable or unwilling to make these materials available to us, or our manufacturers, in required quantities or on acceptable terms, we would likely incur significant costs and delays to qualify alternative manufacturing sources and suppliers. If we are unable to identify and contract with alternative manufacturers when needed, sales of our products would be delayed or reduced and will result in significant additional costs.

We use hazardous materials in our business and any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Prior to our restructuring in January 2004, we used, and during the transition period following that restructuring we may continue to use, radioactive and other materials that could be hazardous to human health, safety or the environment. In connection with our restructuring in January 2004, we are decommissioning our discovery laboratories, which requires the disposal of many of these materials. We are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes. We store these materials and various wastes resulting from their use at our facility pending ultimate use and disposal. Although we believe that our safety procedures for handling and disposing of such materials comply with federal, state and local laws, rules, regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated. We may be required to incur significant costs to comply with environmental laws, rules, regulations and policies. Additionally, if an accident occurs, we could be held liable for any resulting damages, and any such liability could exceed our resources. We do not maintain a separate insurance policy for these types of risks and we do not have reserves set aside for environmental claims. Any future environmental claims could harm our financial conditions, results of operations and prevent or interfere with our product commercialization efforts. In addition, compliance with future environmental laws, rules, regulations and policies could lead to additional costs and expenses.

Table of Contents

The rights that have been and may in the future be granted to holders of our common or preferred stock may adversely affect the rights of other stockholders and may discourage a takeover.

Our board of directors has the authority to issue up to 4,800,000 additional shares of preferred stock and to determine the price, privileges and other terms of such shares. Our board of directors may exercise this authority without the approval of, or notice to, our stockholders. Accordingly, the rights of the holders of our common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. In addition, the issuance of preferred stock may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management. We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. The application of Section 203 could also delay or prevent a third party or a significant stockholder of ours from acquiring control of us or replacing our current management. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Under Delaware law, an interested stockholder is a person who, together with affiliates and associates, owns 15% or more of a corporation's voting stock.

In September 1998, our board of directors adopted a plan that grants each holder of our common stock the right to purchase shares of our series A junior participating preferred stock. This plan is designed to help insure that all our stockholders receive fair value for their shares of common stock in the event of a proposed takeover of us, and to guard against the use of partial tender offers or other coercive tactics to gain control of us without offering fair value to the holders of our common stock. In addition, our charter and bylaws contain certain provisions that could discourage a hostile takeover, such as a staggered board of directors and significant notice provisions for nominations of directors and proposals. The plan and our charter and bylaws may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management.

Our stock price could continue to be volatile.

Our stock price, like the market price of the stock of other development-stage pharmaceutical companies, has been volatile. For example, during 2003 the market price for our common stock traded between \$1.42 and \$4.75 per share. The following factors, among others, could have a significant impact on the market for our common stock:

- results of preclinical studies and clinical trials with respect to our product candidates in development or those of our competitors;
- developments with our collaborators;
- announcements of technological innovations or new products by our competitors;
- litigation or public concern as to the safety or efficacy of our products or our competitors' products;
- the outcome of our currently ongoing class action securities litigation;

Edgar Filing: VIROPHARMA INC - Form 10-K

- developments in patent or other proprietary rights of ours or our competitors (including related litigation);
- any other future announcements concerning us or our competitors;
- any announcement regarding our acquisition of product candidates or entities;
- future announcements concerning our industry;
- governmental regulation;
- actions or decisions by the SEC, the FDA or other regulatory agencies;

Table of Contents

- changes or announcements of changes in reimbursement policies;
- period to period fluctuations in our operating results;
- our cash balances;
- changes in our capital structure;
- changes in estimates or our performance by securities analysts; and
- general market conditions.

Future sales of our common stock in the public market could adversely affect our stock price.

We cannot predict the effect, if any, that future sales of our common stock or the availability for future sale of shares of our common stock or securities convertible into or exercisable for our common stock will have on the market price of our common stock prevailing from time to time. For example, in connection with the purchase of shares of our common stock by Aventis Pharmaceuticals Inc., we filed a registration statement on Form S-3 with the SEC to register 3.0 million shares of our common stock which may be resold by Aventis from time to time. Additionally, the registration statement on Form S-3 filed on July 3, 2001, allows us to sell up to an additional \$212.0 million of securities in a universal shelf offering. The registration statement provides us with the flexibility to determine the type of security we choose to sell, including common stock, preferred stock, warrants and debt securities, as well as the ability to time such sales when market conditions are favorable. The registration statement became effective on October 19, 2001. In order for us to issue securities registered on this registration statement we must either have an aggregate market value of the voting and non-voting common equity excluding shares held by our affiliates of \$75 million or more as of the date of our most recently filed annual report on Form 10-K, or we must file a post effective amendment to the registration statement on Form S-2 or S-1.

As of February 28, 2004, we had outstanding options to purchase 3,740,531 shares of our common stock at a weighted average exercise price of \$10.75 per share (1,611,305 of which have not yet vested) issued to employees, directors and consultants pursuant to our 1995 Stock Option and Restricted Share Plan, and outstanding options to purchase 355,800 shares of our common stock at a weighted average exercise price of \$1.34 per share (223,509 of which have not yet vested) to non-executive employees pursuant to our 2001 Stock Option Plan. In order to attract and retain key personnel, we may issue additional securities, including stock options, in connection with our employee benefit plans, or may lower the price of existing stock options. Sale, or the availability for sale, of substantial amounts of common stock by our existing stockholders pursuant to an effective registration statement or under Rule 144, through the exercise of registration rights or the issuance of shares of common stock upon the exercise of stock options or warrants, or the conversion of our preferred stock, or the perception that such sales or issuances could occur, could adversely affect the prevailing market prices for our common stock.

As of December 31, 2003, we also had outstanding warrants exercisable for 595,000 shares of our common stock with an exercise price of \$9.53 per share.

If we are unable to comply with Nasdaq's continued listing requirements, our common stock could be delisted from The Nasdaq National Market.

Our common stock trades on The Nasdaq National Market, which has certain compliance requirements for continued listing of common stock, including a series of financial tests relating to shareholder equity, public float, number of market makers and shareholders, and maintaining a minimum bid price per share for our common stock. The result of delisting from The Nasdaq National Market could be a reduction in the liquidity of any investment in our common stock and a material adverse effect on the price of our common stock. Delisting

Table of Contents

could reduce the ability of holders of our common stock to purchase or sell shares as quickly and as inexpensively as they could have done in the past. This lack of liquidity would make it more difficult for us to raise capital in the future.

As of December 31, 2003 our stockholders' equity was below \$10 million. If our stockholders' equity remains below \$10 million, then to maintain our Nasdaq listing we will be required to maintain a minimum bid price of \$1.00 per share and a \$50 million market value of our listed securities. If we fail to meet this standard for thirty consecutive days, Nasdaq would send us a deficiency notice informing us that we would be delisted after ninety days unless we meet this standard for at least ten consecutive trading days during such ninety day period. If we were unable to regain compliance for The Nasdaq National Market, we would have the option, subject to Nasdaq approval, of transferring to The Nasdaq SmallCap Market, where we would be permitted additional time to remedy a bid price deficiency, while remaining eligible for The Nasdaq National Market reinstatement.

If our stock is delisted from The Nasdaq National Market and our stock price declines significantly, then our stock could become subject to penny stock rules, which may make it more difficult for you to sell your shares.

The SEC has adopted regulations which define a penny stock to be any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions described below. For any transaction involving a penny stock, unless exempt, these rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule relating to the penny stock market. Disclosure is also required to be made about current quotations for the securities and about commissions payable to both the broker-dealer and the registered representative. Finally, broker-dealers must send monthly statements to purchasers of penny stocks disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The foregoing penny stock restrictions will not apply to our shares of common stock if: (1) they continue to be listed on The Nasdaq National Market; (2) certain price and simple average of the daily volume information is publicly available about our shares on a current and continuing basis; and (3) we meet certain minimum net tangible assets or average revenue criteria. Our common stock may not continue to qualify for an exemption from the penny stock restrictions. If our shares of common stock were subject to the rules on penny stocks, the liquidity of our common stock would be severely harmed.

ITEM 2. PROPERTIES

We lease an aggregate of 119,000 square feet in two facilities located in Exton, Pennsylvania for our corporate and development activities under operating leases expiring in 2008 and 2017, respectively. The lease that expires in 2008 has two 5-year renewal options. Following our restructuring in January 2004, we have reduced our space requirements. We are currently seeking to sublease all unused space. We cannot be certain that we will be able to sublease our unused space on favorable terms or at all.

ITEM 3. LEGAL PROCEEDINGS

In March and May 2002, complaints were filed in the United States District Court for the Eastern District of Pennsylvania against us seeking an unspecified amount of damages on behalf of an alleged class of persons who purchased shares of our common stock at various times between July 13, 1999 and March 19, 2002. In July 2002, the complaints were consolidated into a single action. The consolidated complaint names us, as well as certain of our directors and officers, as defendants. The consolidated complaint alleges that we and/or such directors and officers violated federal securities laws by misrepresenting and failing to disclose certain information regarding Picovir® (pleconaril). In August 2002, we filed a motion to dismiss the consolidated complaint. In April 2003, the court granted in part and denied in part the Company's motion to dismiss the consolidated complaint. In December 2003, we filed a motion for partial summary judgment of this action and a memorandum opposing the

Table of Contents

certification of the plaintiff's class action status. In March 2004, we entered into an agreement in principle with plaintiff's counsel to settle this litigation. The proposed settlement will be paid from our insurance coverage and will not result in the payment of any funds by us. However, the proposed settlement is subject to the approval of the court. If the proposed settlement is not approved by the court, then the range of possible resolutions of these proceedings could include judgments against us or our directors or officers or settlements that could require substantial payments by us, which could have a material adverse impact on our financial position, results of operation and cash flows. These proceedings might require substantial attention of our management team and therefore divert time and attention from our business and operations.

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

None.

Table of Contents**PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market Information**

Our common stock is traded on the National Market segment of The Nasdaq Stock Market under the symbol VPHM. We commenced trading on The Nasdaq Stock Market on November 19, 1996. The following table sets forth the high and low sale prices as quoted on The Nasdaq Stock Market for each quarter of 2002 and 2003 and through February 15, 2004.

	<u>High</u>	<u>Low</u>
Year ended December 31, 2002		
First Quarter	\$ 23.03	\$ 4.88
Second Quarter	\$ 5.17	\$ 1.25
Third Quarter	\$ 1.75	\$ 0.88
Fourth Quarter	\$ 1.90	\$ 0.86
Year ended December 31, 2003		
First Quarter	\$ 2.70	\$ 1.42
Second Quarter	\$ 4.75	\$ 1.59
Third Quarter	\$ 3.35	\$ 1.95
Fourth Quarter	\$ 3.40	\$ 2.47
First Quarter 2004 (through February 15, 2004).	\$ 3.74	\$ 2.63

Holdings and Dividends

There were approximately 738 record holders of our common stock as of March 1, 2004. We have never declared or paid any cash dividends on our common stock. We have declared and paid dividends in the past on our previously outstanding series A convertible participating preferred stock. As of March 1, 2004, we had no shares of preferred stock outstanding. Any future determination to pay dividends will be at the discretion of our board of directors and will be dependent on then existing conditions, including our financial condition, results of operations, contractual restrictions, capital requirements, business and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

During the three months ended December 31, 2003, we issued a total of 473,054 shares of our common stock that were not registered under the Securities Act of 1933, as amended ("1933 Act") in reliance on an exemption pursuant to Section 3(a)(9) of the 1933 Act. These shares of common stock were issued in two separately and privately negotiated transactions occurring on October 2, 2003 and November 26, 2003 in exchange for an aggregate of \$2,000,000 principal amount of our 6% Convertible Subordinated Notes due March 1, 2007. No commission or other remuneration was paid to any person, directly or indirectly, in connection with these transactions.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

The selected financial data presented below under the caption "Consolidated Balance Sheet Data" as of December 31, 1999, 2000, 2001, 2002 and 2003 and under the caption "Consolidated Statement of Operations Data" for the years ended December 31, 1999, 2000, 2001, 2002 and 2003 are derived from the consolidated financial statements of the Company which have been audited by KPMG LLP, independent accountants. The data set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, the Consolidated Financial Statements and the notes thereto and the other financial information included elsewhere in this Report. We are considered a development stage company as described in Note 1 of the Company's Consolidated Financial Statements.

	Year Ended December 31,				
	1999	2000	2001	2002	2003
Consolidated Statement of Operations Data:					
License fee and milestone revenue	\$	\$ 2,000,000	\$ 3,384,615	\$ 5,333,440	\$ 1,084,186
Other revenue				203,400	527,988
Total revenues		2,000,000	3,384,615	5,536,840	1,612,174
Operating expenses:					
Research and development	26,463,229	38,037,733	43,012,588	39,823,069	23,042,772
Acquisition of technology rights			16,500,000		3,500,000
Marketing	1,283,317	2,326,896	11,806,768	6,791,106	
General and administrative	3,295,790	5,662,119	11,248,855	7,834,441	9,035,696
Total operating expenses	31,042,336	46,026,748	82,568,211	54,448,616	35,578,468
Gain on repurchase of debt				27,894,260	3,632,882
Interest income	1,708,212	11,990,551	12,321,542	5,428,831	1,829,021
Interest expense	165,914	9,781,177	11,619,150	11,034,198	8,437,548
Loss from continuing operations	(29,500,038)	(41,817,374)	(78,481,204)	(26,622,883)	(36,941,939)
(Loss) income from discontinued operations			(4,476,244)	10,816,807	
Loss allocable to common stockholders	(34,574,571)	(42,544,726)	(83,302,690)	(15,806,076)	(36,941,939)
Loss per share from continuing operations:					
Basic	\$ (2.42)	\$ (2.75)	\$ (4.32)	\$ (1.11)	\$ (1.43)
Diluted	(2.42)	\$ (2.75)	\$ (4.32)	\$ (1.11)	\$ (1.43)
(Loss) income per share from discontinued operations:					
Basic	\$	\$	\$ (0.25)	\$ 0.45	\$
Diluted			(0.25)	0.45	
Net loss per share allocable to common stockholders:					
Basic	\$ (2.84)	\$ (2.80)	\$ (4.59)	\$ (0.66)	\$ (1.43)

Edgar Filing: VIROPHARMA INC - Form 10-K

Diluted	(2.84)	(2.80)	(4.59)	(0.66)	(1.43)
<hr/>					
Shares used in computing net (loss) income per share:					
Basic	12,181,853	15,210,964	18,167,303	23,952,940	25,916,466
Diluted	12,181,853	15,210,964	18,167,303	23,952,940	25,916,466

As of December 31,

	1999	2000	2001	2002	2003
<hr/>					
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 66,852,920	\$ 203,335,180	\$ 240,040,193	\$ 158,281,544	\$ 121,148,591
Working capital	58,691,259	196,279,631	220,620,940	152,771,841	113,096,747
Total assets	72,085,866	222,438,830	266,180,803	173,530,757	132,845,182
Long term debt less current portion	525,000	180,325,000	180,125,000	134,908,334	127,900,000
Total stockholders equity (deficit)	58,291,236	23,986,548	39,429,714	27,810,771	(7,509,295)

Table of Contents

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

Background

We are a development stage pharmaceutical company focused on the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings. Since commencing operations in December 1994, we have devoted substantially all of our resources to our product development programs, debt service, business development, sales and marketing activities and our former early stage research activities. We have generated no revenues from sales of our own products and have been dependent upon funding primarily from equity and debt financing. We have not been profitable from product sales since inception and have incurred a cumulative net loss of \$257.6 million through December 31, 2003. Losses have resulted principally from costs incurred in research and development activities, write-off of acquired technology rights, general and administrative expenses, debt service and sales and marketing expenses. We expect to incur additional operating and net losses over the next several years.

Strategic Direction

In January 2004, we redefined our strategic direction to focus on development of later stage opportunities, to build specific franchises relating to our current development programs and to expand our product portfolio through the acquisition of complementary late stage or commercial product opportunities as a means to accelerate our path toward becoming a profitable pharmaceutical company. We intend to build franchises within narrowly focused prescribing groups. Initially we will focus on the transplant, hepatology and gastroenterology areas, using our clinical programs in cytomegalovirus (CMV) infections related to hematopoietic stem cell (bone marrow) transplantation, and hepatitis C (HCV), as foundations for that effort. Our CMV product candidate (maribavir, or VP41263) entered phase 1 clinical studies in January 2004. We expect to initiate phase 2 studies with maribavir in the second quarter of 2004. ViroPharma and Wyeth initiated phase 1 clinical trials of our lead product candidate for the treatment of hepatitis C in February 2004.

We intend to pursue aggressively in-licensing or other means of acquiring products in a late stage of clinical development, or that are currently on the market but are under-promoted or not currently promoted. We plan to seek products for diseases treated by physician specialists and in hospital settings to complement the markets that we hope our CMV and HCV programs will serve.

Strategic Risks and Uncertainties

We may not be successful in implementing our strategic direction. There are a variety of risks and uncertainties that we face in executing this strategy. We will face intense competition in acquiring products to expand our product portfolio. Many of the companies and institutions that we will compete with in acquiring products to expand our product portfolio have substantially greater capital resources, research and development staffs and facilities than we have, and substantially greater experience in conducting business development activities.

In implementing our strategic objectives, we expect to have sufficient cash available at the beginning of 2004 to fund our current business operations and debt service requirements until at least the end of 2006. However, the results of our business development efforts could cause our actual results to significantly deviate from this estimate. We may need additional financing in order to acquire new products in connection with our plans as described in this report. We are currently working to restructure our outstanding convertible subordinated notes. Even if we are successful in such restructuring, our outstanding convertible notes may make it more difficult for us to raise additional financing. We may not have sufficient resources to execute our plans, and our actual expenses over the period described in this report may vary depending on a variety

of factors, including:

- the cost of acquiring new product opportunities as a result of our business development efforts;
- the actual cost of conducting clinical trials;

Table of Contents

- the outcome of clinical trials in our CMV, HCV and intranasal pleconaril programs, and our resulting right to receive or obligation to pay milestone payments under agreements relating to those programs; and
- the costs associated with ongoing litigation.

Our ability to achieve profitability is dependent on developing and obtaining regulatory approvals for our product candidates, successfully commercializing such product candidates (which may include entering into collaborative agreements for product development and commercialization), and securing contract manufacturing services and distribution and logistics services. We will need to raise substantial additional funds to continue our business activities and fund our debt service obligations beyond 2006.

Recent Developments

In January 2004, we announced that we began to implement our strategic decision to focus on later stage opportunities. As part of this process, we substantially discontinued our early stage activities, including discovery research and most internal preclinical development activities. We also made reductions in clinical development and general and administrative personnel. We will complete certain discrete efforts related to our early stage programs in order to finalize the transition. Upon completion of these activities in mid-2004, we will have reduced our workforce by approximately 70% overall. We estimate that approximately \$9 million of costs related to this restructuring will be included in ViroPharma's 2004 financial results.

Our discontinuation of our early stage activities requires us to wind down our biodefense program in the coming months as part of the transition. We also ceased efforts to develop pleconaril for the treatment of serious or life-threatening diseases as part of this restructuring. We will continue to conduct initial studies of an intranasal formulation of pleconaril for the treatment of the common cold under our option agreement with Schering. We also will continue our HCV development efforts under our collaboration with Wyeth.

We initiated phase 1 clinical trials with maribavir, our CMV product candidate in January 2004. Together with Wyeth, we initiated Phase 1 clinical trials of our lead product candidate for the treatment of hepatitis C in February 2004.

2003 Key Events

In November 2003, we entered into an agreement granting Schering Corporation an option to license our intranasal formulation of the antiviral compound pleconaril for the treatment of the common cold in the United States and Canada. Schering paid us an upfront option fee of \$3 million, and we are conducting a series of clinical studies to evaluate the antiviral activity, safety and other performance characteristics of the new intranasal pleconaril formulation. After assessing the product's performance in the characterization studies, Schering has the option to enter into a full license agreement with us under which Schering would assume responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. If Schering chooses to exercise its option, we expect to receive an initial license fee of \$10 million and Schering will purchase our existing inventory of bulk drug substance for an additional pre-determined fee. We would also be eligible to receive additional milestone payments upon achievement of certain targeted events as well as royalties on Schering's sales of intranasal pleconaril in the licensed territory. There is no assurance that Schering will exercise its option to continue with the development and commercialization of an intranasal formulation of pleconaril. Schering's failure to exercise this option may cause us to abandon development work on this indication.

Edgar Filing: VIROPHARMA INC - Form 10-K

Also in November 2003, we further amended our agreement with Sanofi-Synthelabo in connection with our entry into the option agreement with Schering Corporation in respect of intranasal pleconaril. If Schering exercises its option to continue the development and commercialization of pleconaril, the November 2003 amendment, among other things, reduces the royalty rate applicable to future product sales, if any, used to calculate royalties payable to Sanofi-Synthelabo.

Table of Contents

In August 2003, we announced the acquisition of worldwide rights (excluding Japan) from GlaxoSmithKline to an antiviral compound (maribavir, or VP41263) that is an inhibitor of cytomegalovirus (CMV). Maribavir is a benzimidazole compound that was originally intended as a treatment for CMV retinitis, and phase 1 data from studies previously conducted by GlaxoSmithKline demonstrated antiviral effect and a favorable safety profile. Under the terms of the agreement, we have exclusive worldwide rights (excluding Japan) to develop and commercialize maribavir for the prevention and treatment of cytomegalovirus infections related to transplant (including solid organ and hematopoietic stem cell transplantation), congenital transmission, and in patients with HIV infection. We plan to focus initially on patients who have undergone allogeneic stem cell (e.g., bone marrow) transplantation. We paid GlaxoSmithKline a \$3.5 million licensing fee upon entering into the agreement and may pay additional milestones based upon the successful outcome of certain clinical development and regulatory events. We also may pay royalties to GlaxoSmithKline and its licensor on product sales, if any, in the United States and the rest of the world (excluding Japan). This product candidate currently is in phase 1 clinical studies, and we expect to initiate a phase 2 clinical trial in the second quarter of 2004. The \$3.5 million up-front licensing fee was recorded as an acquisition of technology rights expense during 2003, as the underlying technology has not reached technological feasibility and has no alternative uses.

In June 2003, we amended our HCV collaboration agreement with Wyeth to, among other things, focus the parties' screening activity on one target, to allocate more of the collaboration's pre-development efforts to ViroPharma (subject to our cost sharing arrangement with Wyeth for this work), and to clarify certain of the reconciliation and reimbursement provisions of the collaboration agreement. In addition, under the amended agreement both companies are permitted to work outside the collaboration on screening against targets other than the target being addressed together under the collaboration. In connection with our restructuring in January 2004, we and Wyeth agreed to cease screening compounds against HCV under our collaboration.

In March and May 2002, complaints were filed in the United States District Court for the Eastern District of Pennsylvania against us seeking an unspecified amount of damages on behalf of an alleged class of persons who purchased shares of our common stock at various times between July 13, 1999 and March 19, 2002. In July 2002, the complaints were consolidated into a single action. The consolidated complaint names us, as well as certain of our directors and officers, as defendants. The consolidated complaint alleges that we and/or such directors and officers violated federal securities laws by misrepresenting and failing to disclose certain information regarding Picovir® (pleconaril). In August 2002, we filed a motion to dismiss the consolidated complaint. In April 2003, the court granted in part and denied in part the Company's motion to dismiss the consolidated complaint. In December 2003, we filed a motion for partial summary judgment of this action and a memorandum opposing the certification of the plaintiffs' class action status. In March 2004, we entered into an agreement in principle with plaintiffs' counsel to settle this litigation. The proposed settlement will be paid from our insurance coverage and will not result in the payment of any funds by us. However, the proposed settlement is subject to the approval of the court. If the proposed settlement is not approved by the court, then the range of possible resolutions of these proceedings could include judgments against us or our directors or officers or settlements that could require substantial payments by us, which could have a material adverse impact on our financial position, results of operations and cash flows. These proceedings might require substantial attention of our management team and therefore divert time and attention from our business and operations.

Liquidity and Capital Resources

Other than detailing fees from discontinued sales operations earned in the first eight months of 2002 for promoting products owned by Aventis, we have not generated revenues from product sales. We expect that our near term source of revenue will arise from milestone and license fee payments that we may receive from Wyeth and Schering if we achieve agreed upon events under our agreements with each of these companies. However, there are no assurances that we can achieve the events that require payments to us under the Wyeth and Schering arrangements.

The cash flows we have used in operations historically have been applied to research and development activities, marketing and business development efforts, general and administrative expenses, and servicing our debt. The process of bringing drugs from the preclinical research and development stage through Phase 1, Phase 2, and Phase 3 clinical trials and FDA approval is a time consuming and expensive process. Because our

Table of Contents

product candidates are currently in the preclinical and clinical stages of development, there are a variety of events that could occur during the development process that will dictate the course we must take with our drug development efforts and the cost of these efforts. As a result, we cannot reasonably estimate the costs that we will incur through the commercialization of any product candidate. Nonetheless, we expect that the most significant uses of our near-term operating cash flows will be:

- ***Development activities in our CMV program*** Through December 31, 2003, we have not incurred material expenses in connection with this program, other than the acquisition fee of \$3.5 million paid to GSK for the rights to maribavir (VP41263). During 2004, we expect to spend between \$9.0 million and \$11.0 million for research and development activities for the development of maribivir. These activities include phase 1 studies with maribavir, initiated in January 2004, and a phase 2 study that we expect to initiate during the second quarter of 2004. The results of these studies will significantly impact the timing and the amount of expenses, including potential milestone payments to GSK, we incur related to this program in future years. In addition, discussions with the FDA regarding planned future studies may impact the timing, nature and cost of future planned studies. We are solely responsible for the cost of developing our CMV product candidate. Should we achieve certain product development events, we are obligated to make certain milestone payments to GlaxoSmithKline, the licensor of maribavir
- ***Predevelopment and development activities with our HCV program*** During 2004 we expect to spend between \$1.5 million and \$3.0 million on predevelopment and development activities. The planned activities include a phase 1 clinical trial in our HCV program, initiated in February 2004, a phase 1b clinical trial and other predevelopment activities. These activities are performed in collaboration with Wyeth, who pays a substantial portion of the collaboration's predevelopment and development expenses. The results of the planned studies, along with other predevelopment activities performed during the year, will significantly impact the timing and amount of expenses we will incur related to this program in future years. Should we achieve certain product development events, Wyeth is required to pay us certain cash milestones and to purchase, in cash, our common stock pursuant to terms of our collaboration agreement. Based on the activities planned by Wyeth and us, there is the potential to achieve these milestones in 2004 or 2005.
- ***Business development activities*** During 2004, we intend to seek new opportunities to expand our pipeline. The costs associated with acquiring any particular product candidate can vary substantially based upon market size of the product, the commercial effort required for the product, the product's current stage of development, the market's potential for generic competition and the market's barriers to non-generic competition, among other factors. Due to the variability of the cost of acquiring a product candidate, it is not feasible to predict what our actual acquisition costs would be, however, the costs could be substantial.
- ***Intranasal pleconaril*** We are conducting studies intended to evaluate the safety, antiviral activity and other performance characteristics of an intranasal formulation of pleconaril which we began development of in 2003. We expect these activities to be completed in mid-2004. In the third quarter of 2003, we received \$3 million under our option agreement with Schering Corporation (Schering) which we will use to fund these studies. We do not expect the costs of the studies to exceed the payment made by Schering during 2003. Should Schering choose to enter into a license agreement with us, Schering will be solely responsible for the future development and commercialization of pleconaril, and we could receive an upfront payment of \$10 million in 2004, as well as an additional pre-determined fee for our existing inventory of bulk drug substance. In addition, should Schering be successful in commercializing the intranasal formulation of pleconaril, we would receive royalties and milestones related to future product sales, if any.
- ***General and Administrative activities*** We expect to spend between \$7.0 and \$9.0 million on general and administrative activities in 2004. This includes costs related to unused office space that we are actively looking to sub-lease.
- ***Payment of our debt service requirements*** Annual interest payments on our outstanding \$127.9 million 6% convertible subordinated notes due 2007 total \$7.7 million.

Table of Contents

We cannot reasonably estimate the period in which we will begin to receive material net cash inflows from our product candidates. Cash inflows from development-stage products are dependent on several factors, including the achievement of milestones and regulatory approvals. We may not receive milestone payments from any existing or future collaborations if a development-stage product fails to meet technical or performance targets or fails to obtain the required regulatory approvals. Further, our revenues from collaborations will be affected by efforts of our collaborative partners. Even if we achieve technical success in developing drug candidates, our collaborative partners may not devote the resources necessary to complete development and commence marketing of these products, when and if approved, or they may not successfully market these products.

Through December 31, 2003, we have used approximately \$243.2 million of cash in operating activities. We invest our cash in short-term investments. Through December 31, 2003, we have used approximately \$125.1 million in investing activities, including \$108.3 million in short-term investments and \$16.8 million in equipment purchases and new construction. Through December 31, 2003, we have financed our operations primarily through private and public offerings of common stock, a convertible subordinated notes offering, private placements of redeemable preferred stock, two bank loans and equipment lease lines totaling approximately \$381.3 million, net of approximately \$18.5 million used to repurchase \$50.1 million in principal amount of our 6% convertible subordinated notes due 2007, and 473,054 shares of our common stock in exchange for the surrender of \$2.0 million in face amount of such notes.

During the twelve months ended December 31, 2003 we used approximately \$34.2 million of cash in operating activities. We invest our cash in short-term investments. For the twelve months ended December 31, 2003, cash provided by investing activities was approximately \$33.3 million, including \$34.3 million from short-term investments, net of \$1.0 million in equipment purchases. For the twelve months ended December 31, 2003, we have used approximately \$2.2 million of cash in financing activities, which primarily relates to \$2.1 million in cash used to repurchase \$5.0 million in principal amount of our 6% convertible subordinated notes due 2007. At December 31, 2003, we had cash and cash equivalents and short-term investments aggregating approximately \$121.1 million. Also, at December 31, 2003 the annualized weighted average nominal interest rate on our short-term investments was approximately 0.91%.

Future contractual obligations and commercial commitments at December 31, 2003 are as follows:

Contractual Obligations	Payments due by period				
	Total	(in millions)			
		Less than 1 year	2-3 years	4-5 years	More than 5 years
Long-term debt	\$ 127.9	\$ 0.0	\$ 0.0	\$ 127.9	\$ 0.0
Capital lease obligations	0.0	0.0	0.0	0.0	0.0
Operating leases	15.6	1.8	3.4	3.5	6.9
Purchase obligations	0.0	0.0	0.0	0.0	0.0
Other long-term liabilities reflected on the registrant's balance sheet under GAAP	0.0	0.0	0.0	0.0	0.0
Total	\$ 143.5	\$ 1.8	\$ 3.4	\$ 131.4	\$ 6.9

We lease an aggregate of 119,000 square feet in two facilities for our corporate and development activities under operating leases expiring in 2008 and 2017, respectively. We also have the right, under certain circumstances, to purchase the facility leased through 2008. During the third quarter of 2003, we determined that we would not utilize 30,000 square feet of this aggregate leased space and we recognized a non-cash charge

Edgar Filing: VIROPHARMA INC - Form 10-K

of approximately \$1.7 million in our general and administrative expenses relating to this space. Following our restructuring in January 2004, we further reduced our space requirements and will record the appropriate non-cash charge relating to our facilities in 2004. We are currently seeking to sublease all unused space. We cannot be certain that we will be able to sublease our unused space on favorable terms or at all.

Table of Contents

As a result of our restructuring in January 2004, particularly the discontinuation of our early stage activities, we expect our monthly expenses and operating losses in 2004 to be lower than we experienced during 2003, and we expect to have sufficient cash available at the beginning of 2004 to fund our current business operations and debt service requirements until at least the end of 2006. We expect that we will need to raise substantial additional funds to continue our business activities and fund our debt service and other obligations beyond 2006. To obtain this financing, we intend to access the public or private equity or debt markets or enter into additional arrangements with corporate collaborators to whom we may issue shares of our stock. We have an effective Form S-3 universal shelf registration statement filed with the Securities and Exchange Commission for the potential additional issuance of up to approximately \$212.0 million of our securities. The registration statement provides us with the flexibility to determine the type of security we choose to sell, including common stock, preferred stock, warrants and debt securities, as well as the ability to time such sales when market conditions are favorable. In order for us to issue securities registered on this registration statement we must either have an aggregate market value of the voting and non-voting common equity excluding shares held by our affiliates of \$75 million or more as of the date of our most recently filed annual report on Form 10-K, or we must file a post effective amendment to the registration statement on Form S-2 or S-1.

If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of existing stockholders.

Additional financing, however, may not be available on acceptable terms from any source as a result of, among other factors, our outstanding convertible subordinated notes due 2007, our inability to achieve regulatory approval of any of our product candidates, our inability to generate revenue through our existing collaborative agreements, the existence of pending litigation involving allegations of securities fraud, and our inability to file, prosecute, defend and enforce any patent claim and or other intellectual property rights. If sufficient additional financing is not available, we may need to delay, reduce or eliminate current development programs, or reduce or eliminate other aspects of our business.

Additionally, Wyeth is required to purchase our common stock at the time of successful completion of certain product development events pursuant to the terms of our collaboration agreement. However, in the event we are not able to successfully achieve the product development events, this additional financing would not be available to us.

In order to improve our capital structure, we are currently working to restructure our existing outstanding convertible subordinated notes. Through December 31, 2003 we have reduced the principal amount of our 6% convertible subordinated notes due in 2007 by \$52.1 million and the outstanding balance of our convertible subordinated notes payable at December 31, 2003 is \$127.9 million. We have purchased an aggregate of \$50.1 million in principal amount of our convertible subordinated notes for approximately \$18.5 million in cash through December 31, 2003. In October and November 2003, we entered into agreements with a third party under which we issued a total of 473,054 shares of our common stock in exchange for the surrender of \$2.0 million of face amount of our 6% convertible subordinated notes held by such third party. As a result of our reduction of \$52.1 million in principal amount of our outstanding 6% convertible subordinated notes through December 31, 2003, our annual interest expense will be reduced by approximately \$3.1 million when compared to our original issuance interest expense. A restructuring of the notes may involve significant dilution of the ownership of existing stockholders. There can be no assurance that we will be able to restructure these notes on favorable terms or at all, or that we will be able to effect future purchases of any additional notes at prices favorable to us, or at all.

Critical Accounting Policies

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Preparing consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and

Table of Contents

expenses and contingent assets and liabilities. These estimates and assumptions are affected by the application of our accounting policies. Critical policies and practices are both most important to the portrayal of a company's financial condition and results of operations, and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Our summary of significant accounting policies is described in Note 2 to our financial statements included in Item 8 of this Form 10-K. Due to the nature of our business and our stage of development, we do not currently face the many complex or subjective judgments that face companies that are further along in their life cycle that may be necessary in applying accounting policies. However, we consider the following policies and estimates to be the most critical in understanding the more complex judgments that are involved in preparing our financial statements and the that could impact our results of operations, financial position, and cash flows:

- **Stock Based Employee Compensation** We apply APB Opinion No. 25, Accounting for Stock Issued to Employees and related interpretations (APB 25) in accounting for all stock-based employee compensation. We have elected to adopt only the disclosure provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. Had we applied SFAS 123 our net loss allocable to common stockholders for the years ended December 31, 2001, 2002 and 2003 would have been increased by approximately \$10.2 million, \$11.7 million, and \$7.6 million, respectively.
- **Revenue Recognition** Our revenue from collaborative agreements consists of up-front fees, and milestone payments. We recognize revenues from these agreements consistent with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104), issued by the Securities and Exchange Commission. Non-refundable upfront fees are deferred and recognized as revenue over the related performance period. We estimate our performance period based on the specific terms of each collaborative agreement, but the actual performance period may vary. We adjust the performance periods based on available facts and circumstances. Contract milestone payments related to the achievement of substantive steps or regulatory events in the development process are recognized as revenues upon the completion of the milestone event or requirement.
- **Restructuring Charges** In 2003, we had costs for which we applied Statement of Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146). These costs related to exiting activities for which there was significant subjectivity and judgment and their impact on our financial condition was material. During 2003, we recorded a \$1.7 million charge related to an operating lease for office space for which we did not expect to utilize in the foreseeable future. The charge was an estimate of the present value of the loss we will incur over the remaining life of the lease, which is 14 years, net of assumed sublease income of \$8.4 million beginning in the fourth quarter of 2004. Management used assumptions in calculating this estimate, including operating and maintenance costs, lease payments and sublease income derived from this office space. Should we negotiate higher than expected sublease rental income agreements, reach a settlement with our lessors to be released from our existing obligations, or should our space requirements change we could realize a favorable benefit to our results of future operations. Should future lease, maintenance or other costs related to these facilities exceed our estimates, we could incur additional expenses in future periods. Following our restructuring in January 2004, we further reduced our space requirements and will record an appropriate charge consistent with SFAS 146, as necessary, at the cease-use date for the facility we currently occupy. We also will reduce the liability recorded in 2003 related to office space that we previously believed we would not occupy. We currently expect to move into a portion of this space in the second quarter of 2004. We are currently seeking to sublease all planned unused space to third parties. We cannot be certain that we will be able to sublease our planned unused space on favorable terms or at all.

Table of Contents

As we progress in our development and move closer to product approval and commercial operations, we may face additional issues that will require increased levels of management estimation and complex judgments.

Results of Operations

Years ended December 31, 2003 and 2002

The net loss allocable to common stockholders increased to approximately \$36.9 million for the year ended December 31, 2003 from a loss of approximately \$15.8 million for the year ended December 31, 2002. Net loss allocable to common stockholders per share for the year ended December 31, 2003 was \$1.43 per share compared to a loss allocable to common stockholders of \$0.66 per share for the same period in 2002.

The loss from continuing operation increased to approximately \$36.9 million for the year ended December 31, 2003 from a loss of approximately \$26.6 million for the year ended December 31, 2002. Loss per share from continuing operations for the year ended December 31, 2003 was \$1.43 per share compared to a loss per share from continuing operations of \$1.11 per share for the same period in 2002. During the year ended December 31, 2003, the Company recognized a gain of \$3.6 million, net of the write-off of \$0.1 million in deferred financing costs, related to the reduction of \$7.0 million in principal of its outstanding 6% convertible subordinated notes due 2007. During the year ended December 31, 2002, the Company recognized a gain of \$27.9 million, net of the write-off of \$0.8 million in deferred financing costs, related to the reduction of \$45.1 million in principal of its outstanding 6% convertible subordinated notes due 2007.

Revenues from continuing operations were approximately \$1.6 million for the year ended December 31, 2003, compared to approximately \$5.5 million during the same period in 2002. During the year ended December 31, 2003, we recognized license fee and milestone revenue from advance payments received under our collaborations with Wyeth and Schering that totaled \$0.6 million and \$0.5 million, respectively. During the same period to 2002, license fee and milestone revenue included an accelerated recognition of \$4.0 million of deferred revenue as a result of the termination of the co-promotion and co-development agreement with Aventis Pharmaceuticals, Inc. in August 2002, \$0.7 million in deferred revenue from the advance payment from Aventis recognized prior to the termination of co-promotion and co-development agreement, and \$0.6 million from advance payments received under our collaboration with Wyeth.

Research and development expenses decreased approximately \$16.8 million to \$23.0 million during the year ended 2003 from \$39.8 million during the same period in 2002. This reduction in research and development expenses included a \$7.2 million reduction in development and manufacturing expenses related to pleconaril, a \$5.1 million reduction in development expenses related to our respiratory syncytial virus (RSV) program which we discontinued in January 2003, a \$2.2 million reduction in research and development expenses related to our collaboration with Wyeth, a \$0.7 million reduction in costs previously borne by Wyeth as a result of our June 2003 amendment, a \$1.3 million reduction in research and development compensation expenses, a \$0.4 million reduction in severance costs related to the August 2002 restructuring, and a \$0.8 million reduction in employee related and other research and development expenses. Offsetting these expense reductions was a \$0.9 million increase in research and development facility costs. During the year ended December 31, 2003, our research and development activities included:

- preparing for the initiation of phase 1 clinical trials in our CMV and hepatitis C programs;
- activities related to exploring the feasibility of pursuing the development of pleconaril for the treatment of serious and life-threatening diseases caused by enterovirus infections;

Edgar Filing: VIROPHARMA INC - Form 10-K

- activities related to developing an intranasal formulation of pleconaril for the treatment of the common cold; and
- discovery research.

In comparison, during 2002 our primary research and development focus related to:

- manufacturing and development of pleconaril for the treatment of the common cold;
- pre-clinical activities in HCV being performed at Wyeth;

Table of Contents

- the preparation of an investigational new drug application (IND) for an HCV product candidate;
- conducting one phase 1 study for the treatment of RSV disease; and
- discovery research.

In September 2003, we paid GlaxoSmithKline a \$3.5 million license fee in connection with our agreement for the worldwide rights (excluding Japan) to maribavir, or VP41263, an inhibitor of cytomegalovirus (CMV). This fee was recognized as an acquisition of technology rights and was expensed during 2003.

During the year ended December 31, 2003, we had no marketing expenses. During the same period in 2002, we incurred \$6.8 million in marketing expenses related to pleconaril as a result of our joint marketing efforts with Aventis Pharmaceuticals Inc. This reduction is due to the termination of the collaboration with Aventis in August 2002. Of the marketing costs incurred during 2002, \$0.3 million related to a restructuring severance charge, and the remaining \$6.5 million represented pleconaril marketing costs.

General and administrative expenses for 2003 of approximately \$9.0 million increased \$1.2 million when compared to the \$7.8 million from the same period in 2002. The increase is primarily due to a non-cash charge of \$1.7 million for a lease associated with our unused office space, and \$0.7 million in expenses related to business development efforts undertaken during 2003. These additional costs are offset by a \$0.7 million reduction in general and administrative compensation expenses, a \$0.4 million reduction in severance costs related to the August 2002 restructuring, and a \$0.1 reduction in other general and administrative expenses.

Interest expense for 2003 decreased to \$8.4 million from \$11.0 million in the same period in the prior year due to the reduction of \$28.4 million in principal amount of our convertible subordinated notes in 2003 and the fourth quarter of 2002. Interest income fell approximately \$3.6 million to \$1.8 million during 2003 when compared to the same period in 2002 primarily due to lower invested balances and lower effective yields on investments due to the relatively lower interest rate environment during the current year versus the prior year.

We discontinued our sales force operations in the third quarter of 2002 as a result of the sale of our sales force to Aventis. Our income from discontinued sales operations for 2002 was \$10.8 million. This included a \$15.4 million gain on sale of the sales force to Aventis, detailing fee revenue of \$17.2 million, \$2.6 million in costs related to both the severance of personnel and the termination of operational commitments related to the sales force and \$19.2 million in sales operations costs. There were no sales force operations during 2003.

Years ended December 31, 2002 and 2001

The net loss allocable to common stockholders decreased to approximately \$15.8 million for the year ended December 31, 2002 from a loss of approximately \$83.3 million for the year ended December 31, 2001. Included in the net loss allocable to common stockholders for the year ended December 31, 2001 was \$0.3 million of dividends paid on preferred stock, which was converted to common stock in May 2001.

Edgar Filing: VIROPHARMA INC - Form 10-K

The loss from continuing operations decreased to approximately \$26.6 million for the period ended December 31, 2002 from a loss of approximately \$78.5 million for the year ended December 31, 2001. During 2002, we recognized a gain on the repurchase of our convertible subordinated notes during the 2002 of approximately \$27.9 million, net of the write-off of \$0.8 million in related deferred financing costs. The repurchase resulted in a \$45.1 million reduction in the principal amount of our outstanding debt.

Revenues from continuing operations were approximately \$5.5 million for the year ended December 31, 2002, compared to approximately \$3.4 million during the same period in 2001. During the year ended December 31, 2002, we recognized license fee and milestone revenue of approximately \$5.3 million from advance payments received under our collaborations with Wyeth and Aventis, compared to recognizing license fee and milestone revenue of approximately \$3.4 million from advance payments received under our collaboration agreements during the same period in 2001. License fee and milestone revenue recognized for the year ended

Table of Contents

December 31, 2002 included an accelerated recognition of \$4.0 million of deferred revenue as a result of the termination of the co-promotion and co-development agreement with Aventis in August 2002. In addition, the revenue recognized from our collaboration with Wyeth was lower in 2002 because the performance period over which we recognized the Wyeth deferred revenue was increased to reflect the extension of the agreement in May 2002.

Research and development expenses decreased approximately \$3.2 million to \$39.8 million during the year ended 2002 from \$43.0 million during the same period in 2001. This reduction in research and development expenses included a \$8.9 million decrease in costs related to pleconaril, net of a decrease in partner reimbursements of \$0.2 million, resulting from the termination of our collaboration with Aventis in August 2002. Also included in this reduction of research and development expenses was an approximately \$0.4 million decrease in employee-related costs, due to lower head-count resulting from our restructuring in August 2002, during the year ended December 31, 2002 when compared to the same period in 2001. Partially offsetting these decreases was a \$0.4 million charge as part of our restructuring plan announced in August 2002, a \$1.4 million increase in manufacturing costs, a \$0.9 million increase in discovery research costs, a \$0.9 million increase in costs related to pre-clinical activities being performed at Wyeth and the preparation of an IND for our HCV product candidate, a \$2.1 million increase in costs related to our RSV disease drug candidate and \$0.4 in other costs. During the quarter ended December 31, 2002, we decided to discontinue the development of our phase 1 and pre-clinical RSV compounds.

Included in operating expenses in the twelve month period ended December 31, 2001 is a non-cash charge of \$16.5 million resulting from the issuance of 750,000 shares of common stock to Sanofi-Synthelabo in exchange for the expansion of our intellectual property rights related to pleconaril, as these additional intellectual property rights licensed from Sanofi-Synthelabo had not reached technological feasibility and had no alternative uses.

Marketing expenses for 2002 were approximately \$6.8 million, which includes Aventis cost sharing of \$1.4 million, compared to approximately \$11.8 million, which includes Aventis cost sharing of \$2.4 million, for the same period of 2001. This reduction was due to the termination of the collaboration with Aventis. Of the marketing costs incurred during 2002, \$0.3 million related to a restructuring severance charge, and the remaining \$6.5 million represented pleconaril marketing costs.

General and administrative expenses for 2002 of approximately \$7.8 million decreased \$3.4 million when compared to the \$11.2 million from the same period in 2001. The decrease is primarily due to costs incurred during the third quarter of 2001 in completing the pleconaril co-promotion and co-development agreement with Aventis. Included in the \$7.8 million of the general and administration expenses for 2002 is a restructuring severance charge of \$0.4 million.

Interest expense for December 31, 2002 decreased slightly when compared to the same period in the prior year due to the repurchase of \$45.1 million of our convertible subordinated notes in the second half of 2002. Interest income fell approximately \$6.9 million during 2002 when compared to the same period in 2001 primarily due to lower invested balances and lower effective yields on investments due to the relatively lower interest rate environment during the current year versus the prior year.

We discontinued our sales force operations in the third quarter of 2002 as a result of the sale of our sales force to Aventis. Our income from discontinued sales operations for 2002 was \$10.8 million. This included a \$15.4 million gain on sale of the sales force to Aventis, detailing fee revenue of \$17.2 million, \$2.6 million in costs related to both the severance of personnel and the termination of operational commitments related to the sales force and \$19.2 million in sales operations costs. Costs associated with the discontinued operations for the same period in 2001 were \$4.5 million and related primarily to sales force start-up activities.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Table of Contents

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our holdings of financial instruments are comprised of a mix of U.S. corporate debt, government securities and commercial paper. All such instruments are classified as securities available for sale. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. Our primary investment objective is the preservation of principal, while at the same time maximizing the generation of investment income. We seek reasonable assuredness of the safety of principal and market liquidity by investing in cash equivalents (such as Treasury bills and money market funds) and fixed income securities (such as US government and agency securities, municipal securities, taxable municipals, and corporate notes) while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. Historically, we have typically invested in financial instruments with maturities less than one year. The carrying amount and the annualized weighted average nominal interest rate of our investment portfolio at December 31, 2003 was approximately \$108.2 million and approximately 0.91%, respectively.

As of December 31, 2003 we had \$127.9 million in principal amount of outstanding convertible subordinated notes due in 2007. The notes are convertible into shares of our common stock at a price of \$109.15 per share, subject to certain adjustments. The notes bear interest at a rate of 6% per annum, payable semi-annually in arrears, and can be redeemed by us, at certain premiums over the principal amount, at any time on or after March 6, 2003. At December 31, 2003, the aggregate market price of our convertible subordinated notes was estimated to be approximately \$86.3 million based on trading prices on that date. The value of our convertible subordinated notes is dependant upon, among other factors, the fair value of our common stock and prevailing market interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements of the Company required by this item are attached to this Report beginning on page 60.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) An evaluation was performed under the supervision and with the participation of the Company's management, including its Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, of the effectiveness of the Company's disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act) as of December 31, 2003. Based on that evaluation, the Company's management, including the CEO and CFO, concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported as specified in Securities and Exchange Commission rules and forms.

(b) There were no significant changes in the Company's internal control over financial reporting identified in connection with the evaluation of such controls that occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents**PART III****ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT****Board of Directors**

Our board of directors currently consists of 6 directors. The board consists of three classes of directors, with each director serving a two-year term. Each year, one class of directors is subject to stockholder vote. At our May 21, 2004 annual meeting, stockholders will vote on the election of two class II directors. Each class II director elected at the annual meeting will serve until the 2007 annual meeting of stockholders and until such director's successor has been elected and qualified, except if the director resigns, is removed or dies before such time.

Class II members are Michel de Rosen and William D. Claypool, M.D. Mr. de Rosen and Dr. Claypool are the director nominees for election to the board of directors at the May 21, 2004 annual meeting. Class I members presently are Paul A. Brooke, Robert J. Glaser and Michael R. Dougherty, and the Class III member is Frank Baldino, Jr., Ph.D.

Described below is certain information regarding each director, including the nominees. Each of the members of the board of directors is independent as defined by the Nasdaq corporate governance listing standards other than Mr. de Rosen who is our Chief Executive Officer. Each of the Class II nominees was nominated by the vote of the entire board of directors.

Name	Director Since	Age
Class II Directors		
Michel de Rosen	May 2000	53
William D. Claypool, M.D.	December 2003	53
Class I Directors		
Paul A. Brooke	February 2001	58
Robert J. Glaser	August 1997	51
Michael R. Dougherty	January 2004	46
Class III Directors		
Frank Baldino, Jr., Ph.D.	June 1995	50

Class II Nominees with Terms Continuing until 2004

Michel de Rosen. Mr. de Rosen has served as our chairman of the board of directors since September 2002, President and Chief Executive Officer since August 2000, and as a director since May 2000. From 1993 to 1999, Mr. de Rosen held several key positions in Rhone-Poulenc Pharma and Rhone-Poulenc Rorer (now Aventis), including chairman and Chief Executive Officer from May 1995 until December 1999. Mr. de Rosen began his career at the French Ministry of Finance and subsequently served in several leading government positions. Mr. de Rosen also served in various executive roles in industry prior to 1993. Mr. de Rosen also is a director of ABB Ltd.

William D. Claypool, M.D. Dr. Claypool has served as one of our directors since December 2003. Dr. Claypool serves as Chief Executive Officer and Chairman of the Board of Phoenix Data Systems, Inc. From January 2001 to June 2001, he served as President and CEO of The GI Company. From 1991 to 2001 Dr. Claypool held a number of management positions with SmithKline Beecham Pharmaceuticals, serving from November 1998 to December 2000 as Senior Vice-President and Director of Worldwide Clinical Development and Medical Affairs. Dr. Claypool received his medical degree from the University of Connecticut School of Medicine.

Table of Contents

Class I Directors for Terms Continuing until 2006

Paul A. Brooke. Mr. Brooke has served as one of our directors since February 2001. Mr. Brooke currently is a managing member of PMSV Holdings LLC, a partner of MPM Bioventures and an advisory director of Morgan Stanley & Co. He was a managing director at Tiger Management LLC from April 1999 to May 2000. Mr. Brooke was a managing director at Morgan Stanley Dean Witter and was global head of healthcare research and strategy from March 1983 to April 1999. Mr. Brooke also is a director of WebMD.com and Incyte Corporation.

Robert J. Glaser. Mr. Glaser has served as one of our directors since August 1997. Mr. Glaser is Executive Vice President of Sales and Marketing of Ancillary Care Management, a healthcare management company. During 2003, Mr. Glaser was Senior Vice President, Caliber Associates. From 2001 to 2002, Mr. Glaser was a consultant to the biotechnology and pharmaceutical industries. From 1998-2001, Mr. Glaser was President of the McKesson HBOC Pharmaceutical Services division of McKesson HBOC. He was President and Chief Operating Officer of Ostex International from 1996-1997. Mr. Glaser was Senior Vice President of Marketing for Merck U.S. Human Health from 1994-1996, Vice President of Marketing from 1993-1994 and Vice President of Merck's Vaccine Division from 1991-1993.

Michael R. Dougherty. Mr. Dougherty has served as one of our directors since January 2004. Mr. Dougherty is Senior Vice President, Chief Operating Officer, Chief Financial Officer and Treasurer of Adolor Corporation, a biopharmaceutical company committed to the development of novel analgesics and other related therapeutics. Mr. Dougherty joined Adolor in November 2002 as its Senior Vice President of Commercial Operations. From November 2000 to November 2002, Mr. Dougherty was President and Chief Operating Officer of Genomics Collaborative, Inc., a privately held functional genomics company. From March 1995 to November 2000, he served in a variety of senior positions at Magainin Pharmaceuticals, Inc. (now known as Genaera Corporation), including, from August 1998 to November 2000, President and Chief Executive Officer.

Frank Baldino, Jr., Ph.D. Dr. Baldino has served as one of our directors since June 1995. Since 1987, he has served as President, Chief Executive Officer and director of Cephalon, Inc., an integrated specialty biopharmaceutical company committed to the discovery, development and marketing of products to treat neurological disorders and cancer. Dr. Baldino is also a director of Pharmacopeia, Inc.

Audit Committee

The audit committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent auditors, (ii) appointing, replacing and discharging the independent auditors, (iii) pre-approving the professional services provided by the independent auditors, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditors, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditors. The current members of the audit committee are Mr. Dougherty (chairman), Dr. Baldino and Mr. Brooke, each of whom meet the definition of an independent as set forth in the Nasdaq corporate governance listing standards and the rules of the Securities and Exchange Commission. The board of directors has determined that Mr. Dougherty is an audit committee financial expert, as defined by the rules of the Securities and Exchange Commission.

Director Nominations

Edgar Filing: VIROPHARMA INC - Form 10-K

The board of directors seeks director candidates based upon a number of qualifications, including their independence, knowledge, judgment, character, leadership skills, education and experience. The board particularly emphasizes significant experience in the pharmaceutical and biotechnology industries. The entire board of directors currently serves as our nominating committee, however, the board of directors intends to establish a standing nominating committee in the coming months as well as a process for permitting stockholders

Table of Contents

to communicate with the board of directors. The nominating committee charter and shareholder communications policy will be posted on our website at www.viropharma.com upon adoption.

As part of the process of selecting board candidates, the board reviews the appropriate skills and characteristics required of board members. The board does not generally rely upon third-party search firms to identify board candidates. Instead, it relies on recommendations from a wide variety of its business contacts, including current executive officers, directors and stockholders, as a source for potential board candidates. The board of directors evaluates the above criteria as well as the current composition of the board of directors and the need for audit committee expertise. The board of directors then nominates the candidates which it believes best suit the needs of the company.

The board of directors will consider stockholder recommendations for directors sent to the General Counsel and Secretary, ViroPharma Incorporated, 405 Eagleview Boulevard, Exton, Pennsylvania 19341. Stockholder recommendations for directors should include (i) the name and address of the stockholder recommending the person to be nominated, (ii) a representation that the stockholder is a holder of record of stock of ViroPharma, including the number of shares held and the period of holding, (iii) a description of all arrangements or understandings between the stockholder and the recommended nominee, (iv) such other information regarding the recommended nominee as would be required to be included in a proxy statement filed pursuant to Regulation 14A promulgated by the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended and (v) the consent of the recommended nominee to serve as a director of ViroPharma if so elected. Stockholders' nominees that comply with these procedures will receive the same consideration that other nominees receive.

Compensation of Directors

Directors that are non-executive officers of ViroPharma, and directors that are not affiliated with a person or entity that has been granted a contractual right to appoint a director to the board of directors, receive a cash retainer of \$7,500 annually. These directors shall receive \$1,500 for each board meeting, and \$1,000 (\$1,500 for committee chairs) for each committee meeting, that they attend, plus travel expenses.

Directors that are non-executive officers of ViroPharma, and directors that are not affiliated with a person or entity that has been granted a contractual right to appoint a director to the board of directors, receive an option grant of 20,000 shares, vesting in equal increments over 3 years, upon his or her initial election to the Board. These directors also shall receive option grants once each year to purchase 10,000 shares of our common stock. Dr. Claypool received 20,000 share option grants in December 2003 upon his election to the Board. Mr. Dougherty received 20,000 share option grants in January 2004 upon his election to the Board. Each director other than Mr. de Rosen received option grants in February 2003 to purchase 10,000 shares of our common stock.

Annual grants to these directors shall not be exercisable if the director attends less than 75% of the combined number of Board meetings and meetings of Committees of which he or she is a member that are held during the year of grant. Otherwise, the annual grant shall vest and be exercisable for the number of shares that is equal to 10,000 shares times the percentage of the combined number of Board and Committee meetings of which he or she is a member that the director actually attended in the year of grant. For purposes of vesting, a director shall be deemed to have attended any meeting that he or she is recused from attending in order to avoid a potential conflict of interest.

Each of our directors and officers are parties to indemnification agreements with us. Under these agreements, they will be indemnified against liabilities and expenses incurred in connection with their services to us to the fullest extent permitted by Delaware law. Their indemnification rights are subject to each director and officer meeting the applicable standard of care and to a determination to indemnify by a majority of disinterested directors or by independent counsel.

Table of Contents**Executive Officers**

The following is a list of our executive officers, including their ages, as of February 28, 2004 as well as certain information regarding each officer, except Michel de Rosen, whose information may be found under the heading Board of Directors :

Name	Age	Position
Michel de Rosen	53	President, Chief Executive Officer and Chairman of the Board of Directors
Thomas F. Doyle	43	Vice President, General Counsel and Secretary
Richard A. Farley	47	Vice President, Human Resources
Mark A. McKinlay, Ph.D.	52	Vice President, Research & Development
Vincent J. Milano	40	Vice President, Chief Financial Officer and Treasurer

Thomas F. Doyle has served as Vice President, General Counsel of ViroPharma since November 1997, as Secretary since February 1997 and as Executive Director, Counsel since joining ViroPharma in November 1996. From 1990 until 1996, Mr. Doyle was a corporate attorney with the law firm of Pepper, Hamilton LLP. Mr. Doyle received his J.D. from Temple University School of Law. Prior to attending Temple University, Mr. Doyle was a Certified Public Accountant. Mr. Doyle received his B.S. in Accounting from Mt. St. Mary's College.

Richard A. Farley has served as Vice President, Human Resources since February 2001. From 1992 to 2000, Mr. Farley was Director of Human Resources for Sphinx Pharmaceuticals, a Division of Eli Lilly and Company. From 1985 through 1992, Mr. Farley served in a variety of human resource management roles with Hewlett-Packard Company. Mr. Farley received his M.B.A. from Duke University and his B.S. in Industrial and Labor Relations from Syracuse University. Mr. Farley is assisting us in certain transitional activities related to our January 2004 restructuring, and will leave ViroPharma during March 2004.

Mark A. McKinlay, Ph.D., a co-founder of ViroPharma, has served as Vice President, Research & Development since our commencement of operations in December 1994, and served as Secretary from December 1994 until February 1997. From 1989 through 1994, Dr. McKinlay served in several positions, including Senior Director, at Sterling Winthrop Pharmaceuticals Research Division, a division of Sterling Winthrop Incorporated, a pharmaceutical company. Dr. McKinlay received his Ph.D. from Rensselaer Polytechnic Institute. Dr. McKinlay is assisting us in certain transitional activities related to our January 2004 restructuring, and will leave ViroPharma during April 2004.

Vincent J. Milano has served as Vice President, Chief Financial Officer of ViroPharma since November 1997, as Vice President, Finance & Administration since February 1997, as Treasurer since July 1996, and as Executive Director, Finance & Administration from April 1996 until February 1997. From 1985 until 1996, Mr. Milano was with KPMG LLP, independent certified public accountants, where he was Senior Manager since 1991. Mr. Milano is a Certified Public Accountant. Mr. Milano received his B.S. in Accounting from Rider College. Mr. Milano also is a director of Verticalnet, Inc.

Compensation Committee Interlocks and Insider Participation

Edgar Filing: VIROPHARMA INC - Form 10-K

No current member of the Compensation Committee is or has been an employee of the company or has any relationship to the company that is required to be disclosed pursuant to regulations of the Securities and Exchange Commission. Furthermore, none of the company's executive officers serves on the board of directors of any company of which a Compensation Committee member is an employee.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires that our directors, certain of our officers and persons who own more than 10% of our common stock, file with the Securities and Exchange Commission initial

Table of Contents

reports of ownership and reports of changes in ownership of such common stock. These directors, officers and greater than 10% stockholders are required by regulation to furnish us with copies of all Section 16(a) forms which they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, our directors, officers and greater than 10% stockholders complied with all fiscal year 2003 Section 16(a) filing requirements applicable to them.

Code of Conduct and Ethics

We have adopted a Code of Conduct and Ethics that applies to all of our employees, including our Chief Executive Officer and Chief Financial Officer. A copy of this Code of Conduct and Ethics is filed as an exhibit to this report.

Table of Contents**ITEM 11. EXECUTIVE COMPENSATION**

The following table provides information on compensation paid or earned during the fiscal years ended December 31, 2001, December 31, 2002 and December 31, 2003 to our Chief Executive Officer, and our four mostly highly compensated executive officers other than our Chief Executive Officer for the fiscal year ended December 31, 2003, collectively referred to as the named executive officers.

Summary Compensation Table

Name and Position	Year	Annual Compensation			Long-term Compensation		
		Salary (\$)	Bonus (1)(\$)	Other Compensation (2)	Restricted		
					Stock Awards (\$)	Securities Underlying Options	All Other Compensation (\$)
Michel de Rosen Chief Executive Officer and President	2003	333,000			45,000	88,743(3)	
	2002	416,000			120,000	88,743(3)	
	2001	400,000	185,000		36,000	88,743(3)	
Mark McKinlay(4) Vice President, Research & Development	2003	257,000	35,980		30,000	3,000(5)	
	2002	257,000			90,000	3,000(5)	
	2001	243,036	126,456		18,000	2,620(5)	
Marc S. Collett(6) Vice President, Discovery Research	2003	222,000	39,960		30,000	3,000(5)	
	2002	222,000			90,000	2,817(5)	
	2001	212,900	81,948		18,000	2,620(5)	
Vincent J. Milano Vice President, Chief Financial Officer and Treasurer	2003	205,000	36,900		30,000	3,000(5)	
	2002	205,000			90,000	2,750(5)	
	2001	195,000	94,250		18,000	2,620(5)	
Thomas F. Doyle Vice President, General Counsel and Secretary	2003	200,000	44,000		30,000	3,000(5)	
	2002	200,000			130,000	2,750(5)	
	2001	190,000	93,500		18,000	2,620(5)	

- (1) Year-end performance-based bonuses to the management team are subject to the review and approval of the Compensation Committee. The Compensation Committee generally meets on this topic in the fiscal year following the completion of the relevant performance period, and in our proxy statements prior to 2002 reflected such compensation in such following fiscal year. We currently report the timing of such performance-based compensation in the fiscal year for which the relevant performance is completed. As a result, to the extent applicable to the named executive officer, the amounts shown above include payments actually received in the year after the period for which the compensation is reported.
- (2) Excludes perquisites and other personal benefits, securities or property which are, in the aggregate, less than 10% of the total annual salary and bonus.
- (3) Represents the amount of debt that was forgiven by the company under the outstanding promissory note between the company and Mr. de Rosen.
- (4) Dr. McKinlay will leave ViroPharma in April 2004.
- (5) Represents contributions made by us on behalf of such person to our 401(k) plan.
- (6) Dr. Collett left ViroPharma in February 2004.

Stock Option Grants

Edgar Filing: VIROPHARMA INC - Form 10-K

The following table summarizes stock options granted to the named executive officers during the fiscal year ended December 31, 2003. The options vest in four annual installments commencing on the first anniversary of the date of grant. The percentage of total options granted is based on an aggregate of 807,000 options granted in 2003 including options granted to our named executive officers.

Table of Contents

The potential realizable value of each grant, as set forth in the table below, is calculated assuming that the market price of the underlying security appreciates at annualized rates of 5% and 10% over the ten-year term of the option. The results of these calculations are based on rates set forth by the Securities and Exchange Commission and are not intended to forecast possible future appreciation of the price of our common stock.

Option Grants in Last Fiscal Year

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation of Option Term	
	Number of Securities Underlying Options Granted	Percentage of Total Option	Exercise Price (\$/share)	Expiration Date	5%	10%
		Granted During Year				
Michel de Rosen	45,000	5.6%	2.09	7/22/13	\$ 59,148	\$ 149,890
Mark A. McKinlay	30,000	3.7%	2.09	7/22/13	\$ 39,432	\$ 99,928
Marc S. Collett	30,000	3.7%	2.09	7/22/13	\$ 39,432	\$ 99,928
Vincent J. Milano	30,000	3.7%	2.09	7/22/13	\$ 39,432	\$ 99,928
Thomas F. Doyle	30,000	3.7%	2.09	7/22/13	\$ 39,432	\$ 99,928

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

The following table shows options exercised by our named executive officers in 2003 and the value of shares of our common stock issued upon exercise of such options. The table also shows 2003 year-end amounts and value of shares of our common stock underlying outstanding options for our named executive officers.

Name	Shares Acquired On Exercise (#)	Value Realized (\$)(1)	Number of Securities Underlying Unexercised Options at December 31, 2003		Value of Unexercised In-The-Money Options at December 31, 2003(2)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Michel de Rosen			303,000	198,000	\$ 53,400	\$ 84,000
Mark A. McKinlay			138,930	91,750	\$ 59,000	\$ 73,800
Marc S. Collett			172,590	91,750	\$ 154,502	\$ 73,800
Vincent J. Milano			122,994	91,750	\$ 54,159	\$ 73,800
Thomas F. Doyle			157,150	111,750	\$ 89,000	\$ 109,400

- (1) Reflects the difference between the aggregate fair market value of the shares of common stock issued upon exercise of the options on the date of exercise and the aggregate exercise price.
- (2) Based on the difference between the closing price per share of \$2.77 on December 31, 2003, and the exercise price of the option.

Change of Control Agreements, Severance Agreements and Severance Plan

In February 2003, we entered into agreements with a number of employees, including each of the named executive officers and the other members of our management team other than Mr. de Rosen. If an employee that is a party to one of these arrangements is terminated or resigns for good reason within twelve months after a change of control, then the employee will receive severance payments equal to his or her monthly base salary over a period that varies from 9 to 18 months. Under these arrangements, each of Mr. Milano and Mr. Doyle will receive severance payments over an 18-month period. We will pay the premiums that would otherwise be paid by the employee if the employee elected to receive continuation coverage under COBRA for a period that matches the employee's severance period. In exchange for these benefits, the employee will release us from any obligations we may have incurred in connection with the employee's employment with us.

Table of Contents

In July 2002, we adopted the ViroPharma Incorporated Severance Pay Plan, which is intended to provide separation benefits to certain employees of our company in the event that they are separated from employment involuntarily. The Severance Plan is administered by the compensation committee of our board of directors. In general, any person who is regularly employed by our company for thirty or more hours per week are eligible for salary continuation and COBRA continuation coverage in an amount that is determined by the Administrator, in its sole discretion, prior to an employee's separation from employment. In exchange for these benefits, the employee will release us from any obligations we may have incurred in connection with the employee's employment with us. Under our company Severance Plan, the administrator has determined that Dr. Collett was eligible to receive, and Dr. McKinlay will be eligible to receive, eighteen months pay and COBRA coverage upon leaving ViroPharma.

In August 2000, we entered into a severance agreement with Dr. Claude Nash, a former member of our board of directors. We amended and restated that agreement in October 2001, as of September 1, 2002 and as of September 1, 2003. Under the amended and restated agreement, Dr. Nash will continue as an employee of the company until August 2004. Provided that Dr. Nash agrees to release us from any obligations we may have incurred in connection with his employment with us, upon termination of his employment with us we will provide to Dr. Nash health care, life insurance and disability insurance benefits (certain of which continue until Dr. Nash reaches age 65).

In August 2000, we entered into a severance agreement with Mr. de Rosen, our President and Chief Executive Officer. Provided that Mr. de Rosen agrees to release us from any obligations we may have incurred in connection with his employment with us, we will pay Mr. de Rosen, under various circumstances, certain amounts upon his termination of employment with us. Depending on his length of service with us at the time of termination, Mr. de Rosen will receive from us up to two years salary and benefits, as well any bonus amount which has been awarded to him but not yet paid, and a pro rata portion of the aggregate value of all contingent bonus awards to which Mr. de Rosen might otherwise have been entitled, if any.

Confidentiality and Inventions Agreements

We have entered into confidentiality and inventions agreements with each of our employees. The agreements provide that, among other things, all inventions, discoveries and ideas made or conceived by an employee during employment which are useful to us or related to our business or which were made or conceived with the use of our time, material, facilities or trade secret information, belong exclusively to us, without additional compensation to the employee. The agreements also have confidentiality provisions in favor of us and noncompetition provisions in favor of us during employment.

Equity Compensation Plans

We maintain the 1995 Stock Option and Restricted Share Plan (the "1995 Plan"), the 2001 Equity Incentive Plan (the "2001 Plan") and the 2000 Employee Stock Purchase Plan (the "ESPP"), pursuant to which we may grant equity awards to eligible persons. The 2001 Plan is described more fully below.

The following table gives information about equity awards under our 1995 Plan, 2001 Plan and ESPP as of February 28, 2004:

(a)

(b)

(c)

Edgar Filing: VIROPHARMA INC - Form 10-K

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	3,333,310(1)	\$ 12.00(1)	1,031,574
Equity compensation plans not approved by securityholders	492,450	\$ 1.38	7,550
Total	3,825,760	\$ 10.63	1,039,124

Table of Contents

- (1) Does not include rights granted under the Employee Stock Purchase Plan. The next scheduled purchase date under the Employee Stock Purchase Plan is June 30, 2004, for which rights were granted in connection with the 6-month offering period that commenced in January 2004.

2001 Equity Incentive Plan

In November 2001, our board of directors adopted the 2001 Plan, which has not been submitted to or approved by stockholders. The 2001 Plan reserves for issuance up to 500,000 shares of our common stock, of which a maximum of 10% may be awarded and sold or granted as restricted shares and the remainder may be issued pursuant to the exercise of options granted under the plan. The number of shares available for future grants and previously granted but unexercised options are subject to adjustment for any future stock dividends, splits, mergers, combinations, or other changes in capitalization as described in the 2001 Plan.

Eligibility for Participation. Generally, any employee, consultant or advisor to us or its subsidiaries is eligible to receive grants under the 2001 Plan; provided, however, officers of the company or its subsidiaries are not eligible to receive any type of grant under the 2001 Plan. Similarly, no options or restricted shares may be granted to any member of our board of directors.

Terms of Options and Restricted Shares. Nonstatutory stock options (NSOs) and restricted shares are available for grant under the 2001 Plan. The exercise price of options granted under the 2001 Plan may be equal to, more or less than the fair market value of our common stock on the date of grant, and the price (if any) of restricted shares will be determined by our board or a committee. Payment of the exercise price or the price of restricted shares may be made in cash, or by personal or certified check. The board or committee has the discretion to permit a participant to exercise or make payment for restricted shares by delivering a combination of shares and cash. The term of an NSO may not exceed ten years.

Options granted to employees may become exercisable based on the attainment of certain vesting conditions as may be set forth in the award agreement (as determined by the Board or committee) for example, an option may become exercisable if the optionee remains employed by the Company until a specified date, or if specified performance goals have been met. If a participant's employment terminates for any reason, the vested portion of an option remains exercisable for a fixed period of three months from the date of the participant's termination, and all of the restricted shares then subject to restrictions will be forfeited. If restricted shares are forfeited, the Company will refund to the participant the amounts paid for the restricted shares.

Acceleration in Connection with a Change of Control. Our 2001 Plan also has provisions that take effect if we experience a change of control. In general, a Change of Control will be deemed to have occurred upon the approval of a plan to dissolve, liquidate, sell substantially all our assets, merge or consolidate with or into another corporation in which we are not the surviving entity or upon a significant change in the composition of the majority of the board.

If a Change of Control occurs and the 2001 Plan is not continued by a successor corporation, the participant is not offered substantially equivalent employment with the successor corporation or the participant's employment is terminated during the six month period following the Change of Control, then depending on whether the participant has been employed by us for at least 2 years, either 50% or 100% of such participant's unvested options will be fully vested and the restrictions on his or her restricted shares will lapse. The provisions in the 2001 Plan regarding a Change of Control are the same as those found in the 1995 Plan.

Edgar Filing: VIROPHARMA INC - Form 10-K

Deduction to the Company. The company will be entitled to an income tax deduction equal to the amount of ordinary income recognized by the participant. The deduction generally will be allowed for our taxable year in which occurs the last day of the calendar year in which the participant recognizes ordinary income.

Table of Contents**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth information regarding the beneficial ownership of our common stock as of March 1, 2004, except as otherwise indicated in the relevant footnote, by (1) each person or group that we know beneficially owns more than 5% of our common stock, (2) each of our directors and director nominees, (3) named executive officers, and (4) all current executive officers and directors as a group. Unless otherwise indicated, the address of each person identified below is c/o ViroPharma Incorporated, 405 Eagleview Boulevard, Exton, Pennsylvania 19341.

The percentages of beneficial ownership shown below are based on 26,491,413 shares of Common Stock outstanding as of March 1, 2004, unless otherwise stated. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes those securities over which a person may exercise voting or investment power. In addition, shares of common stock which a person has the right to acquire upon the exercise of stock options and warrants within 60 days of the date of this table are deemed outstanding for the purpose of computing the percentage ownership of that person, but are not deemed outstanding for computing the percentage ownership of any other person. Except as indicated in the footnotes to this table or as affected by applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned.

Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
Aventis Pharmaceuticals Inc. (1)	2,616,000	9.9
Directors and Executive Officers		
Michel de Rosen (2)	623,150	2.3
Marc S. Collett (3)	402,579	1.5
Mark A. McKinlay (4)	308,380	1.2
Thomas F. Doyle (5)	181,681	*
Vincent J. Milano (6)	173,942	*
Frank Baldino, Jr. (7)	99,000	*
Robert J. Glaser (8)	68,860	*
Paul A. Brooke (9)	30,000	*
William D. Claypool	0	*
Michael R. Dougherty	0	*
All directors and executive officers as a group (11 persons)(10)	1,983,842	7.2

* Represents less than 1% of the outstanding shares of our common stock.

- (1) As reflected in a Form 4 dated January 16, 2004 filed on behalf of Aventis Pharmaceuticals Inc., a Delaware corporation (300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807) (API), as well as on behalf of Aventis Holdings Inc., a Delaware corporation (3711 Kenneth Pike, Suite 200 Greenville, Delaware 19801) (AHI) which owns 100% of the equity of API, and Aventis Inc., a Pennsylvania corporation (300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807) (AI), which owns 100% of the equity of AHI. API, AHI and AI are indirect subsidiaries of Aventis S.A., a French corporation headquartered in Strasbourg, France.
- (2) Includes 12,500 unvested shares of common stock issued to Mr. de Rosen in August 2000, and 323,000 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (3) Based on a Directors and Officer Questionnaire dated January 28, 2004 delivered to us by Dr. Collett. Includes 1,000 shares of common stock held by Dr. Collett as custodian for a minor child, and 187,840 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table. Dr. Collett left the company in February 2004.

Table of Contents

- (4) Includes 154,180 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (5) Includes 172,400 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (6) Includes 138,244 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (7) Includes 50,000 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (8) Includes 50,000 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (9) Represents shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.
- (10) Includes 1,201,914 shares of common stock issuable upon the exercise of stock options which are exercisable within 60 days of the date of this table.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Certain Transactions

We have sold assets and services to other companies, including in some instances, other companies for whom members of our Board serve as executive officers or directors. In 2003 and 2004 through the date of this report, none of the transactions between ViroPharma and other companies for whom members of our Board serve as executive officers or directors was individually reportable. In 2004, we expect to transfer at no cost certain chemicals and cabinets previously used by us in our discovery research efforts to Adolor Corporation. Michael Dougherty, a member of our board of directors and chairman of our audit committee, is an executive officer of Adolor Corporation. We estimate the fair market value of these chemicals and cabinets to be approximately \$25,000. If we were to dispose of the chemicals, we estimate that the cost would be between \$80,000 and \$120,000. Adolor Corporation will pay all costs of transporting these materials to their facility. Our audit committee authorized us to transfer these chemicals and cabinets to Adolor Corporation.

Promissory Note

In September 2000, Mr. de Rosen signed a promissory note in favor of us in the principal amount of \$354,973 bearing an interest rate of 6.05% of which \$88,743 in principal amount (plus accrued interest) is still outstanding. The principal amount of the note represents taxes paid by the company on Mr. de Rosen's behalf when he made an 83(b) election with the Internal Revenue Service after we issued 50,000 shares of common stock to Mr. de Rosen when he commenced his employment with us. 25% of the principal amount of the note is forgiven on each anniversary of the date of the note, provided that Mr. de Rosen is then still employed by us. In September 2003, we forgave \$88,743 of the principal amount of this promissory note. In the event of a change of control of the company, any remaining balance due under the note is forgiven. If Mr. de Rosen resigns from the Company, any remaining balance due under the note is due and payable by him. If Mr. de Rosen is terminated by us, any remaining balance due under the note is payable to us in monthly installments beginning on the date of termination and extending over a period of between 18 months and 72 months, depending upon when the termination of his employment occurs.

Table of Contents**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

KPMG LLP has served as our independent certified public accountants since 1995. KPMG LLP has been selected to continue as our independent certified public accountants for the current year. A representative of that firm is expected to be present at the annual meeting, will have the opportunity to make a statement if he or she desires to do so and will be available to respond to appropriate questions.

During the fiscal years ended December 31, 2003 and 2002, fees in connection with services rendered by KPMG LLP, the Company's independent auditors were as set forth below:

Fee Category	Fiscal 2002	Fiscal 2003
Audit Fees	\$ 118,500	\$173,000
Audit-Related Fees	8,900	84,080
Tax Fees	88,700	33,800
All Other Fees		
TOTAL	\$ 216,100	\$ 290,880

Audit fees consisted of fees for the audit of the Company's annual financial statements and review of quarterly financial statements as well as services normally provided in connection with statutory and regulatory filings or engagements, consents and assistance with and review of Company documents filed with the SEC.

Audit-related fees consisted of fees for assurance and related services, including primarily employee benefit plan audits and due diligence related to proposed acquisitions.

Tax fees consisted primarily of fees for tax compliance, tax advice and tax planning services.

We made no other payments to KPMG LLP during 2003 which constituted other fees.

Policy for Pre-Approval of Audit and Non-Audit Services

Edgar Filing: VIROPHARMA INC - Form 10-K

The Audit Committee's policy is to pre-approve all audit services and all non-audit services that the Company's independent auditor is permitted to perform for the Company under applicable federal securities regulations. As permitted by the applicable regulations, the Committee's policy utilizes a combination of specific pre-approval on a case-by-case basis of individual engagements of the independent auditor and pre-approval of certain engagements up to predetermined dollar thresholds that are reviewed annually by the Committee. Specific pre-approval is mandatory for the annual financial statement audit engagement, among others.

All engagements of the independent auditor to perform any audit services and non-audit services have been pre-approved by the Committee in accordance with the pre-approval policy. The policy has not been waived in any instance.

The audit committee may delegate pre-approval authority to the Chairman of the Audit Committee. The Chairman of the Audit Committee must report any decisions to the audit committee at the next scheduled meeting.

Table of Contents**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

(a) List of documents filed as part of this report:

(1) *Financial Statements.* The Consolidated Financial Statements listed in the accompanying Index to Consolidated Financial Statements appearing on page 59, are filed as part of this Annual Report on Form 10-K.

(2) *Financial Statement Schedules.* All schedules are omitted because they are not applicable, or not required, or because the required information is included in the Consolidated Financial Statements or notes thereto.

(3) *Exhibits.* The following is a list of Exhibits filed as part of this Annual Report on Form 10-K. Where so indicated by footnote, Exhibits which were previously filed are incorporated by reference. For Exhibits incorporated by reference, the location of the Exhibit in the previous filing is indicated in parentheses.

<u>Exhibit No.</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended by a Certificate of Amendment of Amended and Restated Certificate of Incorporation dated May 18, 1999, as further amended by a Certificate of Amendment of Amended and Restated Certificate of Incorporation dated May 24, 2000. (9) (Exhibit 3.1)
3.2	Certificate of Designation establishing and designating the Series A Junior Participating Preferred Shares. (4) (Exhibit 3.2)
3.3	Amended and Restated By-Laws of the Company. (20) (Exhibit 3.3)
3.4	Certificate of Designation establishing and designating the Series A Convertible Participating Preferred Stock. (5) (Exhibit 3.4)
4.1	Rights Agreement, dated as of September 10, 1998, between ViroPharma Incorporated and StockTrans, Inc., as Rights Agent. (3) (Exhibit 4.1)
4.2	Amendment No. 1 to Rights Agreement. (5) (Exhibit 4.2)
4.3	Indenture dated as of March 1, 2000 of ViroPharma Incorporated to Summit Bank as Trustee (including the form of note). (7) (Exhibit 4.3)
10.1	Form of Employment Agreement. (1) (Exhibit 10.8)
10.2	Form of Indemnification Agreement. (1) (Exhibit 10.9)
10.3	Restricted Stock Purchase Agreement dated as of January 17, 1996, by and between the Company and Frank Baldino, Jr. (1) (Exhibit 10.11)
10.4	Amendment to Restricted Stock Purchase Agreement dated as of January 17, 1996, among the Company and Frank Baldino, Jr., dated as of January 17, 1996. (1) (Exhibit 10.18)
10.5	Lease, dated July 21, 1997, between the Company and The Hankin Group. (2) (Exhibit 10.23)
10.6	Purchase Option Agreement, dated July 21, 1997, between the Company and The Hankin Group. (2) (Exhibit 10.24)
10.7	Escrow Agreement, dated July 21, 1997, among the Company, The Hankin Group and Manito Abstract Company, Inc. (2) (Exhibit 10.25)

Edgar Filing: VIROPHARMA INC - Form 10-K

- 10.8 Investment Agreement among ViroPharma Incorporated and Perseus-Soros Biopharmaceutical Fund, L.P. dated May 5, 1999. (5) (Exhibit 10.21)
- 10.9 ViroPharma Incorporated Common Stock Purchase Warrant (5) (Exhibit 10.22)
- 10.10 Stock Purchase Agreement dated December 9, 1999 between American Home Products Corporation and ViroPharma Incorporated. (6) (Exhibit 10.26)

Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
10.11	Purchase Agreement dated February 24, 2000 by and among ViroPharma Incorporated, Morgan Stanley & Co. Incorporated and US Bancorp Piper Jaffray Inc. (7) (Exhibit 10.27)
10.12	Registration Rights Agreement dated as of March 1, 2000 by and among ViroPharma Incorporated, Morgan Stanley & Co. Incorporated and US Bancorp Piper Jaffray Inc. (7) (Exhibit 10.28)
10.13	Restricted Stock Agreement dated August 21, 2000 between ViroPharma Incorporated and Michel de Rosen. (10) (Exhibit 10.30)
10.14	Severance Agreement dated August 21, 2000 between ViroPharma Incorporated and Michel de Rosen. (10) (Exhibit 10.31)
10.15	Promissory Note of Michel de Rosen dated August 21, 2000. (10) (Exhibit 10.32)
10.16	First Amended and Restated Agreement dated February 27, 2001 between Sanofi-Synthelabo and ViroPharma Incorporated. (11) (Exhibit 10.32)
10.17	Stock Purchase Agreement dated February 27, 2001 between Sanofi-Synthelabo and ViroPharma Incorporated. (11) (Exhibit 10.33)
10.18	Stock Purchase Agreement dated as of September 9, 2001 between ViroPharma Incorporated and Aventis Pharma Inc. (12) (Exhibit 10.36)
10.19	Agreement of Lease dated as of September 24, 2001 between LV Associates, L.P. and ViroPharma Incorporated. (12) (Exhibit 10.37)
10.20	2001 Equity Incentive Plan. (13) (Exhibit 10.33)
10.21	Letter Agreement between ViroPharma Incorporated and Wyeth dated May 29, 2002. (14) (Exhibit 10.35)
10.22	Settlement Agreement and Release dated August 1, 2002 between ViroPharma Incorporated and Aventis Pharmaceuticals Inc. (15) (Exhibit 10.1)
10.23	Sales Force Transfer Agreement dated August 1, 2002 between ViroPharma Incorporated and Aventis Pharmaceuticals Inc. (15) (Exhibit 10.2)
10.24	Agreement dated June 14, 2002 between Ellen Cooper and the Company. (16) (Exhibit 10.30)
10.25	Settlement Agreement and Release dated October 11, 2002 between ViroPharma Incorporated and PCAS SA (16) (Exhibit 10.31)
10.26	Amended and Restated ViroPharma Incorporated Employee Stock Purchase Plan. (17)
10.27	Form of Change of Control Agreement between ViroPharma and certain of its employees. (18) (Exhibit 10.32)
10.28	First Amended and Restated Collaboration and License Agreement dated June 26, 2003 between ViroPharma Incorporated and Wyeth. (19) (Exhibit 10.33)
10.29	Amendment to Stock Purchase Agreement dated June 26, 2003 between ViroPharma Incorporated and Wyeth. (19) (Exhibit 10.34)
10.30	License Agreement dated August 8, 2003 by and between GlaxoSmithKline and ViroPharma Incorporated. (20) (Exhibit 10.35)
10.31*	Third Amended and Restated Severance Agreement dated as of September 1, 2003 between Claude Nash and the Company. (Exhibit 10.31)
10.32*	Exchange Agreement dated as of October 2, 2003 between Everspring Master Fund Ltd. and ViroPharma Incorporated. (Exhibit 10.32)
10.33*	Option Agreement dated November 25, 2003 between Schering Corporation and the Company. (Exhibit 10.33)

Table of Contents

Exhibit No.	Description
10.34*	Letter Agreement dated November 24, 2003 between Sanofi-Synthelabo and the Company. (Exhibit 10.34)
10.35*	Exchange Agreement dated as of November 26, 2003 between Everspring Master Fund Ltd. and ViroPharma Incorporated. (Exhibit 10.35)
12.1*	Schedule of Ratio of Earnings to Fixed Charges.
14*	Code of Conduct and Ethics
21*	List of Subsidiaries
23*	Consent of KPMG LLP.
24*	Power of Attorney (included on signature page).
25.1	Form of T-1 Statement of Eligibility of Trustee for Indenture Under the Trust Indenture Act of 1939. (8) (Exhibit 25.1)
31.1*	Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

Portions of this exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 246-2 under the Securities Exchange Act of 1934, as amended.

Compensation plans and arrangements for executives and others.

- (1) Filed as an Exhibit to Registration Statement on Form S-1 (File No. 333-12407), as amended, initially filed on September 20, 1996.
- (2) Filed as an Exhibit to Registration Statement on Form S-1 (File No. 333-30005), as amended, initially filed on June 25, 1997.
- (3) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on September 21, 1998.
- (4) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 1998.
- (5) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 1999.
- (6) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 1999.
- (7) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2000.
- (8) Filed as an Exhibit to Registration Statement on Form S-3 (File No. 333-37960), as amended, initially filed on May 26, 2000.
- (9) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2000.
- (10) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2000.
- (11) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2001.
- (12) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2001.
- (13) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2001.
- (14) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2002.
- (15) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on August 1, 2002
- (16) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2002.
- (17) Filed as an Annex to Registrant's Proxy Statement filed with the Commission on March 27, 2003.
- (18) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2003.
- (19) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2003.
- (20) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2003.

Table of Contents

Copies of the exhibits are available to stockholders from Thomas F. Doyle, Vice President, General Counsel and Secretary, ViroPharma Incorporated, 405 Eagleview Boulevard, Exton, Pennsylvania 19341. There will be a fee to cover the Company's expenses in furnishing the exhibits.

(b) Reports on Form 8-K

We filed the following Current Reports on Form 8-K during the quarter ended December 31, 2003:

(i) We filed a Current Report on Form 8-K dated October 2, 2003 to report, pursuant to item 5, that we were awarded two SBIR grants for Biodefense Antiviral Drug Discovery Programs

(ii) We filed a Current Report on Form 8-K dated November 25, 2003 to report, pursuant to item 5, that we had entered into an agreement with Schering for the intranasal formulation of pleconaril.

(iii) We filed a Current Report on Form 8-K dated December 3, 2003 to report, pursuant to Item 5, a set of Frequently Asked Questions describing information that experience has demonstrated to be often requested by analysts and investors, and the answers to these questions.

Table of Contents**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 our behalf by the undersigned, thereunto duly authorized.

VIROPHARMA INCORPORATED

By: /s/ MICHEL de ROSEN

Michel de Rosen

President, Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michel de Rosen and Vincent J. Milano as his or her attorney-in-fact, with the full power of substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

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>Name</u>	<u>Capacity</u>	<u>Date</u>
<u> /s/ MICHEL de ROSEN </u> Michel de Rosen	President, Chief Executive Officer (Principal Executive Officer)	March 19, 2004
<u> /s/ VINCENT J. MILANO </u> Vincent J. Milano	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 19, 2004
<u> /s/ MICHEL de ROSEN </u> Michel de Rosen	Chairman of the Board	March 19, 2004
<u> /s/ FRANK BALDINO, JR., PH.D. </u> Frank Baldino, Jr., Ph.D.	Director	March 19, 2004

Edgar Filing: VIROPHARMA INC - Form 10-K

/s/ PAUL A. BROOKE	Director	March 19, 2004
<hr/>		
Paul A. Brooke		
/s/ WILLIAM CLAYPOOL, M.D.	Director	March 19, 2004
<hr/>		
William Claypool, M.D.		
/s/ MICHAEL R. DOUGHERTY	Director	March 19, 2004
<hr/>		
Michael R. Dougherty		
/s/ ROBERT J. GLASER	Director	March 19, 2004
<hr/>		
Robert J. Glaser		

Table of Contents

ViroPharma Incorporated
(A Development Stage Company)

Index to Consolidated Financial Statements

	Page
<u>Independent Auditors Report</u>	60
<u>Consolidated Balance Sheets at December 31, 2002 and 2003</u>	61
<u>Consolidated Statements of Operations for the years ended December 31, 2001, 2002 and 2003, and the period December 5, 1994 (Inception) to December 31, 2003</u>	62
<u>Consolidated Statements of Comprehensive Loss for the years ended December 31, 2001, 2002 and 2003, and the period December 5, 1994 (Inception) to December 31, 2003</u>	63
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the period December 5, 1994 (Inception) to December 31, 2000, and the years ended December 31, 2001, 2002 and 2003</u>	64
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2002 and 2003, and the period December 5, 1994 (Inception) to December 31, 2003</u>	65
<u>Notes to Consolidated Financial Statements</u>	66

Table of Contents

Independent Auditors Report

The Stockholders and Board of Directors

ViroPharma Incorporated:

We have audited the accompanying consolidated balance sheets of ViroPharma Incorporated (A Development Stage Company) and subsidiary as of December 31, 2002 and 2003, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2003 and for the period from December 5, 1994 (Inception) to December 31, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of ViroPharma Incorporated (A Development Stage Company) and subsidiary as of December 31, 2002 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2003 and for the period from December 5, 1994 (Inception) to December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Princeton, New Jersey

February 6, 2004, except as to the eighth sentence

of the last paragraph of Note 13,

which is as of March 9, 2004

Table of Contents

ViroPharma Incorporated
(A Development Stage Company)
Consolidated Balance Sheets
December 31, 2002 and 2003

	December 31,	
	2002	2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,987,056	\$ 12,969,261
Short-term investments	142,294,488	108,179,330
Notes receivable from officers - current	88,743	88,743
Other current assets	3,447,928	2,392,037
	161,818,215	123,629,371
Equipment and leasehold improvements, net	8,515,248	7,212,493
Restricted investments	353,169	
Notes receivable from officers - noncurrent	88,743	
Debt issue costs, net	2,612,366	1,908,860
Other assets	143,016	94,458
	\$ 173,530,757	\$ 132,845,182
Liabilities and Stockholders' equity (deficit)		
Current liabilities:		
Loans payable - current	\$ 116,667	\$ 8,334
Accounts payable	979,909	649,561
Due to partners	693,778	
Accrued expenses and other current liabilities	6,739,353	6,800,484
Deferred revenue - current	516,667	3,074,245
	9,046,374	10,532,624
Loans payable - noncurrent	8,334	
Convertible subordinated notes	134,900,000	127,900,000
Deferred revenue - noncurrent	1,765,278	1,127,273
Other liabilities		794,580
	145,719,986	140,354,477
Commitments and Contingencies		
Stockholders' equity (deficit):		
Preferred stock, par value \$.001 per share. 5,000,000 shares authorized; Series A convertible participating preferred stock; no shares issued and outstanding		
Series A junior participating preferred stock; 200,000 shares designated; no shares issued and outstanding		
Common stock, par value \$.002 per share. Authorized 100,000,000 shares; issued and outstanding 25,933,096 at December 31, 2002 and 26,462,738 at December 31, 2003	51,866	52,925

Edgar Filing: VIROPHARMA INC - Form 10-K

Additional paid-in capital	248,782,497	250,320,035
Deferred compensation	(435,093)	(209,654)
Accumulated other comprehensive loss	(2,086,601)	(101,343)
Deficit accumulated during the development stage	(218,501,898)	(257,571,258)
	<u> </u>	<u> </u>
Total stockholders' equity (deficit)	27,810,771	(7,509,295)
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity (deficit)	\$ 173,530,757	\$ 132,845,182
	<u> </u>	<u> </u>

See accompanying notes to consolidated financial statements.

Table of Contents

ViroPharma Incorporated
(A Development Stage Company)
Consolidated Statements of Operations
Years ended December 31, 2001, 2002 and 2003,
and the period December 5, 1994 (Inception) to December 31, 2003

	Year ended December 31,			Period December 5, 1994 (Inception)
	2001	2002	2003	to December 31, 2003
Revenues:				
License fee and milestone revenue	\$ 3,384,615	\$ 5,333,440	\$ 1,084,186	\$ 15,802,241
Grant revenue			410,863	937,757
Other revenue		203,400	117,125	320,525
Total revenues	3,384,615	5,536,840	1,612,174	17,060,523
Continuing operating expenses incurred in the development stage:				
Research and development	43,012,588	39,823,069	23,042,772	216,139,187
Acquisition of technology rights	16,500,000		3,500,000	20,000,000
Marketing	11,806,768	6,791,106		23,360,873
General and administrative	11,248,855	7,834,441	9,035,696	46,397,137
Total operating expenses	82,568,211	54,448,616	35,578,468	305,897,197
	(79,183,596)	(48,911,776)	(33,966,294)	(288,836,674)
Gain on repurchase of debt, net		27,894,260	3,632,882	31,527,142
Interest income	12,321,542	5,428,831	1,829,021	34,820,170
Interest expense	11,619,150	11,034,198	8,437,548	41,422,459
Loss from continuing operations	(78,481,204)	(26,622,883)	(36,941,939)	(263,911,821)
Discontinued operations:				
Income (loss) from discontinued sales operations (including gain on disposal of \$15,410,000)	(4,476,244)	10,816,807		6,340,563
Net loss	(82,957,448)	(15,806,076)	(36,941,939)	\$ (257,571,258)
Preferred stock dividends	345,242			
Net loss allocable to common stockholders	\$ (83,302,690)	\$ (15,806,076)	\$ (36,941,939)	

Edgar Filing: VIROPHARMA INC - Form 10-K

Basic and diluted loss per share from continuing operations	\$ (4.32)	\$ (1.11)	\$ (1.43)
Basic and diluted income (loss) per share from discontinued sales operations	\$ (0.25)	\$ 0.45	\$
Basic and diluted net loss per share allocable to common stockholders	\$ (4.59)	\$ (0.66)	\$ (1.43)
Shares used in computing basic and diluted income (loss) per share amounts	18,167,303	23,952,940	25,916,466

See accompanying notes to consolidated financial statements.

Table of Contents

ViroPharma Incorporated
(A Development Stage Company)
Consolidated Statements of Comprehensive Loss
Years ended December 31, 2001, 2002 and 2003,
and the period December 5, 1994 (Inception) to December 31, 2003

	Year ended December 31,			Period December 5, 1994 (Inception)
	2001	2002	2003	to December 31, 2003
Net loss	\$ (82,957,448)	\$ (15,806,076)	\$ (36,941,939)	\$ (257,571,258)
Other comprehensive income (loss):				
Unrealized holding losses arising during period	(1,011,566)	(2,086,601)	(101,343)	(1,536,764)
Less: reclassification adjustment for gains (losses) included in net income (loss)	1,229,131	(1,011,566)	40,820	692,000
Adjustment to unrealized loss on available for sale securities			2,127,421	2,127,421
Unrealized gains (losses) on available for sale securities	(2,240,697)	(1,075,035)	1,985,258	(101,343)
Comprehensive loss	\$ (85,198,145)	\$ (16,881,111)	\$ (34,956,681)	\$ (257,672,601)

See accompanying notes to consolidated financial statements.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Consolidated Statements of Stockholders' Equity (Deficit)****Period December 5, 1994 (Inception) to December 31, 2000, and years ended December 31, 2001, 2002 and 2003**

	Preferred stock		Common stock		Additional paid-in capital	Notes Receivable on common stock	Deferred compensation	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Number of shares	Amount	Number of shares	Amount						
Balance, December 5, 1994 (Inception)		\$		\$	\$			\$		\$
Issuance of common stock to founders			828,750	1,657	79,593		(79,625)			1,625
Deferred compensation resulting from grant of options					753,461		(753,461)			
Issuance costs of Series A, B and C preferred stock					(74,012)					(74,012)
Exercise of common stock options and warrants			373,120	746	1,194,608					1,195,354
Issuance of common stock to partner			200,993	402	5,999,598					6,000,000
Issuance of restricted stock			50,000	100	1,056,151		(1,056,251)			
Value attributed to issuance of warrants					153,751					153,751
Issuance of preferred stock, net of issuance costs	2,300,000	2,300			13,308,600					13,310,900
Consulting expense related to option grants					46,975					46,975
Accretion of redemption value attributable to mandatorily redeemable convertible preferred stock					(1,616,445)					(1,616,445)
Conversion of preferred stock to common stock			5,588,191	11,177	16,253,022					16,264,199
Initial issuance of common stock, net of issuance costs			2,587,500	5,175	16,246,502					16,251,677
Follow-on issuance of common stock, net of issuance costs			3,450,000	6,900	61,449,741					61,456,641
Follow-on issuance of common stock, net of issuance costs			2,300,000	4,600	29,510,475					29,515,075
			71,795	143	(143)					

Edgar Filing: VIROPHARMA INC - Form 10-K

Cashless exercise of warrants											
Preferred dividends								(909,052)		(909,052)	
Amortization of deferred compensation							899,103			899,103	
Unrealized gains on available for sale securities								1,229,131		1,229,131	
Net loss									(119,738,374)	(119,738,374)	
Balance, December 31, 2000	2,300,000	\$ 2,300	15,450,349	\$ 30,900	\$ 143,452,825	\$	\$	(990,234)	\$ 1,229,131	\$ (119,738,374)	\$ 23,986,548
Conversion of preferred stock	(2,300,000)	(2,300)	2,346,295	4,693	(2,393)						
Issuance of common stock, net of issuance costs			4,000,000	8,000	82,692,000						82,700,000
Employee Stock Purchase Plan			30,447	62	397,729						397,791
Exercise of common stock options			153,723	307	1,034,093						1,034,400
Issuance of stock options to non-employees					90,146		(90,146)				
Issuance of common stock for technology rights			750,000	1,500	16,498,500						16,500,000
Issuance of restricted stock			10,000	20	216,855		(216,875)				
Preferred dividends					(345,242)						(345,242)
Amortization of deferred compensation							354,362				354,362
Unrealized loss on available for sale securities								(2,240,697)			(2,240,697)
Net loss									(82,957,448)	(82,957,448)	
Balance, December 31, 2001		\$	22,740,814	\$ 45,482	\$ 244,034,513	\$	\$	(942,893)	\$ (1,011,566)	\$ (202,695,822)	\$ 39,429,714
Issuance of common stock to partner			3,000,000	6,000	4,584,000						4,590,000
Employee Stock Purchase Plan			181,370	362	226,000						226,362
Issuance of stock options to non-employees					25,800		(25,800)				
Exercise of common stock options			18,412	37	38,680						38,717
Forfeiture of restricted stock			(7,500)	(15)	(126,496)		126,511				
Amortization of deferred compensation							407,089				407,089
Unrealized loss on available for sale securities								(1,075,035)			(1,075,035)
Net loss									(15,806,076)	(15,806,076)	
Balance, December 31, 2002		\$	25,933,096	\$ 51,866	\$ 248,782,497	\$	\$	(435,093)	\$ (2,086,601)	\$ (218,501,898)	\$ 27,810,771
Issuance of common stock for note and accrued interest reduction			473,054	946	1,173,057						1,174,003
Employee Stock Purchase Plan			48,438	97	79,972						80,069

Edgar Filing: VIROPHARMA INC - Form 10-K

Exercise of common stock options	8,150	16	2,859	2,875				
Issuance of stock options to non-employee			281,650	281,650				
Amortization of deferred compensation			225,439	225,439				
Unrealized loss on available for sale securities			(142,163)	(142,163)				
Adjustment to unrealized loss on available for sale securities			2,127,421	(2,127,421)				
Net loss				(36,941,939)				
Balance, December 31, 2003	\$	26,462,738	\$ 52,925	\$ 250,320,035	\$ (209,654)	\$ (101,343)	\$ (257,571,258)	\$ (7,509,295)

See accompanying notes to consolidated financial statements.

Table of Contents

ViroPharma Incorporated
(A Development Stage Company)
Consolidated Statements of Cash Flows
Years ended December 31, 2001, 2002 and 2003,
and the period December 5, 1994 (Inception) to December 31, 2003

	Year ended December 31,			Period
	2001	2002	2003	December 5, 1994 (Inception) to December 31, 2003
Cash flows from operating activities:				
Net loss	\$ (82,957,448)	\$ (15,806,076)	\$ (36,941,939)	\$ (257,571,258)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash gain on sale of sales force		(15,410,000)		(15,410,000)
Non-cash gain on repurchase of convertible subordinated notes		(28,724,875)	(3,724,498)	(32,449,373)
Non-cash settlement of interest payable related to note reduction			23,501	23,501
Write-off of deferred financing costs on note repurchase		830,615	91,616	922,231
Non-cash charge for lease costs			1,650,000	1,650,000
Non-cash write-off of fixed assets		1,517,172		1,517,172
Non-cash acquisition of technology rights	16,500,000			16,500,000
Non-cash compensation expense	354,362	407,089	507,089	2,167,643
Non-cash warrant value				153,751
Non-cash consulting expense				46,975
Non-cash interest expense	818,458	785,715	611,890	2,894,326
Depreciation and amortization expense	1,482,806	2,132,025	2,286,646	8,119,116
Changes in assets and liabilities:				
Other current assets	(319,122)	851,624	1,055,891	(2,392,037)
Notes receivable from officers	110,976	156,363	88,743	(88,743)
Due (to) from partners	(3,376,676)	8,049,862	(693,778)	
Other assets		(97,117)	48,558	(94,458)
Accounts payable	(889,046)	(1,677,688)	(330,348)	649,561
Deferred revenue	3,615,384	(5,333,439)	1,919,573	4,201,518
Accrued expenses and other current liabilities	15,772,469	(9,413,755)	(794,289)	15,945,064
Other liabilities	10,000,000			10,000,000
Net cash used in operating activities	(38,887,837)	(61,732,485)	(34,201,345)	(243,215,011)
Cash flows from investing activities:				
Purchase of equipment and leasehold improvements	(4,753,401)	(4,034,452)	(983,891)	(17,045,318)
Proceeds from sale equipment		196,537		196,537
Purchases of short-term investments	(367,060,963)	(178,627,897)	(141,811,552)	(1,166,164,723)
Sales of short-term investments				9,680,414
Maturities of short-term investments	335,981,776	266,668,519	176,137,716	1,048,203,635
Net cash provided by (used in) investing activities	(35,832,588)	84,202,707	33,342,273	(125,129,455)
Cash flows from financing activities:				
Net proceeds from issuance of preferred stock				27,242,143
Net proceeds from issuance of common stock	84,132,191	265,079	82,944	198,898,960
Preferred stock cash dividends	(345,242)			(1,254,294)
Proceeds from loans payable and milestone advance				2,100,000

Edgar Filing: VIROPHARMA INC - Form 10-K

Payment of loans payable	(200,000)	(199,999)	(116,667)	(2,091,666)
Payment on repurchase of convertible subordinated notes		(16,375,125)	(2,125,000)	(18,500,125)
Proceeds received on notes receivable				1,625
Gross proceeds from notes payable				180,692,500
Issuance costs on notes payable				(5,725,416)
Payment of notes payable				(50,000)
Obligation under capital lease				
Net cash provided by (used in) financing activities	83,586,949	(16,310,045)	(2,158,723)	381,313,727
Net increase (decrease) in cash and cash equivalents	8,866,524	6,160,177	(3,017,795)	12,969,261
Cash and cash equivalents at beginning of period	960,355	9,826,879	15,987,056	
Cash and cash equivalents at end of period	\$ 9,826,879	\$ 15,987,056	\$ 12,969,261	\$ 12,969,261
Supplemental disclosure of non-cash transactions:				
Conversion of Note Payable to Series A and Series B Preferred Stock	\$	\$	\$	\$ 642,500
Conversion of mandatorily redeemable convertible preferred stock to common shares				16,264,199
Notes issued for 828,750 common shares				1,625
Deferred compensation	307,021	25,800		2,222,158
Forfeiture of restricted stock		126,511		126,511
Accretion of redemption value attributable to mandatorily redeemable converted preferred stock				1,616,445
Conversion of milestone advance to loan payable				1,000,000
Unrealized gains (losses) on available for sale securities	(2,240,697)	(1,075,035)	(142,163)	(101,343)
Issuance of common stock in note reduction			1,150,502	1,150,502
Issuance of common stock to Aventis Pharmaceuticals Inc.		4,590,000		4,590,000
Settlement of milestone advances to Aventis Pharmaceuticals Inc.		20,000,000		20,000,000
Supplemental disclosure of cash flow information:				
Cash paid for interest	\$ 10,835,693	\$ 10,812,200	\$ 7,944,000	\$ 35,581,443

See accompanying notes to consolidated financial statements.

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to the Consolidated Financial Statements

Years ended December 31, 2001, 2002 and 2003,

and the period December 5, 1994 (Inception) to December 31, 2003

1. Organization and Business Activities

ViroPharma Incorporated (a development stage company) commenced operations on December 5, 1994. ViroPharma Incorporated and its subsidiary (the Company or ViroPharma) is a development stage pharmaceutical company focused on the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings.

The Company is devoting substantial effort towards conducting drug development, conducting clinical trials, pursuing business development opportunities, pursuing regulatory approval for products under development, and raising capital. The only revenues from product sales that the Company has earned are detailing fees from discontinued sales operations during the first eight months of 2002 for detailing products owned by Aventis Pharmaceuticals Inc. The Company has earned no significant revenue or product sales and has not achieved profitable operations or positive cash flow from continuing operations. The Company's deficit accumulated during the development stage aggregated \$257.6 million through December 31, 2003. There is no assurance that profitable operations can ever be achieved, and even if achieved, could be sustained on a continuing basis. Effective on August 31, 2002, the Company discontinued its sales force operations related to two products owned by Aventis Pharmaceuticals Inc. (Aventis) and all related sales administration activities.

The Company plans to continue to finance its operations with a combination of cash, cash equivalents, and short-term investments, stock issuances and debt issuances, as available, license payments, payments from strategic research and development arrangements when and if agreed upon milestones are achieved and, in the longer term, revenues from product sales or collaborations, if its planned products are commercialized. There are no assurances, however, that the Company will be successful in obtaining regulatory approval for any of its product candidates or in obtaining an adequate level of financing needed for the long-term development and commercialization of its product candidates.

2. Basis of Accounting and Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of ViroPharma and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash and cash equivalents are held in United States (U.S.) financial institutions.

Short-term investments

Short-term investments consist primarily of debt securities backed by the U.S. government and commercial paper. The Company's entire short-term investment portfolio is currently classified as available for sale and is stated at fair value as determined by quoted market values. All short-term investments, including securities with maturities in excess of one year, are classified as current, as management can sell them any time at their option. Changes in the net unrealized holding gains and losses are included in accumulated other comprehensive loss. For purposes of determining gross realized gains and losses, the cost of short-term investments sold is based upon specific identification. The Company has not experienced any significant realized gains or losses on its investments through December 31, 2003.

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

During the second quarter of 2003, the Company discovered that it had been accounting for the discounts and premiums associated with its short-term investments incorrectly. The amortization of these discounts and premiums should have been recorded ratably over the holding period for each investment to interest income. In financial statements prior to the second quarter of 2003, the Company reported these amounts as a change in accumulated other comprehensive income (loss), a component of stockholders' equity, in the consolidated balance sheet. Due to the lack of materiality, the cumulative net effect of the activity of approximately \$2.1 million was relieved from accumulated other comprehensive income (loss) and charged directly to deficit accumulated during the development stage in the consolidated balance sheet in 2003. The effects of this charge on loss from continuing operations for each of the years ended December 31, 2000, 2001, 2002 and 2003 and on the deficit accumulated during the development stage as of each period end is immaterial.

Concentration of credit risk

The Company invests its excess cash and short-term investments in accordance with a policy objective that seeks to ensure both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by the U.S. government and institutions with strong investment grade credit ratings and places restrictions in their terms and concentrations by type and issuer.

Equipment and leasehold improvements

Equipment and leasehold improvements are recorded at cost. Depreciation and amortization is computed on a straight-line basis over the useful lives of the assets or the lease term, whichever is shorter, ranging from two to ten years.

The Company leases certain of its equipment and facilities under operating leases. Operating lease payments are charged to operations over the related period that such leased equipment is utilized in service. Expenditures for repairs and maintenance are expensed as incurred.

Research and development

Research and product development costs are expensed as incurred. Reimbursements of research and development costs under cost sharing collaborations are recorded as a reduction of research and development expenses. Research and development costs include costs for discovery research, pre-clinical and clinical trials, manufacture of drug supply, supplies and acquired services, employee-related costs and allocated and direct facility expenses.

Licensed technology

Costs incurred in obtaining the license rights to technology in the research and development stage are expensed as incurred and in accordance with the specific contractual terms of such license agreements.

Accounting for income taxes

Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

Revenue recognition collaborative research, contract and license agreements

Contract revenues are earned and recognized according to the provisions of each agreement. Contract milestone payments related to the achievement of substantive steps or regulatory events in the development process are recognized as revenues upon the completion of the milestone event or requirement. Payments, if any, received in advance of performance under a contract are deferred and recognized as revenue when earned. Up-front licensing fees where the Company has continuing involvement are deferred and amortized over the estimated performance period. Revenue from government grants is recognized as the related performance to which they are related occurs.

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Stock-based compensation

The Company accounts for its stock option plans in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations (APB 25). As such, compensation cost is measured on the date of grant as the excess of the current market price of the underlying stock over the exercise price of the option. Such compensation amounts are amortized over the respective vesting periods of the option grant. The Company adopted the disclosure provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), which permits entities to provide pro forma net income (loss) and pro forma income (loss) per share disclosures for employee stock option grants as if the fair-value based method defined in SFAS No. 123 had been applied. In addition, the Company adopted the disclosure requirements of SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, which amends the disclosure requirements of Statement No. 123 to require prominent disclosures in both annual and interim financial statements.

Compensation expense for options granted to non-employees is determined in accordance with SFAS No. 123, and related interpretations, as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. Compensation expense for options granted to non-employees is remeasured each period as the underlying options vest.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

The Company applies APB Opinion No. 25 in accounting for its stock option plans. Had the Company determined compensation cost for options granted based on their fair value at the grant date under SFAS No. 123, the Company's net loss allocable to common stockholders and net loss per share allocable to common stockholders would have been increased as indicated below:

	<u>2001</u>	<u>2002</u>	<u>2003</u>
Net loss allocable to common stockholders:			
As reported	\$ (83,302,690)	\$ (15,806,076)	\$ (36,941,939)
Add: stock-based employee and directors compensation expense included in net income (loss) allocable to common stockholders			
Deduct: total stock-based employee and directors compensation expense determined under the fair value-based method for all employee and director awards	(10,185,610)	(11,740,178)	(7,635,869)
Proforma net loss allocable to common stockholders	\$ (93,488,300)	(27,546,254)	(44,577,808)
Net loss per share allocable to common stockholders - basic and diluted:			
As reported	\$ (4.59)	\$ (0.66)	\$ (1.43)
Proforma	(5.15)	(1.15)	(1.72)

Financial Instruments

The Company's financial instruments, principally short-term investments, are carried at fair value. Cash and cash equivalents, notes receivable from officers, due to partners, accounts payable, accrued expenses and other current liabilities are carried at cost which approximate fair value due to their short-term nature. The Company's loans payable are carried at cost as the debt bears interest at rates approximating current market rates. At December 31, 2003, the market value of the Company's convertible subordinated notes was approximately \$86.3 million, based on quoted market prices.

Segment information

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and does not have separately reportable segments as defined by SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information .

Net loss per share

Basic earnings per share (EPS) is calculated by dividing earnings (loss) allocable to common stockholders by the weighted average shares of common stock outstanding. Net loss allocable to common stockholders includes preferred stock dividends. Diluted EPS would also include the effect of dilution to earnings of convertible securities, stock options and warrants. The Company has convertible debt, options and warrants

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

which have not been used in the calculations of diluted loss per share amounts because to do so would be anti-dilutive. As such, the numerator and denominator used in computing both basic and diluted loss per share amounts are equal. Potentially dilutive to EPS as of December 31, 2003 are outstanding options exercisable for 3,825,760 shares of common stock, outstanding warrants exercisable for 595,000 shares of common stock and convertible securities convertible into 1,171,782 shares of common stock.

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for reporting and presentation of comprehensive loss and its components in a full set of financial statements. Comprehensive loss consists of net loss and net unrealized gains (losses) on securities and is presented in the consolidated statements of comprehensive loss. SFAS No. 130 requires only additional disclosures in the financial statements; it does not affect the Company's financial position or results of operations.

Impairment or Disposal of Long-Lived Assets

SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which supersedes both SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and the accounting and reporting provisions of APB Opinion No. 30, *Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*, for the disposal of a business segment (as previously defined in that Opinion), retains the fundamental provisions in SFAS No. 121 for recognizing and measuring impairment losses on long-lived assets held for use and long-lived assets to be disposed of by sale, while also resolving significant implementation issues associated with SFAS No. 121. For example, SFAS No. 144 provides guidance on how long-lived assets that are used as part of a group should be evaluated for impairment, establishes criteria for when a long-lived asset is held for sale, and prescribes the accounting for a long-lived asset that will be disposed of other than by sale. SFAS No. 144 retains the basic provisions of APB No. 30 on how to present discontinued operations in the income statement but broadens that presentation to include a component of an entity (rather than a segment of a business). Unlike SFAS No. 121, an impairment assessment under SFAS No. 144 will never result in a write-down of goodwill. Rather, goodwill is evaluated for impairment under SFAS No. 142, *Goodwill and Other Intangibles Assets*. The Company adopted SFAS No. 144 in 2002. The adoption of SFAS No. 144 had no impact on the Company's consolidated financial statements. However, the Company applied SFAS No. 144 in determining the treatment of its discontinued sales operations.

Exit or Disposal Activities

SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity*. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. This statement requires a liability for a cost associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. It does not apply to costs associated with an entity newly acquired in a business combination or with a disposal activity covered by SFAS No. 144.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation.

3. Short-Term Investments

Short-term investments consist of fixed income securities with original maturities of greater than three months including U.S. treasury instruments of agencies of the U.S. Government and high-grade commercial paper. At December 31, 2002 and 2003, all of the short-term investments were deemed as available for sale investments.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

The following summarizes the available for sale investments at December 31, 2002 and 2003:

	Cost	Gross unrealized gains	Gross unrealized losses	Fair value
Certificate of deposit	\$ 11,177,774	\$	\$	\$ 11,177,774
Obligations of the U.S.				
Government and agencies of the U.S.	46,507,389	27,610	522,458	46,012,541
Commercial paper	86,695,926		1,591,753	85,104,173
December 31, 2002	\$ 144,381,089	\$ 27,610	\$ 2,114,211	\$ 142,294,488
Certificate of deposit	\$ 11,704,669	\$	\$	\$ 11,704,669
Obligations of the U.S.				
Government and agencies of the U.S.	51,247,385	3,023	28,168	51,222,240
Commercial paper	45,328,619		76,198	45,252,421
December 31, 2003	\$ 108,280,673	\$ 3,023	\$ 104,366	\$ 108,179,330
At December 31, 2003, maturities of investments were as follows:				
Less than 1 year	\$ 108,280,673	\$ 3,023	\$ 104,366	\$ 108,179,330

4. Equipment and Leasehold Improvements

Equipment and leasehold improvements consist of the following at December 31, 2002 and 2003:

	2002	2003
Computers and equipment	\$ 8,479,131	\$ 9,462,984
Leasehold improvements	5,750,900	5,750,938
	14,230,031	15,213,922
Less: accumulated depreciation and amortization	5,714,783	8,001,429
	\$ 8,515,248	\$ 7,212,493

Included in leasehold improvements is \$385,865 and \$119,334 related to construction in progress (CIP) at December 31, 2002 and December 31, 2003, respectively.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following at December 31, 2002 and 2003:

	December 31,	
	2002	2003
Interest payable	\$ 2,698,000	\$ 2,558,000
Payroll and employee benefits	1,195,391	1,831,651
Other current liabilities	767,793	932,899
Clinical development and research	1,231,491	797,928
Lease exit costs		680,006
Severance payable	607,863	
Sales and commercial operations costs	238,815	
	\$ 6,739,353	\$ 6,800,484

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

6. Convertible Subordinated Notes

The Company made a private offering of \$180.0 million of convertible subordinated notes due 2007, which closed on March 8, 2000. Gross proceeds from the issuance of convertible subordinated notes were \$180.0 million. Debt issuance costs of \$5,725,416 have been capitalized and are being amortized over the term of the notes. The notes are convertible into shares of the Company's common stock at a price of \$109.15 per share, subject to certain adjustments. The notes bear interest at a rate of 6% per annum, payable semi-annually in arrears, and can be redeemed by the Company, at certain premiums over the principal amount, at any time on or after March 6, 2003. The notes are subordinated in right of payment to all senior indebtedness of the Company. The notes may be required to be repaid on the occurrence of certain fundamental changes, as defined.

Through December 31, 2003, the Company has reduced \$52.1 in principal amount of its 6% convertible subordinated notes due in 2007. The Company has purchased for cash an aggregate of \$50.1 million in principal amount of its convertible subordinated notes for approximately \$18.5 million through December 31, 2003. In October and November 2003, the Company entered into agreements with a third party under which it issued 473,054 shares of its common stock in exchange for the surrender of \$2.0 million of face amount of its 6% convertible subordinated notes held by such third party. The shares issued in these transactions had a market value of \$1.2 million at the date of issuance. During 2003, the Company recognized a \$3.6 million gain related to the reduction of \$7.0 million in principal amount of its convertible subordinated notes, net of the write-off of \$0.1 million in related deferred financing costs. During 2002, the Company recognized a \$27.9 million gain related to the repurchase of \$45.1 million in principal amount of its convertible subordinated notes, net of the write-off of \$0.8 million in related deferred financing costs. These gains are classified as Gain on Repurchase of Debt, net.

7. License and Research Agreements

GlaxoSmithKline Agreement

In August 2003, ViroPharma announced the acquisition of worldwide rights (excluding Japan) from GlaxoSmithKline to an antiviral compound (maribavir, or VP41263) that is an inhibitor of cytomegalovirus (CMV). ViroPharma plans to advance maribavir initially for the prevention and treatment of CMV infection in transplant patients.

Under the terms of the agreement, ViroPharma has exclusive worldwide rights (excluding Japan) to develop and commercialize maribavir (VP41263) for the prevention and treatment of cytomegalovirus infections related to transplant (including solid organ and hematopoietic stem cell transplantation), congenital transmission, and in patients with HIV infection. ViroPharma will focus initially on patients who have received a hematopoietic stem cell (bone marrow) transplant, and are at risk for or have been infected with CMV. ViroPharma paid GlaxoSmithKline a \$3.5 million up-front licensing fee and may pay additional milestones based upon the achievement of defined clinical development and regulatory events, if any. The Company also will pay royalties to GlaxoSmithKline and its licensor on product sales in the United States and the rest of the world (excluding Japan). The \$3.5 million up-front licensing fee was recorded as an acquisition of technology rights expense during 2003 as the underlying technology has not reached technological feasibility and has no alternative uses.

Wyeth Agreement

In December 1999, the Company entered into a licensing agreement with Wyeth for the discovery, development and commercialization of hepatitis C drugs. In connection with the signing of the agreement, the Company received \$5.0 million from Wyeth. This amount is non-refundable and a portion of it was recorded as Deferred Revenue at December 31, 1999. This Deferred Revenue is being recognized as revenue as certain activities are performed by the Company over the estimated performance period. The original performance

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

period was 5 years. In 2002, the Company and Wyeth extended the compound screening portion of the agreement by two years, and as a result the Company extended the performance period from 5 years to 7 years. The unamortized balance of the Deferred Revenue will be amortized over the balance of the extended performance period. Of this deferred revenue, the Company recognized \$1.0 million as revenue in 2001, \$0.7 million as revenue in 2002, \$0.6 million as revenue in 2003 and \$1.7 million is recorded as deferred revenue at December 31, 2003. Additionally, the Company received \$2.0 million in milestone payments during 2001. If drug candidates are successfully commercialized, the Company has the right to co-promote the products and share equally in the net profits in the United States and Canada. The Company is entitled to milestone payments upon the achievement of certain development milestones and royalties for product sales, if any, outside of the United States and Canada.

In October 2000, the Company sold an aggregate of 200,993 shares of common stock to Wyeth for aggregate proceeds of \$6.0 million. The sales of common stock were as a result of progress made under the companies' hepatitis C virus collaboration. In connection with the collaboration and license agreement, Wyeth is required to purchase predetermined dollar amounts of additional shares of our common stock at a market value premium at the time of completion of certain product development stages. If additional shares are purchased, this excess will be accounted for as a credit to additional paid-in capital.

In June 2003, the Company amended its collaboration agreement with Wyeth to, among other things, focus the parties' screening activity on one target, to allocate more of the collaboration's pre-development efforts to ViroPharma (subject to our cost sharing arrangement with Wyeth for this work), and to clarify certain of the reconciliation and reimbursement provisions of the collaboration agreement. In addition, under the amended agreement both companies are permitted to work outside the collaboration on screening against targets other than the target being addressed by each company under the collaboration. In connection with the Company's restructuring in January 2004, it agreed with Wyeth that both would cease screening compounds against HCV under our collaboration. During the term of the agreement, the two parties will work exclusively with each other on any promising compounds and in one particular HCV target.

In connection with the collaboration, both parties perform certain research and development activities and share in the costs of those activities. At December 31, 2002, the Company owed Wyeth approximately \$0.7 million for research and development activities incurred by Wyeth during 2002, on behalf of the collaboration, which was reflected as additional costs to the Company of approximately \$0.7 million during 2002. As a result of the June 2003 amendment, the Company offset the \$0.7 million liability to Wyeth against 2003 alliance related research and development costs that the Company incurred and no balance remained outstanding between the companies as December 31, 2003.

Sanofi-Synthelabo Agreement

In December 1995, the Company entered into a license agreement with Sanofi-Synthelabo for pleconaril.

In February 2001, the Company revised its agreement with Sanofi-Synthelabo. The original agreement signed in 1995 provided the Company with exclusive rights to develop and commercialize the product in the United States and Canada. Under the revised agreement, the Company expanded its intellectual property position, eliminated obligations for future milestone payments, reduced royalty rate obligations to

Edgar Filing: VIROPHARMA INC - Form 10-K

Sanofi-Synthelabo on future sales of products, if any, under certain conditions, in exchange for a reduction of royalty rate obligations by Sanofi-Synthelabo to the Company on future sales of products, if any, under certain conditions, outside of the United States and Canada and the issuance of 750,000 shares of the Company's common stock. Included in operating expenses during the year ended December 31, 2001 is a non-cash charge of \$16.5 million resulting

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

from the issuance of the 750,000 shares of common stock to Sanofi-Synthelabo in exchange for the expansion of the Company's intellectual property rights related to pleconaril as these additional intellectual property rights licensed from Sanofi-Synthelabo had not reached technological feasibility and had no alternative uses.

The Company further amended its agreement with Sanofi-Synthelabo in November 2003 in connection with its entry into the option agreement with Schering Corporation in respect of intranasal pleconaril. If Schering exercises its option to continue the development and commercialization of pleconaril, the November 2003 amendment, among other things, reduces the royalty rate applicable to product sales, if any, in calculating the royalty payable to Sanofi-Synthelabo.

Schering

In November 2003, the Company entered into an agreement granting Schering Corporation the option to license its intranasal formulation of pleconaril for the treatment of the common cold in the United States and Canada. Under terms of the agreement, Schering paid ViroPharma an up-front option fee of \$3 million which is being recognized over its estimated performance period. ViroPharma is conducting a series of clinical studies designed to evaluate the antiviral activity, safety and other performance characteristics of the new intranasal pleconaril formulation. The Company expects results from these studies to be available in mid-2004.

Based on its assessment of the product's performance in these characterization studies, Schering has the option to enter into a full license agreement with ViroPharma under which it would assume responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. If Schering chooses to exercise its option, the Company expects to receive an initial license fee of \$10 million and Schering will purchase the Company's existing inventory of bulk drug substance for an additional pre-determined fee. The Company would also be eligible to receive additional milestone payments upon achievement of certain targeted events as well as royalties on Schering's sales of intranasal pleconaril in the licensed territory.

Other Agreements

The Company has entered into various other licensing, research and other agreements. Under these other agreements, the Company is working in collaboration with various other parties. Should any discoveries be made under such arrangements, the Company would be required to negotiate the licensing of the technology for the development of the respective discoveries. There are no significant funding commitments under any of these other agreements.

8. Common Stock and Common Stock Options

Common Stock

In August 2002, in connection with the transaction described in note 15, the Company sold Aventis Pharmaceuticals 3 million shares of the Company's common stock with a fair value of \$4.59 million.

In July 2001, the Company filed a Form S-3 universal shelf registration statement with the Securities and Exchange Commission (the "SEC") for the registration and potential issuance of up to \$300 million of the Company's securities, of which \$212 million remains at December 31, 2003. The registration statement will provide ViroPharma the flexibility to determine the type of security it chooses to sell, including common stock, preferred stock, warrants and debt securities, as well as the ability to time such sales when market conditions are favorable. In order for the Company to issue securities registered on this registration statement it must either have an aggregate market value of the voting and non-voting common equity excluding shares held by its affiliates of \$75 million or more, or it must file a post effective amendment to the registration statement on Form S-2 or S-1.

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

On October 19, 2001 the SEC declared the registration statement effective. On November 15, 2001, the Company entered into an underwriting agreement with Morgan Stanley & Co. Incorporated (Morgan Stanley) for the sale of 4,000,000 shares of its common stock. The sale was completed on November 19, 2001 and net proceeds from the sale were approximately \$82.7 million.

Effective May 7, 2001, pursuant to the terms of our Series A Convertible Participating Preferred Stock, 2,300,000 shares of preferred stock were converted into 2,346,295 shares of common stock (See note 9).

In February 2001, the Company revised its agreement with Sanofi-Synthelabo for Pleconaril. In conjunction with this revision the Company issued 750,000 shares of common stock to Sanofi-Synthelabo (See note 7).

In October 2000, the Company sold an aggregate of 200,993 shares of common stock to Wyeth for aggregate proceeds of \$6.0 million (See note 7).

On October 21, 1999, the Company completed a follow-on public offering of common stock. The Company sold 3,450,000 shares (including 450,000 shares exercised by the underwriters for over allotment). Net proceeds approximated \$61,450,000.

Stock Option Plans

In 1995, the Company adopted a Stock Option Plan and Restricted Share Plan, and amended and restated the Stock Option Plan in 1998, 2000 and 2001 (as amended and restated, the 1995 Plan), to provide eligible individuals with an opportunity to acquire or increase an equity interest in the Company and to encourage such individuals to continue in the employment of the Company. Stock options are granted with an exercise price at the fair market value of the stock on the date of grant. Stock options are exercisable for a period not to exceed ten years from the date of grant. Vesting schedules for the stock options vary, but, generally vest 25% per year, over four years.

In June 2001, the stockholders of the Company approved an amendment to increase the number of shares eligible to grant under the 1995 Plan by 1,000,000 shares and allow for the issuance of restricted shares. In May 2002, the stockholders of the Company approved an amendment to the Company's 1995 plan to increase the number of shares eligible for grant under the plan by 750,000 shares.

In November 2001, the Board of Directors amended and restated the 1995 Plan in order to provide for the delegation of certain administrative powers to a committee comprised of Company officers, and to normalize across all option holders the acceleration of unvested options under certain circumstances upon a change of control of the Company. As of December 31, 2003 there were approximately 367,100 options whose

Edgar Filing: VIROPHARMA INC - Form 10-K

vesting would have accelerated as a result of this amendment if these change of control circumstances had occurred and which would have resulted in approximately \$0.2 million of compensation expense as measured by the difference in the exercise price of the options with potentially accelerated vesting and the fair value of the Company's common stock on the Plan amendment date. A charge will be recorded in the future upon a change in control for only those options which would have otherwise expired unvested except for the resulting acceleration of vesting as a result of this amendment.

Also, in November 2001, the Company adopted a new Stock Option Plan (the 2001 Plan) allowing for the issuance of an additional 500,000 option awards to eligible individuals. The provisions with respect to the awarding, vesting and exercise of option grants under the 2001 Plan are similar to those of the 1995 Plan, except that under the 2001 Plan options can be granted at an exercise price that is less than the fair market value of the Company's stock at the time of grant.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

There are 5,000,000 combined shares in the aggregate reserved under the 1995 Plan and the 2001 Plan (together, the Plans). Stock option activity for the three years ended December 31, 2003 is as follows:

	Share Options	Weighted average exercise price per share
Balance, December 31, 2000	2,002,764	\$ 17.61
Granted	836,650	23.06
Exercised	(153,723)	6.73
Canceled	(92,850)	23.54
Balance, December 31, 2001	2,592,841	19.80
Granted	1,885,175	5.77
Exercised	(18,412)	2.11
Canceled	(1,104,467)	16.16
Balance at December 31, 2002	3,355,137	13.22
Granted	807,000	2.11
Exercised	(8,150)	0.35
Canceled	(328,227)	16.36
Balance at December 31, 2003	3,825,760	\$ 10.63

Stock options outstanding and exercisable as of December 31, 2003:

	Exercise Price Range of Options	Share Options	Weighted average remaining contractual life (Years)	Weighted average exercise price per share
Options Outstanding as of December 31, 2003	\$ 0.10-1.00	769,664	8.08	\$ 0.91
	1.07-1.58	129,150	8.96	1.49
	1.67-2.09	550,100	9.51	2.06
	2.16-8.75	726,304	7.01	4.81
	9.94-17.63	656,089	5.42	13.73
	17.75-22.99	584,676	7.03	21.21
	23.50-81.75	409,777	6.74	33.55

Edgar Filing: VIROPHARMA INC - Form 10-K

	\$ 00.10-81.75	3,825,760	7.34	\$ 10.63
Options Exercisable as of December 31, 2003	\$ 0.10-1.00	420,439		\$ 0.85
	1.07-1.58	13,575		1.27
	1.67-2.09	40,000		1.77
	2.16-8.75	507,456		5.27
	9.94-17.63	561,822		13.71
	17.75-22.99	350,356		21.08
	23.50-81.75	268,300		34.39
	\$ 00.10-81.75	2,161,948		\$ 12.69

At December 31, 2003, there were 689,457 shares available for grant under the Plans.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

The weighted average fair value of option grants during 2001, 2002, and 2003 was \$21.81, \$5.48, and, \$1.86 respectively. The fair value of each option grant is estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions for the Plans:

	<u>2001</u>	<u>2002</u>	<u>2003</u>
Expected dividend yield:			
Risk free interest rate:	4.4%	3.4%	3.7%
Volatility:	154%	155%	149%
Expected option life (in years):	5.9	5.7	5.4

Employee Stock Purchase Plan

In 2000, the stockholders of the Company approved an employee stock purchase plan. A total of 300,000 shares originally were available under this plan. In May 2003, the stockholders of the Company approved an amendment to the plan to increase the number of shares available for issuance under the plan by 300,000 shares. Under this plan, employees may purchase common stock through payroll deductions in semi-annual offerings at a price equal to the lower of 85% of the closing price on the applicable offering commencement date or 85% of the closing price on the applicable offering termination date. Under this plan 30,447 shares were sold to employees during 2001, 181,370 shares were sold to employees during 2002, and 48,438 were sold to employees during 2003. As of December 31, 2003 there are approximately 339,745 shares remaining under this plan. The plan qualifies under Section 423 of the Internal Revenue Code.

Restricted Common Stock

In 2000 and 2001, the Company issued 50,000 and 10,000 shares, respectively, of restricted common stock to executive officers of the Company. These shares vest ratably over 48 months. The fair value of such stock at the respective issuance dates was \$1.1 million and \$0.2 million, respectively. These amounts are reflected in deferred compensation and are being amortized to operations over the vesting period. During 2002 and 2003, no shares of restricted common stock were issued by the Company and 7,500 of restricted shares were forfeited by employees who had left the Company during 2002. The value of the shares forfeited during 2002 was approximately \$0.1 million. Compensation expense related to these issuances for the years ended December 31, 2001, 2002 and 2003 was \$0.3 million, \$0.3 million, and \$0.2 million, respectively.

9. Preferred Stock

The Company adopted a Stockholders Rights Plan (the Plan) in September 1998. In connection with the Plan, the Company designated from its Preferred Stock, par value \$.001 per share, Series A Junior Participating Preferred Stock, par value \$.001 per share (the Series A Preferred

Edgar Filing: VIROPHARMA INC - Form 10-K

Shares), and reserved 200,000 Series A Preferred Shares for issuance under the Plan. The Company declared a dividend distribution of one right for each outstanding share of common stock. The rights entitle stockholders to purchase one one-hundredth of a share of Series A Junior Participating Preferred Stock. The rights expire in 2008. Each holder of a right, other than the acquiring person, would be entitled to purchase \$250 worth of common stock of the Company for each right at the exercise price of \$125 per right, which would effectively enable such rights holders to purchase common stock at one-half of the then current price. At December 31, 2003, the rights were neither exercisable nor traded separately from the Company's common stock, and become exercisable only if a person or group becomes the beneficial owner of 20% or more of the Company's common stock or announces a tender offer which would result in ownership of 20% or more of the Company's common stock.

On May 5, 1999, the Company completed the sale of 2,300,000 shares of Series A Convertible Participating Preferred Stock (preferred stock). Net proceeds approximated \$13,300,000. In addition, the Company issued

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

warrants to purchase 595,000 shares of common stock at \$9.53 per share to the purchasers of the preferred stock. The warrants expire on May 5, 2004.

Effective May 7, 2001, pursuant to the terms of our Series A Convertible Participating Preferred Stock, 2,300,000 shares of preferred stock were converted into 2,346,295 shares of common stock.

Our Board of Directors has the authority, without action by the holders of common stock, to issue up to 4,800,000 additional shares of preferred stock from time to time in such series and with such preference and rights as it may designate.

10. Income Taxes

As of December 31, 2003, the Company has approximately \$123.2 million of Federal and \$123.2 million of state net operating loss carry forwards available to offset future taxable income. In addition, the Company has approximately \$7.4 million of Federal research and development credits available to offset future taxable income. The federal and state net operating loss carry forwards as well as the federal research and development credits will begin expiring in 2009, 2005 and 2009, respectively, if not utilized. In addition, the utilization of the state net operating loss carry forwards is subject to a \$2.0 million annual limitation. Also, based on "change in ownership" provisions of the Tax Reform Act of 1986, net operating loss carry forwards may be subject to annual limitations that could significantly reduce the Company's ability to utilize these carry forwards in the future.

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2002 and 2003 are shown below. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2002 and 2003. The change in the valuation allowance for 2002 and 2003 was an increase of approximately \$7.8 million and \$16.3 million, respectively. Additionally, at December 31, 2003, approximately \$1.7 million of gross deferred tax assets will reduce equity to the extent such assets are realized.

	December 31,	
	2002	2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 36,488,211	\$ 49,997,717
Research and development credits	6,978,118	7,442,311
Capitalized research and development costs	50,919,787	51,890,962
Income recorded for tax but not recorded on books, net	1,276,414	2,604,274

Total gross deferred tax assets	95,662,530	111,935,264
Valuation allowance	\$ (95,662,530)	\$ (111,935,264)
Net deferred taxes		

11. 401(k) Employee Savings Plan

In 1998, the Company adopted a new 401(k) Employee Savings Plan (the "401(k) Plan") available to all employees meeting certain eligibility criteria. The 401(k) Plan permits participants to contribute up to 15% of their compensation not to exceed the limits established by the Internal Revenue Code. All contributions made by participants vest immediately in the participant's account and the Company matches of 25% on the first 6% of participating employee contributions. The Company contributed \$130,086, \$234,719 and \$85,340 to the 401(k) Plan in 2001, 2002 and 2003, respectively. The Company's contributions are made in cash. The Company's common stock is not an investment option available to participants in the 401(k) Plan.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)****12. Loss per Share**

The following table shows the amounts used in computing loss per share:

	<u>2001</u>	<u>2002</u>	<u>2003</u>
Loss from continuing operations	\$ (78,481,204)	\$ (26,622,883)	\$ (36,941,939)
Income (loss) from discontinued sales operations	(4,476,244)	10,816,807	
Preferred stock dividends	345,242		
	<u> </u>	<u> </u>	<u> </u>
Net loss allocable to common stockholders	\$ (83,302,690)	\$ (15,806,076)	\$ (36,941,939)
	<u> </u>	<u> </u>	<u> </u>
Shares used in computing basic and diluted income (loss) per share amounts	18,167,303	23,952,940	25,916,466
	<u> </u>	<u> </u>	<u> </u>
Loss per share from continuing operations:			
Basic and diluted	\$ (4.32)	\$ (1.11)	\$ (1.43)
	<u> </u>	<u> </u>	<u> </u>
Income (loss) per share from discontinued sales operations:			
Basic and diluted	\$ (0.25)	\$ 0.45	\$
	<u> </u>	<u> </u>	<u> </u>
Net loss per share allocable to common stockholders:			
Basic and diluted	\$ (4.59)	\$ (0.66)	\$ (1.43)
	<u> </u>	<u> </u>	<u> </u>

13. Commitments and Contingencies

In March 1998, the Company entered into a lease for laboratory and office space. The term of the lease is ten years with two five-year renewal options. The Company also has the right, under certain circumstances, to purchase the facility. In September 2001, the Company entered into a fifteen year lease for additional office space. In the third quarter of 2003, the Company recognized a non-cash charge of approximately \$1.7 million in its general and administrative expenses for the operating lease related to this additional office space in accordance with SFAS 146. The charge was an estimate of the present value of the loss the Company will incur over the remaining life of the lease, which is 14 years, net of assumed sublease income of \$8.4 million beginning in the fourth quarter of 2004. The balance of the reserve at December 31, 2003 is \$1.5 million and has been reduced by payments made under our lease and accretion. Following our restructuring in January 2004, we further reduced our space requirements (see note 14). We will also reduce the liability recorded in 2003 related to space that we previously believed we would not occupy. We currently expect to move into a portion of this space in the second quarter of 2004. We are currently seeking to sublease all planned unused space to a third party. We cannot be certain that we will be able to sublease our planned unused space on favorable terms or at all.

In November 2001, the Company entered into an automobile fleet leasing arrangement for its sales force that was secured by a two-year letter of credit which was collateralized with a \$1 million certificate of deposit. During 2002, the Company terminated this lease agreement incurring termination costs that were included as part of its loss from discontinued sales operations (see note 15). Also during 2002, the Company reduced its letter of credit collateralizing this agreement to \$0.1 million and as of December 31, 2003, had no material obligation under this arrangement.

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

The Company's future minimum lease payments under the aforementioned leases and other operating leases related to equipment for years subsequent to December 31, 2003 are as follows:

Year ending	Operating
December 31,	leases
2004	\$ 1,784,917
2005	1,782,505
2006	1,751,497
2007	1,763,988
2008	1,776,729
Thereafter	6,890,636
Total minimum lease payments	\$ 15,570,272

Rent expense for the years ended December 31, 2001, 2002, and 2003 aggregated \$1,087,763, \$1,095,897 and \$1,776,729, respectively.

The Company has a severance plan and severance agreements for certain employees and change of control agreements for executive officers and certain other employees. Under its severance plan and severance agreements, certain employees may be provided separation benefits from the Company if they are involuntarily separated from employment. Under the Company's change of control agreements, certain employees are provided separation benefits if they are either terminated or resign for good reason from the Company within 12 months from a change of control.

In March and May 2002, complaints were filed in the United States District Court for the Eastern District of Pennsylvania against us seeking an unspecified amount of damages on behalf of an alleged class of persons who purchased shares of our common stock at various times between July 13, 1999 and March 19, 2002. In July 2002, the complaints were consolidated into a single action. The consolidated complaint names us, as well as certain of our directors and officers, as defendants. The consolidated complaint alleges that we and/or such directors and officers violated federal securities laws by misrepresenting and failing to disclose certain information regarding Picovir® (pleconaril). In August 2002, we filed a motion to dismiss the consolidated complaint. In April 2003, the court granted in part and denied in part the Company's motion to dismiss the consolidated complaint. In December 2003, we filed a motion for partial summary judgment of this action and a memorandum opposing the certification of the plaintiffs' class action status. On March 9, 2004, we entered into an agreement in principle with plaintiffs' counsel to settle this litigation. The proposed settlement will be paid from our insurance coverage and will not result in the payment of any funds by us. However, the proposed settlement is subject to the approval of the court. If the proposed settlement is not approved by the court, then the range of possible resolutions of these proceedings could include judgments against us or our directors or officers or settlements that could require substantial payments by us, which could have a material adverse impact on our financial position, results of operations and cash flows. These proceedings might require substantial attention of our management team and therefore divert time and attention from our business and operations.

14. Subsequent Events

In January 2004, the Company announced that it had restructured its organization to focus its resources on the advancement and development of later stage products. At the completion of certain activities required in connection with the restructuring in mid-2004, the Company will have reduced its workforce, including discontinuing its early stage activities, including discovery research and most internal preclinical activities, and reductions in clinical development and general and administrative personnel. The Company estimates that approximately \$9 million of severance, asset impairment, lease and other costs related to this restructuring will be included in the Company's 2004 financial results.

Table of Contents

ViroPharma Incorporated

(A Development Stage Company)

Notes to Consolidated Financial Statements (continued)

15. Restructuring

In August 2002, the Company adopted a restructuring plan.

Continuing Operations

As part of its restructuring plan, the Company announced that it would terminate 33 employees within the development, commercial operations, and administration departments of the Company. In August 2002, the Company accrued \$1.2 million in expenses associated with this portion of its restructuring plan, which primarily was comprised of employee severance costs associated with downsizing. This charge is included in the operating expenses of the Company for the year ended December 31, 2002. As of December 31, 2003, the Company paid \$1.2 million of termination benefits associated with the termination of 33 employees. There were no other changes to the accrued liability and no balance remained outstanding as of December 31, 2003.

Discontinued Operations

On September 1, 2002, Aventis acquired the Company's sales force, which totaled nearly 200 people, for \$15.41 million, which was recorded as a gain in 2002. There were no costs related to this transaction.

During the year ended December 31, 2002, the income from discontinued sales operations of the Company totaled \$10.8 million. This income included detailing fees of \$17.2 million, and \$2.6 million in costs of discontinuing the sales force operations for both the severance of 11 sales administration and sales force employees and the cost of terminating related operational commitments. An adjustment of \$0.4 million was recorded during 2002 to reduce the initial estimate of costs related to discontinuing the sales force operations. Also included in the loss for the year ended December 31, 2002, was \$19.2 million in sales operations costs. Costs associated with the discontinued operations for the same period in 2001 totaled \$4.5 million and consisted primarily of sales force start-up costs. As of December 31, 2003, the Company had paid \$2.6 million related to the costs of discontinuing the sales operations, primarily for severance, and no balance remained outstanding as of December 31, 2003.

Aventis Termination Agreement

In September 2001, the Company entered into a collaboration to co-develop and co-promote pleconaril in the United States with Aventis. This agreement was terminated on August 1, 2002.

Under the agreement ending their collaboration to co-develop and co-promote pleconaril, Aventis returned pleconaril to the Company, and both parties received mutual releases of all obligations without incurring termination fees. Aventis compensated the Company for Aventis' share of development and commercial expenses through July 2002 and the Company's detailing fees through August 2002, and the Company has returned to Aventis advance milestone payments of \$20.0 million. Aventis also purchased 3 million shares of the Company's common stock with a fair value of \$4.59 million. In accordance with the terms of the aforementioned agreements, the Company and Aventis offset all amounts due to each other with respect to the settlement, purchase of stock and sale of the sales force.

As a result of the termination of the Aventis agreement, the Company accelerated the recognition of the remaining \$4.0 million of deferred revenue related to the \$5.0 million up-front payment received in September 2001.

As part of the co-development and co-promotion agreement, the Company received an initial payment of \$25.0 million from Aventis. \$5.0 million of the initial payment received was reflected in Deferred Revenue, and

Table of Contents**ViroPharma Incorporated****(A Development Stage Company)****Notes to Consolidated Financial Statements (continued)**

was recognized as revenue on a straight-line basis through July 31, 2002 based on the then estimated performance period ending December 31, 2005. From September 2001 to July 31, 2002, the Company and Aventis shared the cost of preparing for the commercial launch of pleconaril and the continued marketing and commercialization efforts: 55 percent by Aventis and 45 percent by ViroPharma. Additionally, the agreement called for Aventis to fund 50 percent of the Company's research and development efforts for the use of pleconaril in the treatment of adult and pediatric viral respiratory infection (VRI). For the year ended December 31, 2002, approximately \$4.5 million and \$3.6 million were reflected as reductions of pleconaril research and development and marketing costs, respectively.

16. Quarterly Financial Information (unaudited)

This table summarizes the unaudited consolidated financial results of operations for the quarters ended:

	<u>March 31,</u>	<u>June 30,</u>	<u>September 30,</u>	<u>December 31,</u>
2003				
Revenues	\$ 202,309	\$ 140,909	\$ 217,734	\$ 1,051,222
Loss from continuing operations	(6,846,803)	(7,234,524)	(15,761,743)	(7,098,869)
Income (loss) from discontinued operations				
Net loss allocable to common stockholders	(6,846,803)	(7,234,524)	(15,761,743)	(7,098,869)
Basic and diluted income (loss) per share from continuing operations allocable to common stockholders	\$ (0.27)	\$ (0.28)	\$ (0.61)	\$ (0.27)
Basic and diluted income per share from discontinued operations allocable to common stockholders	\$	\$	\$	\$
Basic and diluted net loss per share allocable to common stockholders	\$ (0.27)	\$ (0.28)	\$ (0.61)	\$ (0.27)
2002				
Revenues	\$ 538,461	\$ 538,462	\$ 4,220,175	\$ 239,742
Income (loss) from continuing operations	(19,428,310)	(16,876,176)	5,128,180	4,553,423
Income (loss) from discontinued operations	(2,048,405)	115,223	12,314,570	435,419
Net income (loss) allocable to common stockholders	(21,476,715)	(16,760,953)	17,442,750	4,988,842
Basic and diluted income (loss) per share from continuing operations allocable to common stockholders	\$ (0.86)	\$ (0.74)	\$ 0.21	\$ 0.18
Basic and diluted income per share from discontinued operations allocable to common stockholders	\$ (0.09)	\$ 0.01	\$ 0.50	\$ 0.01
Basic and diluted net income (loss) per share allocable to common stockholders	\$ (0.95)	\$ (0.74)	\$ 0.71	\$ 0.19

