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# PEOPLE PRODUCTS PROGRESS

VIROPHARMA INCORPORATED 2004 ANNUAL REPORT

## OUR VISION

to become a profitable North America-based pharmaceutical company recognized worldwide for developing and marketing innovative products that address unmet medical needs. We are initially focusing on transplant and hospital settings, and on hepatologists and gastroenterologists, using our current product portfolio as our foundation, and expanding on those franchises by capitalizing on business development.

## VIROPHARMA INCORPORATED CORE VALUE DRIVERS

COMPOUND	DISEASE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKETED
Vancocin <sup>®</sup> Pulvules <sup>™</sup> HCl	<i>C. difficile</i> Colitis, <i>S. aureus</i> Enterocolitis*					
Maribavir	Cytomegalovirus					
HCV-796	Hepatitis C					
Intranasal Pleconaril	Common Cold	Under development by Schering-Plough Corporation				

\*Approved indication: Antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcal aureus*

Our annual report contains forward-looking statements relating to our belief that Vancocin sales will provide an excellent return on investment and fund our development programs and operational costs over the next several years; our hope that maribavir will offer patients an effective and better tolerated option than currently available alternatives; that each of our development compounds could be a breakthrough product and that patient demographics and antibiotic use may cause an increase in demand for Vancocin. These statements are based on management's current expectations, but the development and commercialization of pharmaceutical products is subject to many risks and uncertainties. Factors that could cause our actual results to differ significantly from these expectations are described in detail in our 2007 Annual Report to Stockholders filed with the Securities and Exchange Commission.

Information on our cover: Mary Schumacher,  
Viropharma Manager, Medical Writing

## MILESTONES

□ Shareholder approval of convertible financing	1Q '05
□ Results of HCV-086 Phase 1b POC trial	1Q '05
□ Began Vancocin medical education efforts	1Q '05
□ Integrated Vancocin into business	1Q '05
□ Presented maribavir Phase 1 data	1Q '05
□ Initiated HCV-796 Phase 1a trial	1Q '05
□ Initiate HCV-796 Phase 1b POC trial*	2Q '05
□ Results of maribavir Phase 2 trial*	3Q '05
□ Results of HCV-796 Phase 1b POC trial*	4Q '05
□ Quarterly updates on Vancocin progress	2005
□ Potential clinical/product portfolio additions	2005
□ Initiate maribavir Phase 3 trial*	1Q '06

\* Timeline reflects current estimates; also assumes that data support further development

Dear fellow shareholders,

PEOPLE. PRODUCTS. PROGRESS.

These three words define the fundamental nature of ViroPharma today, and will define us as we move forward.

At the beginning of 2004, we took the necessary step of dramatically changing our company to become a late stage, commercially focused organization with the goal of returning value to our shareholders by accelerating on our path toward generating revenues and achieving positive cash flows.

We are now a company building two franchises - products for use in transplant and hospital settings, and by hepatologists and gastroenterologists. Our four core value drivers are:

- **Vancocin Pulvules**, our marketed product;
- **Maribavir**, our product candidate for the treatment and prevention of cytomegalovirus disease in transplant patients;
- **HCV-796**, our product candidate targeting hepatitis C; and
- **Pleconaril**, the only drug to demonstrate antiviral efficacy against the predominant cause of the common cold, now in the hands of Schering-Plough Corporation.

I will now provide some detail on each of these core value drivers to give you a sense of the dramatic progress we made during the last calendar year.

### Vancocin Pulvules

During 2004, we fulfilled a promise that we made to our shareholders several years ago: to become a pharmaceutical company that develops and commercializes drugs that improve and save the lives of patients. We did so through our purchase from Eli Lilly and Company of Vancocin Pulvules, an important orally administered product used to treat two lower intestinal tract bacterial diseases. For patients at highest risk of disease caused by *Clostridium difficile*, Vancocin is a product that saves lives.

Vancocin is well known by physicians, with over 1.5 million prescriptions written for it since its approval. The number of patients at high risk of the disease is growing. As our population ages, spends increasing amounts of time in the hospital, and relies more on broad spectrum antibiotics, we believe that the demand for products like Vancocin will also grow. We are proud to be the company commercializing this important product, and believe it can provide an excellent return on our investment.

Over the past decade, sales of Vancocin have grown approximately 10 percent per year on an annualized basis, with no promotional effort by Eli Lilly. More recently, net sales grew significantly from \$40 million in 2003 to \$54 million in 2004. We believe that, because of the medical need, the specific qualities of the product, and our



#### Executive Officers

*Top row, Joshua Tarnoff, Colin Broom, Thomas Doyle  
Bottom row, Vincent Milano, Michel de Rosen*

educational efforts, sales of Vancocin should continue to grow. Thus, the product's contribution should fund our operational costs over the next several years. Nearer term, we expect that revenue from sales of Vancocin will enable us to be cash flow neutral or better this year, in 2005.

#### Maribavir for prevention of cytomegalovirus disease

Approximately 80 percent of adults are infected with cytomegalovirus (CMV). In the majority of these people, the infection is latent and not dangerous. However, in the 43,000 stem cell (bone marrow) or solid organ transplant patients in the United States each year, infection can lead to significant illness, and even death.

Maribavir, our anti-cytomegalovirus product candidate, passed the important hurdle of Phase 1 clinical evaluation and moved into Phase 2 testing during 2004. Although we still have much clinical work to do, we hope that maribavir may in the future offer patients undergoing stem cell and solid organ transplants a better tolerated option than current therapies.

#### HCV-796 for the treatment of Hepatitis C

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 hepatitis C virus (HCV).

Our diligence and work during 2004, and that of our partners at Wyeth Pharmaceuticals, resulted in different outcomes for our two anti-HCV compounds.

- Our Phase 1a work with HCV-086 was completed during 2004, and allowed us to enter into a Phase 1b proof of concept study with the compound. In this trial, HCV-086 demonstrated favorable pharmacokinetics and was generally safe and well tolerated. The results of the study indicated that after 14 days of treatment the greatest mean change in plasma HCV RNA concentrations ( $-0.32 \log_{10}$  IU/mL) occurred in the highest dose group. However, we decided with Wyeth that the antiviral activity, though encouraging, did not support further development of HCV-086.
- During 2004, we completed with Wyeth the preclinical evaluation of our third value driver, HCV-796, and now recognize that it may have significant advantages over all of the anti-HCV product candidates on which we have worked together in the past. We are excited about HCV-796 because it is from the same chemical series as HCV-086 with the added advantage of being significantly more potent *in vitro* and, importantly, because it has demonstrated antiviral activity in an animal model of hepatitis C infection. This compound is now being evaluated in humans in a Phase 1a study;

If the data from the first trial support advancement, we expect to initiate a Phase 1b proof of concept trial with the compound during the second quarter of 2005, with results due in the fourth quarter of this year.

#### **Pleconaril targeting the common cold**

Our fourth value driver, pleconaril – the product opportunity targeting the common cold that was once synonymous with ViroPharma – also met with great success during 2004. First, we reformulated pleconaril into an intranasal product. Then, in two clinical trials, we demonstrated similar efficacy to that shown by the oral product, and very low or undetectable plasma concentrations of pleconaril with no evidence of drug interaction. With those data in hand, we out-licensed pleconaril to Schering-Plough Corporation, a pharmaceutical company with excellent strengths in drug development and commercialization for respiratory medicine. Now a financial value driver for us, pleconaril has already provided us \$16 million in initial payments from the deal, and could result in not only an additional \$65 million in milestones, but also meaningful royalties on sales of the product in the United States, if indeed Schering-Plough is successful in its clinical and regulatory endeavors with the product.

There are similarities among all four of these value drivers: They all are focused in areas with a great unmet medical need, and have the opportunity to improve the lives of numerous patients. Moreover, each of our clinical compounds could be a breakthrough product if we are successful in their development, and may provide a valuable tool for physicians treating these significant diseases.

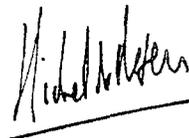
Our first purpose is to serve people: our patients, healthcare providers, and shareholders. We simply could not do it without the diligence of the people of ViroPharma, to whom I want to express my gratitude for their extraordinary work in 2004. Some of our people are new, and bring new strengths and talents to our team. Among them are:

- Colin Broom, our Chief Scientific Officer, who joined us from Amgen, Inc., where he was most recently the Vice President of Clinical Development and Medical Affairs, Europe;
- Josh Tarnoff, our Chief Commercial Officer, who joined us from AstraZeneca, where he most recently was the Senior Marketing Director for their established brand focused 'Phoenix Business Unit'; and
- Will Roberts, our head of Communications and Investor Relations, who joined ViroPharma after 12 years at MedImmune.

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We are now a company with a new focus, a new mission, a new team, a new product, and an entirely new and more balanced risk profile. The pace at which we completed our changes during 2004 is the pace at which we want to continue to evolve and bring new value to our shareholders. Our mandate is to bring better products to market and to build shareholder value. We will leverage the strengths of our people and products to continue our progress. And, we will work to provide value to our shareholders, our patients, and the physicians who treat them as we move forward.

2004 was the first year of the new ViroPharma. In 2005 we are working very hard to continue to build our new company. Thank you for your support, and here's to a bright future – for ViroPharma, for the patients whose lives we can impact, and for our shareholders.



Michel de Rosen  
*Chairman of the Board of Directors,  
President and Chief Executive Officer*

## VANCOCIN PULVULES

Vancocin Pulvules is indicated for antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile*, and enterocolitis caused by *Staphylococcal aureus*. Though staphylococcal

enterocolitis is uncommon, there are estimated to be over 400,000 cases of *C. difficile*-associated disease per year in the United States. The severity of disease ranges from troublesome diarrhea to severe

inflammation of the lining of the colon – called pseudomembranous colitis – that can lead to enlargement or perforation of the colon, and even death.



*With Vancocin, and through our efforts in medical education, we are saving lives, decreasing the financial burden of this disease, and helping patients suffering from C. difficile disease get home to their families and back to their lives.*

PATTY ACRI — MANAGER, BUSINESS DEVELOPMENT & MEDICAL INFORMATION



## Value Through Meeting Patients' Needs

What is the value of reliable and proven products? What is the value of effective treatments for dangerous bacterial diseases? Vancocin Pulvules is one of those products. At ViroPharma, we plan to measure this value by demonstrating a reduction in hospitalization days for patients taking this life saving medicine.

The vision of the founders of ViroPharma was to become a pharmaceutical company that develops and commercializes drugs that improve and save the lives of patients. That vision has become a reality through our acquisition and commercialization of Vancocin Pulvules, an important FDA-approved antibiotic indicated to treat two serious diseases of the lower gastrointestinal tract caused by *Clostridium difficile* and *Staphylococcus aureus*. This orally administered product is unique in that, unlike many other antibiotics, it is not absorbed into the bloodstream. As a result, high concentrations of Vancocin are maintained in the lower GI tract.

There is great medical need for Vancocin. More than 3 million cases of infectious diarrhea occur in the United States annually according to the CDC, and one of the single greatest contributors is *C. difficile* bacterial infection. Vancocin, which is specifically indicated for antibiotic-associated pseudomembranous colitis caused by *C. difficile* infection, is the only product approved by the FDA for this indication.

Patients at high risk of this disease are generally the elderly who have been hospitalized and have received broad-spectrum antibiotics that disturb the normal bacteria in the lower GI tract, thereby allowing *C. difficile* to flourish. These patients need an effective product to get them out of the hospital and back home to their families. Over the past

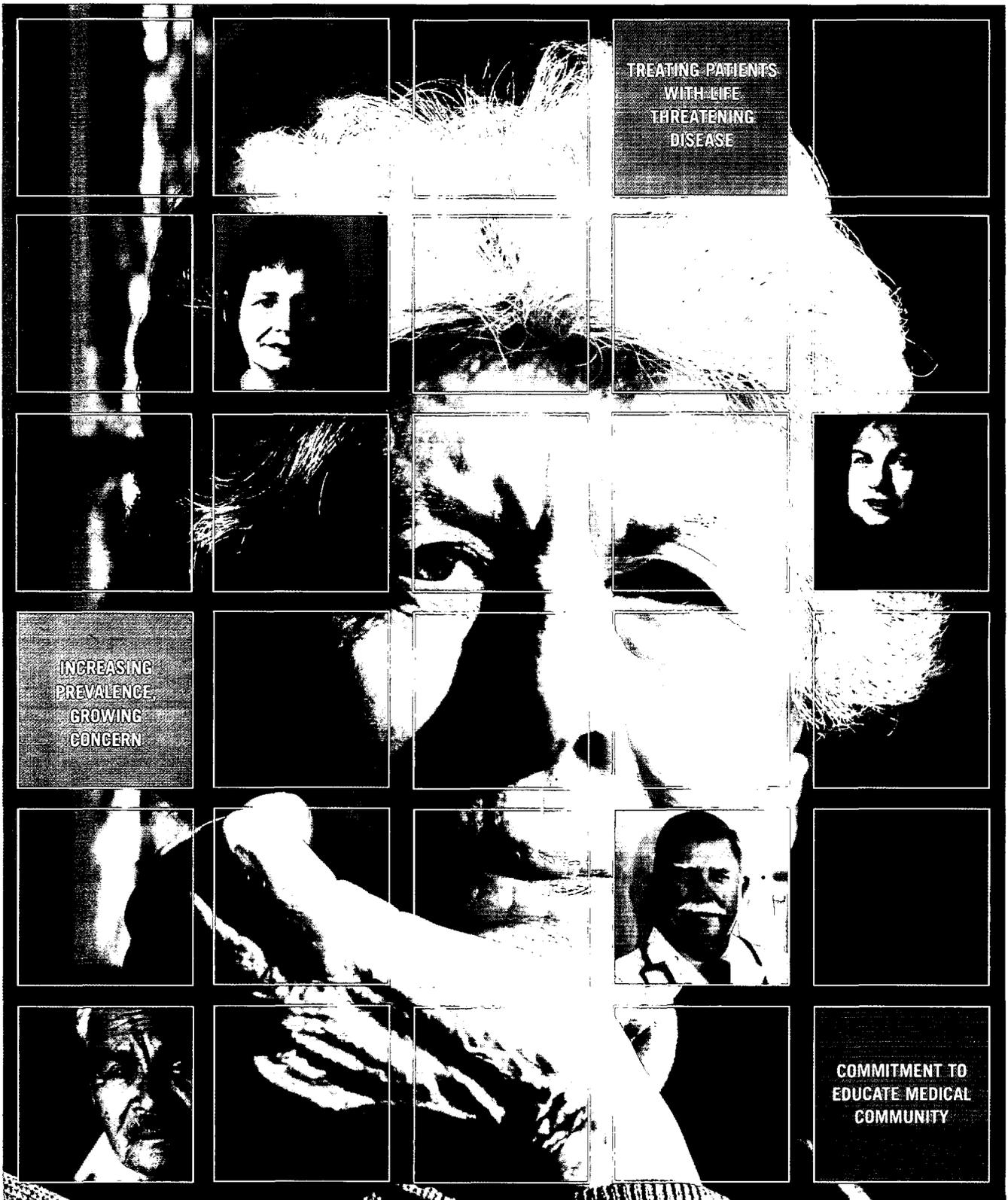
decade, the need for Vancocin has increased significantly, as the proportion of the population struck by significant disease from *C. difficile* has grown.

Through research and medical education programs, we intend to better understand the patients, the bacterium, and the epidemiology of infection; to find better ways to identify patients who may be at highest risk of serious disease; and to improve our understanding of how we can optimize the use of Vancocin.

Our 2004 acquisition of Vancocin from Lilly was an excellent deal for us and our shareholders. Sales have historically grown, with no promotional effort. Most recently, net sales in 2003 of \$40 million grew to \$54 million in 2004. In addition, our supply and distribution risks have been largely mitigated, through the quality of the transitional supply chain provided by Lilly, and the new supply chain we are building together. Overall, the Vancocin product contribution is expected to be robust. Going forward, our commercialization and medical education efforts can be effective with minimal expenses, and we expect that the manufacturing costs will continue to improve as we shift to our third party providers.

At ViroPharma, our people are dedicated to commercializing safe and effective products for patients who need them most. We are making a difference in patients' lives, each and every day.

*Pictured top left:  
Anne Andrei,  
Manager, Market  
Research &  
Business  
Development  
Pictured middle  
right: Michele  
Roy, Manager,  
Drug Safety &  
Regulatory  
Affairs*



TREATING PATIENTS  
WITH LIFE  
THREATENING  
DISEASE

INCREASING  
PREVALENCE.  
GROWING  
CONCERN

COMMITMENT TO  
EDUCATE MEDICAL  
COMMUNITY



43,000 U.S.  
TRANSPLANT  
PATIENTS  
PER YEAR



CYTOMEGALOVIRUS

NEED FOR IMPROVED  
THERAPIES



## CYTOMEGALOVIRUS



Physicians treating cytomegalovirus in transplant patients want an antiviral therapy with equivalent efficacy to currently available therapies, but with an improved side effect profile. There are approximately 18,000

autologous and allogeneic stem cell transplant patients, and 25,000 solid organ transplant patients annually in the United States who are at increased risk of serious repercussions from infection.

Maribavir, our specific anti-cytomegalovirus product opportunity targeting the UL97 gene product involved in viral maturation, may one day provide an improved therapeutic option to these patients.

*Cytomegalovirus is often misunderstood to be a virus causing an ocular disease in some HIV-positive patients; in reality, it's far more prevalent and dangerous.*

*CMV is a virus that most of us carry, and that can cause severe disease or death in anyone who has to undergo stem cell or solid organ transplantation.*

CAROLYN DOUGHERTY, MANAGER, CLINICAL PROGRAMMING

## Value Through Clinical Development

What is the value of prevention? What is the value of effective, better-tolerated therapies to treat life-threatening infections? At ViroPharma we hope to measure it in improved patient outcomes, and through a reduction in the impact of cytomegalovirus and hepatitis C.

Cytomegalovirus, or CMV, is an endemic virus that most of us harbor. A healthy immune system keeps the virus at bay, and most people who carry the virus will never suffer from disease. However, for the 43,000 patients in the United States who must undergo stem cell (bone marrow) or solid organ transplant each year, CMV infection can lead to significant illness, or even death.

Physicians treating patients at high risk of CMV disease have a difficult decision: Current therapies are effective against infections; however the side effects from these medicines, which include bone marrow suppression and kidney impairment are significant and difficult to manage.

At ViroPharma, we believe there could be an alternative.

Maribavir, our antiviral product opportunity targeting CMV, may one day offer patients something different: medicine to prevent CMV infection, with an improved side effect profile. ViroPharma acquired maribavir from GlaxoSmithKline in 2003, after several years of early clinical development as an anti-CMV agent for CMV retinitis in HIV-positive patients. Thus far, the compound has shown a favorable side effect profile compared to currently available products. Maribavir is in Phase 2 clinical testing in stem cell transplant patients. If successful, we hope that our Phase 3 trials, planned for the beginning of 2006, may lead us to a new, effective and well-tolerated option for the prevention of CMV disease in transplant patients.

*Pictured  
Middle Right:  
Sylvie Laquerre,  
Director,  
Clinical Virology*

## HEPATITIS C

Approximately four million Americans have been infected with Hepatitis C virus, or HCV, of whom an estimated 2.7 million are chronically infected. This makes it one

of the greatest public health threats faced last century, and one of the greatest threats yet to be successfully faced in the current century. HCV causes chronic liver disease,

which may lead to death in up to 5 percent of chronically infected patients, and is the leading indication for liver transplant.

*Hepatitis C infects 170 million people worldwide. Though there are risks associated with the development of safe, effective antiviral compounds targeting the virus, a success would have a major impact on worldwide health. So, for the sake of those suffering with the virus, it's a risk we are willing to take.*

CLAYTON FLETCHER — DIRECTOR, BUSINESS DEVELOPMENT & PROJECT MANAGEMENT



Hepatitis C is one of the most prevalent and significant viral diseases throughout the world. There are over 4 million hepatitis C-positive patients in the United States, and over 170 million people infected with hepatitis C worldwide. According to the CDC, deaths from hepatitis C infection may eclipse that of HIV by 2010.

For patients suffering from the disease, therapies are available. However, though effective, they may cause difficult side effects including anemia and neurological effects, and carry a low effectiveness against genotype 1, the most prevalent type of hepatitis C virus in the western world.

At ViroPharma, our people believe that we can do better.

With our partners at Wyeth, ViroPharma scientists have utilized cutting edge technologies to identify specific, novel compounds targeting the hepatitis C virus. Clinical evaluation is progressing on our product candidate, HCV-796, the most potent of all of the anti-HCV compounds developed between ViroPharma and Wyeth.

HCV-796 has the opportunity to build on the encouraging data gained from our proof of concept study with HCV-086, including excellent safety, tolerability and pharmacokinetics, and encouraging antiviral data. HCV-796 has the advantage of being from the same chemical class as HCV-086. It is more potent *in vitro* and, importantly, has demonstrated antiviral activity in an animal model of hepatitis C infection.

HCV-796 is in Phase 1a clinical testing in healthy adults. We expect to initiate Phase 1b clinical testing of the compound in the second quarter of 2005, with data from that trial available in the fourth quarter of this year. It is our hope that the efforts of our scientists, and of our partners at Wyeth, will demonstrate that HCV-796 is an effective and better-tolerated medicine to target hepatitis C virus, and will improve the lives of patients suffering from the disease.

At ViroPharma, we are making progress in bringing important new products to the patients suffering from illnesses with few, if any, well tolerated treatment options.

*Pictured  
Lower Left:  
Doug Pedersen,  
Senior Scientist II*



HEPATITIS C

4 MILLION  
INFECTED  
AMERICANS

170 MILLION  
WORLDWIDE

Excellence in business development has changed pleconaril, once synonymous with ViroPharma, into a financial value driver for the company. Through the efforts of the business development team

at ViroPharma, the company has found new ways of increasing its value. ViroPharma's business development efforts in out-licensing pleconaril to Schering-Plough and our preclinical biodefense assets

to SIGA Technologies, and in-licensing maribavir from GlaxoSmithKline and Vancocin Pulvules from Eli Lilly & Company are directed toward maximizing the value of our compounds.

## Value Through Business Development

What is the value of business development, and expanding the opportunities for a company? At ViroPharma, we believe it can be measured by the successes we have with products we acquire, and by the successes of other companies as they develop products originally discovered or developed by ViroPharma.

Throughout our history, we have proven ourselves to have significant skills in business development. Through these relationships, we have created new and exciting opportunities for increasing our corporate value. Among others, we entered into a productive relationship with Wyeth Pharmaceuticals to develop anti-viral medications targeting hepatitis C; we acquired from GlaxoSmithKline the worldwide rights (excluding Japan) to develop and potentially commercialize maribavir, our anti-cytomegalovirus compound; we out-licensed our promising, though early stage, biodefense assets to SIGA Technologies; and we acquired the rights to our first marketed product, Vancocin Pulvules, from Eli Lilly and Company.

In addition to the acquisition of Vancocin, one of our most significant business development efforts occurred in 2004, when we announced that Schering-Plough Corporation had licensed pleconaril, our compound targeting the common cold. The progress we made with the compound during the last 18 months was significant and

impressive: We reformulated pleconaril into an intranasal formulation to reduce the likelihood of drug interaction; we evaluated the antiviral activity and drug interaction potential of the compound in two clinical trials; and we found an excellent partner in Schering-Plough, a large and primary care-focused pharmaceutical company now controlling the development and ultimately, if successful, the commercialization of pleconaril.

For ViroPharma, pleconaril is now a financial value driver. We have already received \$16 million from Schering-Plough in initial payments; we may receive not only an additional \$65 million in milestones, but also a meaningful royalty on sales of the product, if pleconaril is successfully developed and commercialized by Schering-Plough.

Business development is only a tool — a tool to serve our goal of creating shareholder value by addressing unmet medical needs. People, products, progress: At ViroPharma, everyone has the same focus.

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# 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, 2004

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  
incorporation or organization)

**23-2789550**

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

**397 Eagleview Boulevard,  
Exton, Pennsylvania**

(Address of principal executive offices)

**19341**

(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:

None

Name of each exchange on which registered:

None

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

Common Stock, par value \$0.002

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.

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

The approximate aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$45.6 million as of June 30, 2004, based upon the closing sale price per share of the Common Stock as quoted on the Nasdaq National Market on that date.

The number of shares of the registrant's Common Stock outstanding as of March 1, 2005 was 27,460,024 shares.

### DOCUMENTS INCORPORATED BY REFERENCE

As stated in Part III of this Annual Report on Form 10-K, portions of the registrant's definitive proxy statement for the registrant's 2005 Annual Meeting of Stockholders to be held on May 20, 2005 are incorporated by reference in Part III of this Annual Report on Form 10-K.

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**VIROPHARMA INCORPORATED**  
**FORM 10-K ANNUAL REPORT**  
**For Fiscal Year Ended December 31, 2004**

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*"ViroPharma," "ViroPharma" plus the design, "Vancocin", and "Pulvules" are trademarks and service marks of ViroPharma or its licensors. "Pulvules" is a registered U.S. trademark owned by Eli Lilly and Company under license to ViroPharma Incorporated. 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.*

## PART I

### ITEM 1. BUSINESS

ViroPharma Incorporated is a pharmaceutical company dedicated to the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings. We market and sell Vancocin® Pulvules® HCl, the oral capsule formulation of Vancocin (vancomycin hydrochloride), in the United States and its territories. Oral Vancocin is a potent antibiotic approved by the U.S. Food and Drug Administration, or FDA, to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). We are focusing our current product development activities on viral diseases, including those caused by cytomegalovirus (CMV) and hepatitis C virus (HCV) infections. The status of our current product development activities is described under the heading "Product Pipeline."

We were incorporated in Delaware in September 1994 and commenced operations in December 1994. Our executive offices are located at 397 Eagleview Boulevard, Exton, PA 19341, our telephone number is 610-458-7300 and our website address is [www.viropharma.com](http://www.viropharma.com). Information contained on our website is not incorporated into this annual report on Form 10-K.

#### *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 clinical development stage or commercial product opportunities as a means to accelerate our path toward becoming a profitable pharmaceutical company.

We intend to initially build two franchises. We are focusing on transplant and hospital settings and hepatologists and gastroenterologists, using Vancocin and our two core clinical programs in CMV infections related to hematopoietic stem cell / bone marrow transplantation, and HCV infection, as foundations for that effort. To expand further our product portfolio, we plan to seek additional products for diseases treated by physician specialists and in hospital settings to complement the markets that Vancocin serves and that we hope our CMV and HCV programs will serve. To build these franchises we intend to:

- focus on the development of our two current core clinical programs;
- market Vancocin; and
- expand our product portfolio.

#### **Marketed Products**

Our first significant step toward becoming a company focused on product development and commercialization by establishing franchises within narrowly focused prescribing groups was our acquisition of Vancocin. In November 2004, we acquired all rights in the United States and its territories to manufacture, market and sell Vancocin Pulvules, as well as rights to certain related vancomycin products, from Eli Lilly and Company (Lilly). Oral Vancocin is a potent antibiotic approved by the FDA to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Lilly retained its rights to Vancocin outside of the United States and its territories.

*C. difficile* is a bacterium, which under certain circumstances, usually after or during antibiotic therapy, can colonize the lower gastrointestinal tract where it may produce toxins which cause inflammation of the colon and diarrhea. Hospitalized patients, particularly the elderly who have received broad spectrum antibiotics, are at greater risk of acquiring diseases related to *C. difficile* infection, which is now one of the most common nosocomial (spread patient to patient in a hospital) infections.

Gastrointestinal infections due to *C. difficile* range in severity from asymptomatic colonization to severe diarrhea, pseudomembranous colitis, toxic megacolon, colonic perforation and occasionally death. Advanced age, gastrointestinal surgery/manipulation, long length of stay in healthcare settings, a serious underlying illness and immunocompromising conditions are associated with increased risk of disease.

Vancocin Pulvules is currently the only approved oral antibiotic used to treat antibiotic-associated pseudomembranous colitis caused by an overgrowth of *C. difficile* in the colon and staphylococcal enterocolitis, an inflammation of the mucus membrane of the intestine caused by *S. aureus*. There are estimated to be at least 400,000 cases of *C. difficile*-associated diarrhea annually in the United States. Pseudomembranous colitis is one of the primary manifestations of *C. difficile*-associated diarrhea.

**Product Pipeline**

We have two core and one non-core product development programs. Our core programs target: (1) CMV with an initial focus on CMV infections in recipients of hematopoietic stem cell / bone marrow transplants, and (2) HCV. These programs are within the transplant and hospital settings, focus on diseases treated by hepatologists and gastroenterologists, and are at the center of our strategic focus. The non-core development program targets picornaviruses with intranasal pleconaril and has been licensed to Schering-Plough Corporation (“Schering-Plough”).

The following chart generally describes our clinical development programs:

Program / Disease Indication	Product Candidate	Development Status	ViroPharma Commercialization Rights
CMV	Maribavir	Phase 2	Worldwide, other than Japan
HCV	HCV-796	Phase 1	Co-promotion rights in the United States and Canada with Wyeth
Picornaviruses / common cold	Intranasal pleconaril	Licensed to Schering-Plough	Royalties on net sales in the United States and Canada, if any

*Cytomegalovirus*

In the first quarter of 2004, we initiated a program to further evaluate the clinical pharmacological properties of maribavir, including the potential of maribavir to interact with other drugs and to assess the pharmacokinetics of maribavir in subjects with renal impairment. We initiated a dose-ranging phase 2 clinical trial with maribavir for the prevention of CMV infections in allogeneic stem cell / bone marrow transplant patients in July 2004. We expect to have the results of our phase 2 clinical trial in the third quarter of 2005. If these data are supportive, we plan to initiate phase 3 clinical trials in the first quarter of 2006.

Cytomegalovirus, or CMV, 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, CMV has the ability to remain dormant in the body for long periods of time. 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. Currently, patients who are immunosuppressed following hematopoietic stem cell / 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, or even death. There are approximately 19,000 autologous and allogeneic stem cell / bone marrow transplant patients, and 26,000 solid organ transplant patients in the U.S. on an annual basis who are at increased risk of serious repercussions from infection.

Stem cell / bone marrow 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 are associated with the adverse effect of neutropenia, which may limit their use in certain patients. 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. The objective of the maribavir clinical program is to demonstrate that maribavir is at least as efficacious as the currently existing treatments with a better safety profile.

### *Hepatitis C*

In January 2005, Wyeth submitted an investigational new drug application to the FDA for HCV-796, and Wyeth and we initiated a phase 1 single dose clinical trial with HCV-796 in healthy subjects in February 2005. In March 2005, we announced results from our proof of concept study with HCV-086, and concluded that overall, the antiviral activity of HCV-086 did not support further development of the compound. The results of this ascending dose study indicated that after 14 days of treatment the greatest mean change in plasma HCV RNA concentrations ( $-0.32 \log_{10}$  IU/mL) occurred in the highest dose group. HCV-086 demonstrated favorable pharmacokinetics and was generally safe and well tolerated, although in the highest dose group gastrointestinal adverse events occurred in several subjects and caused discontinuation of treatment in two subjects. HCV-796 is from the same chemical series as HCV-086 with the advantage of being more potent *in vitro* and has demonstrated antiviral activity in an animal model of hepatitis C infection. Our Wyeth collaboration is a co-development and co-promotion agreement.

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.

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 who 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 several companies, in addition to Wyeth and us, 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 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.

In November 2004, we entered into a license agreement with Schering-Plough under which Schering-Plough has assumed responsibility for all future development and commercialization of intranasal pleconaril in the United States and Canada. Sanofi-Aventis has exclusive rights to market and sell pleconaril in countries other than the United States and Canada.

#### *Other*

We also have other non-core research and development programs that we have either discontinued, out-licensed or are attempting to out-license.

### **Business Development**

We intend to continue to evaluate in-licensing or other means of acquiring products in 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 and in which Vancocin is currently prescribed, or may be products to treat other diseases for which patients are treated by physician specialists or in hospital settings.

Competition for products in 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 may 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**

#### *Cytomegalovirus and 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 CMV disease. Maribavir is a benzimidazole compound that was in development by GSK for the treatment of CMV retinitis in HIV positive patients. We initiated a dose-ranging phase 2 clinical trial with maribavir for the prevention of CMV infections in allogeneic stem cell / bone marrow transplant patients in July 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 / bone marrow 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 cash 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 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.

### *Hepatitis C and 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 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' activity on one target, to allocate more of the collaboration's pre-development efforts to us (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 the 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, 2004, Wyeth has purchased an aggregate of 200,993 shares of our common stock for \$6.0 million 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.

### *Picornaviruses and Schering-Plough*

In November 2004, we entered into a license agreement with Schering-Plough under which Schering-Plough has assumed responsibility for all future development and commercialization of pleconaril in the United States and Canada. Schering-Plough paid us an initial license fee of \$10.0 million in December 2004 and purchased our inventory of bulk drug substance for an additional \$6.0 million in January 2005. We are also eligible to receive up to an additional \$65.0 million in milestone payments upon achievement of certain targeted regulatory and commercial events, as well as royalties on Schering-Plough's sales of intranasal pleconaril in the licensed territories. Schering-Plough paid us an upfront option fee of \$3.0 million in November 2003. In August 2004, Schering-Plough exercised its option to enter into the full license agreement with us following its assessment of the intranasal product's performance in characterization studies. Other than transitioning the technology to Schering-Plough, we will have no further continuing operational involvement with the development and commercialization of the intranasal formulation of pleconaril for the treatment of the common cold.

### *Picornaviruses and Sanofi-Aventis*

In our agreement with Sanofi-Aventis, originally entered into in December 1995 and amended and restated in February 2001, we received exclusive rights under patents owned by Sanofi-Aventis 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-Aventis in November 2003 in connection with our entry into the option agreement with Schering-Plough in respect of intranasal pleconaril. As a result of Schering-Plough's August 2004 exercise of its option to continue the development and commercialization of pleconaril, the November 2003 amendment provided that, among other things, the royalty rate payable to Sanofi-Aventis was reduced. 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-Aventis to prosecute and maintain certain of these patents, and to file any applications for patent term extension. We also may be dependent on Sanofi-Aventis to protect such patent rights.

Under our agreement with Sanofi-Aventis, 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-Plough's sales of the drug, which extends indefinitely. We are entitled to royalties from Sanofi-Aventis on sales of products by Sanofi-Aventis outside the United States and Canada. Sanofi-Aventis will make a milestone payment to us upon submission of pleconaril for regulatory approval in Japan. We are required to pay a portion of these royalties and milestones payable to Schering-Plough under our agreement with them.

Our patent licenses under the amended and restated agreement with Sanofi-Aventis 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-Aventis's patents and trademarks terminate, under certain circumstances the agreement may restrict our ability to market pleconaril and compete with Sanofi-Aventis. In addition, Sanofi-Aventis 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 contract with third parties for the manufacture and distribution of our product candidates.

We have entered into a supply agreement with Lilly for the manufacture and supply of the active pharmaceutical ingredient (API) of Vancocin and the Vancocin finished product for an agreed-upon time period. Vancocin finished product is sold in 125 mg and 250 mg capsules.

We are negotiating agreements with a supplier of the Vancocin API and with a manufacturer of finished products. Upon completion of the preparation of the finished product manufacturing facility and the receipt of required regulatory approvals, Lilly will cease supplying us with Vancocin and we will purchase API and finished products directly from these third parties.

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 FDA's 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 marketed drug and 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.

## **Marketing and Sales**

We have the exclusive right to market and sell Vancocin in the United States and its territories. Vancocin is distributed through wholesalers that sell the product to pharmacies and hospitals. In order to assist in the distribution of Vancocin in the United States we engaged Cardinal Health PTS, LLC in January 2005 to manage our warehousing and inventory program and to handle fulfillment of customer orders. Cardinal Health PTS, LLC also provides us with order processing, order fulfillment, shipping, collection and invoicing services related to our product sales. We currently have a limited marketing staff and do not have a sales staff. We do not anticipate developing a sales staff for oral Vancocin, rather we intend to focus on educational initiatives, thought leader development, physician education, and the targeted education of health professionals by utilizing a small number of medical science liaisons.

Under our agreement with GSK, 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 in the United States and Canada hepatitis C products arising from our collaboration. Under our agreement with Schering-Plough, they have the exclusive right to market and sell pleconaril in the United States and Canada.

The success and commercialization of our hepatitis C product candidates depend in part on the performance of Wyeth. Schering-Plough has the exclusive right to develop and commercialize pleconaril in the United States and Canada, thus the success and commercialization of pleconaril in those territories will depend entirely on the performance of Schering-Plough. 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 our marketing efforts for Vancocin will be successful, that any of our collaboration partners will be successful in commercializing the products that we have licensed to them, that our partners will adequately perform their obligations as expected, or that any revenue would be derived from such arrangements. In addition, 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. The last core patent protecting Vancocin expired in 1996. In order to continue to obtain commercial benefits from Vancocin, we will rely on product manufacturing trade secrets, know-how and related non-patent intellectual property. We own two issued United States patents covering Vancocin related technology. We currently have received two issued United States patent 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 three 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 respiratory syncytial virus (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 twenty-one 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 one pending United States patent application covering methods of reducing rhinovirus contagion. 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 are issued (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 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 FDA 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, or IND, and the filing of the corresponding New Drug Application, or NDA, plus the period of time between the filing of the NDA 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 the testing, manufacture, processing, quality control, safety, effectiveness, labeling, packaging, storage, handling, distribution, record keeping, approval, advertising, 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 maintain, 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;
- submission to and approval by the FDA of an Investigational New Drug Application (IND), including the results of preclinical evaluations and tests, along with manufacturing information and analytical data;
- 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, excretion and evidence of biological activity;
  - *Phase 2:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of patients to identify possible adverse effects and safety risks, to determine dose tolerance and the optimal effective dosage, and to collect initial efficacy data of the product for specific targeted diseases or medical conditions;
  - *Phase 3:* The drug is studied in an expanded, controlled patient population at multiple clinical study sites to demonstrate 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 and patent certification information on the drug to the FDA in a NDA;
- undergoing a successful FDA pre-approval inspection prior to approval of an NDA; and
- obtaining FDA approval of the NDA 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, and we cannot be certain that any approval will be granted on a timely basis, if at all. 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. In addition, an independent IRB at each clinical site proposing to conduct the clinical trials must review and approve each study protocol and oversee the conduct of the trial. The FDA may also raise questions about the conduct of the trials as outlined in the IND and impose a clinical hold on the trial. If a clinical hold is imposed, all of FDA's concerns must be resolved before the trial may begin again. Preclinical and clinical studies may take several years to complete, and there is no guarantee that an IND we submit on the based on such studies will become effective within any specific time period, if at all.

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 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 the FDA or additional trials may be required. As a condition of approval FDA 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 NDA.

Any products manufactured or distributed by us pursuant to FDA approval are subject to extensive continuing post-approval regulation by the FDA, including record-keeping requirements, obligations to investigate, analyze and report adverse experiences, and restrictions on advertising and promotional activities. 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. 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 NDA supplement to the FDA, and will not be able to commercialize any product modifications until FDA approval is received. 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.

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 (cGMPs) and undergo periodic inspections by the FDA.

In complying with the FDA's cGMP requirements, 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 cGMPs. Failure to comply with FDA requirements, including cGMPs, subjects the manufacturer to possible FDA action, such as untitled letters, Warning Letters, suspension of manufacturing operations, seizure of the product, voluntary or mandatory recall of a product, injunctive action, or

suspension or revocation of product approval, 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 FDA requirements, including cGMPs. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of non-compliance could have a material adverse impact on our business.

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. Foreign establishments manufacturing drug products for distribution in the United States also must list their products with the FDA and comply with cGMPs. They also are subject to periodic inspection by the FDA or by local authorities under agreement with the FDA.

The FDA's laws, regulations and policies may change, and additional governmental regulations or requirements may be enacted that could delay, limit or restrict, or prevent regulatory approval of our products or affect our ability to test, manufacture, market, or distribute our products following approval.

On December 8, 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) was signed into law and provides outpatient prescription drug coverage to eligible Medicare beneficiaries. The MMA established an interim prescription drug discount card program in June 2004 which allowed Medicare beneficiaries to obtain a Medicare endorsed, drug-discount card from prescription drug card sponsors, including pharmacy benefit management companies, wholesale or retail pharmacy delivery systems, insurers, and Medicare Advantage plans. The primary prescription drug benefit under the MMA, the new Medicare Part D coverage, is scheduled to begin January 2006. The new Part D prescription drug benefit will be administered regionally through Medicare-approved insurance plans. The legislation allows for the importation of prescription drugs from Canada, but only if the Secretary of the U.S. Department of Health and Human Services certifies to Congress that such importation would pose no additional risk to the public's health and safety and would result in significant reduction in the cost to customers, which the Secretary thus far has not done. There can be no assurance that this certification requirement will be maintained in future legislation or that the certification will continue to be withheld. Prior to the MMA, federal law would have permitted importation of medicines into the U.S. from a considerably larger group of developed countries, provided the U.S. Health and Human Services Department made the same safety and cost-savings certifications. We cannot predict the potential impact that the MMA will have on our business, because it is not clear how the law will be implemented by regulators or received by consumers and physicians. While the overall usage of pharmaceuticals may increase as the result of the expanded access to prescription drugs afforded under Medicare Part D, this may be offset by reduced pharmaceutical prices resulting from limited coverage of particular products in a therapeutic category and the enhanced purchasing power of the Medicare Part D plan sponsors. The impact could also be negative over the intermediate and longer term for our business generally as greater federal involvement and budget constraints may increase the likelihood of pricing pressures or controls in the future.

Federal and state governments also have pursued direct methods to reduce the cost of drugs for which they pay. We participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs whereby discounts and mandatory rebates are provided to participating state and local government entities. We also participate in other programs with government entities, the most significant of which are the U.S. Department of Defense and the U.S. Department of Veterans Affairs. These entities receive minimum discounts based off a defined "non-federal average manufacturer price" for purchases. Additional programs in which we participate provide mandatory discounts for outpatient medicines purchased by certain Public Health Service entities and "disproportionate share" hospitals (hospitals meeting certain criteria).

Our operations are also subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribe or rebate) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors. Because of the far-reaching nature of these laws, there can be no assurance that the occurrence of one or more violations of these laws would not result in a material adverse effect on our business, financial condition and results of operations.

We are also subject to various federal, state and local laws, rules, regulations and policies relating to safe working conditions, clinical, laboratory and manufacturing practices, environmental protection, 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, regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated. We may also incur significant costs to comply with such laws and regulations now and in the future, and the failure to comply may have a material adverse impact on our business.

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**

Patients with *C. difficile* associated diseases are generally treated with metronidazole, a generic product, and Vancocin is generally held in reserve for patients with severe disease or patients who have failed to respond to metronidazole. We are aware of several companies with product candidates in clinical development for treatment of *C. difficile* associated disease including, Oscient Pharmaceuticals Corporation, Genzyme Corporation, and Optimer Pharmaceuticals. In addition, there are marketed products that are not approved by the FDA for the treatment of *C. difficile* associated diseases but might, on occasion, be prescribed by physicians including cholestyramine and rifampin. It is also possible that other companies are or will be developing competitive products for this indication. Vancocin is not protected by patents and thus could also become subject to generic competition.

Stem cell / bone marrow 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 are associated with the adverse effect of neutropenia, which may limit their use in certain patients. Foscarnet (AstraZeneca) and cidofvir (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 used for the prevention of CMV infection in some patients. Additionally, we believe that there is at least one vaccine product in early-phase clinical trials and that there are several preclinical drug development initiatives targeted for this indication.

The most commonly used treatment for HCV are alfa-interferon products, alone or in combination with ribavirin. There are a number of products in clinical development including immunomodulators and specific inhibitors of HCV, making this a highly competitive field of clinical research.

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 include both public and private entities, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions. 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.

We intend to evaluate in-licensing or other opportunities to acquire products in 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 or in which Vancocin is prescribed. 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.

Many 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 March 1, 2005, we had 36 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.

## Executive Officers

The following is a list of our executive officers, including their ages, as of March 1, 2005 as well as certain information regarding each officer:

Name	Age	Position
Michel de Rosen . . . . .	54	President, Chief Executive Officer and Chairman of the Board of Directors
Colin Broom, M.D. . . . .	49	Vice President, Chief Scientific Officer
Thomas F. Doyle . . . . .	44	Vice President, General Counsel and Secretary
Vincent J. Milano . . . . .	41	Vice President, Chief Financial Officer and Treasurer
Joshua M. Tarnoff . . . . .	41	Vice President, Commercial Operations

Michel 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 Sanofi-Aventis), including Chief Executive Officer from May 1995 until December 1999, and Chairman and CEO from 1996 to 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 holds a MBA from the Ecole des Hautes Etudes Commerciales in France. Mr. de Rosen also is a director of ABB Ltd.

Colin Broom, M.D. has served as Vice President, Chief Scientific Officer of ViroPharma since May 2004. From 2000 until December 2003, Dr. Broom served as vice president of clinical development and medical affairs, Europe, for Amgen Inc. From 1998 to 1999, Dr. Broom served as senior vice president of global clinical development for Hoechst Marion Roussel, now Sanofi-Aventis. From 1987 until 1998 Dr. Broom held positions of increasing seniority in clinical pharmacology at SmithKline Beecham in Europe before moving to the U.S. to head global oncology and subsequently becoming Vice President of CNS/GI. From 1984 through 1987, Dr. Broom was a research physician with Glaxo Group Research Ltd. Dr. Broom holds a Bachelor of Science degree in pharmacology from University College London, and a Bachelor of Medicine and Bachelor of Surgery degree from St. George's Hospital Medical School. Dr. Broom is a Member of the Royal College of Physicians and a Fellow of the Faculty of Pharmaceutical Medicine of the UK Colleges of Physicians.

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.

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 received his B.S. in Accounting from Rider College. Mr. Milano also is a director of Verticalnet, Inc.

Joshua M. Tarnoff has served as Vice President, Commercial Operations since August 2004. Prior to joining ViroPharma, he served as the Senior Marketing Director, Phoenix Business Unit (Established Brands Business Unit), at AstraZeneca Pharmaceuticals. During his tenure, Mr. Tarnoff created the Phoenix Business Unit with responsibility for improving and maximizing AstraZeneca Pharmaceuticals' established brands portfolio. Prior to AstraZeneca Pharmaceuticals, he held positions of increasing seniority at Astra Merck and Astra Pharmaceuticals, including his service as the Director of Marketing of the Respiratory Therapeutics Area and similar roles in the Cardiovascular Therapeutic Area. Mr. Tarnoff holds a Bachelor of Arts degree in biology from LaSalle University.

**Available Information**

Our Internet website is [www.viopharma.com](http://www.viopharma.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.

## 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.*

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

We have incurred losses in each year since our inception in 1994. As of December 31, 2004, we had an accumulated deficit of approximately \$277.1 million. Our ability to achieve profitability is dependent on a number of factors, including our ability to integrate the Vancocin product line into our business, 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 further 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. We expect to incur additional net losses over the next several years, primarily due to our general and administrative expenses, interest payments on our outstanding debt, amortization of the purchase price of Vancocin, development costs from our CMV and HCV programs, and business development activities seeking new opportunities to expand further our product pipeline.

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

We have not completed the development of or received regulatory approval to commercialize any of our existing product candidates. Our failure to develop, receive regulatory approvals and commercialize our product candidates successfully may cause us to cease operations. Our development product candidates are at early stages of development and may not be shown to be safe or effective. We are performing phase 2 clinical research on a product candidate for the prevention and treatment of CMV and clinical research on a product candidate for the treatment of HCV and we out-licensed an intranasal product candidate for the treatment of the common cold to Schering-Plough. Our potential therapies under development for the treatment of CMV and HCV will require significant additional development efforts and regulatory approvals prior to any commercialization. We cannot be certain that our efforts and the efforts of our partners in this regard will lead to commercially viable products. For example, 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. Negative, inconclusive or inconsistent clinical trial results

could prevent regulatory approval, increase the cost and timing of regulatory approval, cause us to perform additional studies or to file for a narrower indication than planned. We do not know what the final cost to manufacture our CMV and HCV 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.

If we are unable to successfully develop our product candidates, and if we are unable to acquire additional marketed products through our business development efforts, we will not have a source of revenue other than Vancocin and may not achieve profitability or be able to service our debt requirements.

The development of 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 the product candidate delay or prevent regulatory approval;
- the FDA forbids us to initiate or continue testing of the product candidates in human clinical trials;
- the product candidate cannot be developed into a commercially viable product;
- the product candidate is difficult and/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;
- third party competitors hold proprietary rights that preclude us from marketing the product candidate; 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 a product candidate, regulators may disagree with us, which could delay, limit or prevent the approval of such product candidate. 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 additional already approved products, 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.

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.

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

**We will be heavily dependent on the continued sales of Vancocin.**

If revenue from Vancocin materially declines from the historical rate of sales for the product, our financial condition and results of operations will be materially harmed because, other than potential royalties and

milestone payments, sales of Vancocin may be our only source of revenue for the next several years. Competition from generics or the FDA approval of other drugs which compete with Vancocin would lead to greater competitive pressure on Vancocin sales.

Vancocin product sales could also be adversely affected by a number of other factors, including:

- manufacturing or supply interruptions, including but not limited to difficulties encountered in qualifying a third party supply chain;
- decreases in the rate of infections for which Vancocin is prescribed;
- decrease in the sensitivity of the relevant bacterium to Vancocin;
- the development of new competitive pharmaceuticals and technological advances to treat the conditions addressed by Vancocin;
- changes in terms required by wholesalers;
- marketing or pricing actions by one or more of our competitors;
- our ability to transition the Vancocin product line and enter all necessary contracts or obtain all necessary rights under applicable federal and state rules and regulations;
- the approval of legislative proposals that would authorize re-importation of Vancocin into the United States from other countries;
- regulatory action by the FDA and other government regulatory agencies;
- changes in the prescribing or procedural practices of infectious disease, gastroenterologists and internal medicine doctors;
- changes in the reimbursement or substitution policies of third-party payors or retail pharmacies; and
- product liability claims.

We cannot assure you that revenues from the sale of Vancocin will remain at or above current or historical levels. A decrease in sales of Vancocin could result in our inability to be at least cash flow neutral in 2005.

**Even if we are successful in integrating Vancocin, 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 HCV programs and in order to repay our debt obligations.**

We will need to raise substantial additional funds to continue our business activities and repay our debt obligations. We expect that Vancocin will generate significant cash flows for us and should allow us to substantially fund our development and other operating costs over the next several years. However, we expect to incur additional net losses over at least the next several years primarily due to our general and administrative expenses, interest payments on our outstanding debt service requirements, amortization charges related to the purchase price of Vancocin, development costs from our CMV and HCV programs, and business development activities seeking new opportunities to expand further our product pipeline. We believe that we will require additional capital by March 2007 when our 6% convertible subordinated notes mature. 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 reducing the principal amount of our indebtedness;
- our actual sales of Vancocin;
- the cost of commercializing Vancocin and our product candidates;

- our ability to generate revenue and positive cash flow through our HCV collaboration agreement with Wyeth;
- whether we receive the additional milestone payments and royalties associated with certain events along the development and commercialization lifecycle of pleconaril in connection with our November 2004 license agreement with Schering-Plough;
- the cost and progress of our clinical development programs;
- the cost of milestone payments that may be due to GlaxoSmithKline under our license agreement with them for maribavir, our product candidate to treat CMV, if pre-defined clinical and regulatory events are achieved;
- the time and cost involved in obtaining regulatory approvals;
- the cost of acquiring products in clinical development;
- the cost of acquiring commercialized products;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- our ability to license our early stage and other non-core assets to third parties; and
- the effect of changes and developments in our existing collaborative, licensing and other relationships.

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

- public and private securities offerings;
- debt financing, such as bank loans; and
- 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 expectation that we will sell additional 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.

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

We are highly leveraged and have significant debt service requirements. As of March 1, 2005 we had \$127.9 million in principal amount of indebtedness outstanding in the form of our convertible subordinated notes due 2007 and \$61.0 million in principal amount of indebtedness outstanding in the form of our 6% Convertible Senior Secured Notes due 2009, or senior convertible notes. Moreover, the holders of our senior convertible notes have the option to purchase an additional \$12.5 million principal amount of such notes from us in April 2005.

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.

Our ability to meet our debt service obligations and to reduce our total indebtedness depends on the results of our clinical development efforts, our future operating performance, our ability to generate cash flow from the sale of Vancocin through increased sales and receivables collections and on general economic, financial, competitive, legislative, 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.

If we incur new indebtedness in the future, the related risks that we now face could intensify. Whether we are able to make required payments on our outstanding indebtedness and to satisfy any other future debt obligations will depend on our future operating performance and our ability to obtain additional debt or equity financing.

**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 convertible subordinated notes and the senior convertible notes. If our cash, cash equivalents, short and long 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 the convertible subordinated notes and the senior convertible notes or our other obligations, we would be in default under the terms thereof, which would permit the holders of the senior convertible notes and the convertible subordinated notes to accelerate their maturities 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. Moreover, any default under our convertible subordinated notes also would cause a default under our senior convertible notes. A default under our senior convertible notes could result in the holders of the senior convertible notes foreclosing upon our Vancocin related assets which secure the senior convertible notes. We cannot be sure that we would be able to repay amounts due in respect of the convertible subordinated notes and the senior convertible notes if payment of our outstanding indebtedness were to be accelerated following the occurrence of an event of default as defined in the respective indentures of the foregoing convertible subordinated notes and senior 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.**

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 2004, we announced that we entered into a license agreement with Schering-Plough under which Schering-Plough assumed responsibility for all future development and commercialization of pleconaril. Pursuant to the agreement, Schering-Plough paid us an initial license fee of \$10.0 million and purchased our existing inventory of bulk drug substance for an additional \$6.0 million. We will also receive up to an additional \$65.0 million in milestone payments upon achievement of certain targeted regulatory and commercial events, as well as royalties on Schering-Plough's sales of intranasal pleconaril in the licensed territories. Sanofi-Aventis 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. Schering-Plough will receive a portion of any royalty payments made to us under our agreement with Sanofi-Aventis.

In August 2003, we entered into a license agreement with GSK under which we acquired worldwide rights, excluding Japan, from GSK to an antiviral compound, maribavir, for the prevention and treatment of CMV infections related to transplant (including solid organ and hematopoietic stem cell / bone marrow

transplantation), congenital transmission, and in patients with HIV infection. GSK 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 HCV 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 Wyeth, Schering-Plough and Sanofi-Aventis 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 from Sanofi-Aventis and GSK, 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 or others. Any license or sublicense of our commercial rights may reduce our 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 we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.**

Two of our current product candidates are based on intellectual property that we have licensed from Sanofi-Aventis and GSK. Another clinical development program involves a joint development program with Wyeth pursuant to which we licensed to Wyeth worldwide rights within a certain field under patents and know-how owned by us or created under the agreement. We depend, and will continue to depend, on these license agreements. All of our license agreements may be terminated if, among other events, we fail to satisfy our obligations as they relate to the development of the particular product candidate. All of our license agreements (other than the agreements with Lilly regarding Vancocin), may also be terminated if we breach that license agreement and do not cure the breach within specified time periods or in the event of our bankruptcy or liquidation. Our agreement with Lilly permits it to suspend the licenses granted to us by Lilly in the event of uncured defaults by us.

Our license agreement with GSK imposes various obligations on us, including milestone payment requirements and royalties. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

Disputes may arise with respect to our licensing agreements regarding manufacturing, development and commercialization of any of the particular product candidates. These disputes could lead to delays in or termination of the development, manufacture and commercialization of our product candidates or to litigation.

**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 GSK worldwide rights, excluding Japan, to an antiviral compound, maribavir, for the prevention and treatment of CMV infections related to transplant (including solid organ and hematopoietic stem cell/bone marrow 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-Aventis 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-Aventis, certain of which describe pleconaril and others of which describe compounds that are either related to pleconaril or have antiviral activity. We sublicensed our rights under these patents to Schering-Plough. We depend on GSK and Sanofi-Aventis to prosecute and maintain many of these patents and patent applications and protect such patent rights. Failure by GSK or Sanofi-Aventis 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 GSK and Sanofi-Aventis 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 HCV. In addition, several other companies, are developing compounds to treat HCV. Pfizer, Inc. may be developing a compound to treat infections caused by rhinoviruses, which are viruses included in the picornavirus family. Metronidazole is a generic product and is regularly prescribed to treat *C. difficile*-associated disease. Oscient Pharmaceuticals and Optimer Pharmaceuticals are developing antibiotics to treat *C. difficile*-associated diarrhea and Genezyme Corporation is developing compounds to treat the symptoms of *C. difficile*-associated diarrhea. Vancocin could also become subject to additional generic competition. 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. Our products could also be rendered obsolete or uneconomical by regulatory or competitive changes.

**Many other entities seek to establish collaborative arrangements for product research and development, or otherwise acquire products, in competition with us.**

We face competition from large and small companies within the pharmaceutical and biotechnology industry as well as public and private research organizations, academic institutions and governmental agencies in acquiring products and 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 further our pipeline through the in-license or acquisition of additional products in 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. We may need additional financing in order to acquire additional new products. Our outstanding indebtedness may make it more difficult for us to raise additional financing.

**Core patent protection for Vancocin has expired, which could result in significant competition from generic products resulting in a significant reduction in sales of Vancocin.**

The last core patent protecting Vancocin expired in 1996, which could result in significant competition from generic products and, particularly in the United States, can result in a significant reduction in sales of Vancocin. In order to continue to obtain commercial benefits from Vancocin, we will rely on product manufacturing trade secrets, know-how and related non-patent intellectual property. The effect of this patent expiration depends upon:

- the nature of the market and the position of Vancocin in the market from time to time;
- the growth of the market;
- the complexities and economics of manufacture of a competitive product; and
- the regulatory approval requirements of generic drug laws.

**We will rely on our employees and consultants to keep our trade secrets confidential.**

We rely on trade secrets, trademarks, and unpatented proprietary know-how and continuing technological innovation in developing and manufacturing our products, including Vancocin. We require each of our employees, consultants and advisors to enter into confidentiality agreements prohibiting them from taking our proprietary information and technology or from using or disclosing proprietary information to third parties except in specified circumstances. The agreements also provide that all inventions conceived by an employee, consultant or advisor, to the extent appropriate for the services provided during the course of the relationship, are our exclusive property, other than inventions unrelated to us and developed entirely on the individual's own time. Nevertheless, these agreements may not provide meaningful protection of our trade secrets and proprietary know-how if they are used or disclosed. Despite all of the precautions we may take, people who are not parties to confidentiality agreements may obtain access to our trade secrets or know-how. In addition, others may independently develop similar or equivalent trade secrets or know-how.

**We depend on patents and proprietary rights for our products which are in clinical development, 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 in clinical development, 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 eight issued United States patents, five non-United States patents and have twenty-four 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.

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.

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 seek to enforce 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.

**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.

**We rely on a third party to perform the distribution and logistics services for Vancocin.**

We rely on a single third party to provide distribution and logistics services including warehousing of finished product, accounts receivable management, billing, collection and recordkeeping. If the third party ceases to be able to provide us with these services, or does not provide these services in a timely or professional manner, we may not be able to successfully integrate Vancocin into our business, which may result in us not achieving the sales of Vancocin that we expect. Additionally, any delay or interruption in the process or in payment could result in a delay delivering product to our customers, which could have a material effect on our business.

The third party service provider stores and distributes our products from a single warehouse located in the central United States. A disaster which occurs at or near this facility could materially and adversely impact our ability to supply Vancocin to our wholesalers which would result in a reduction in revenues from sales of Vancocin.

**We have limited sales and marketing infrastructure 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 GSK, 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 HCV products arising from our collaboration in the United States and Canada. Schering-Plough is solely responsible for the marketing, promotion and sale of intranasal pleconaril following its approval. We intend to continue to pursue in-licensing or other means of acquiring products in clinical development, or that are currently on the market but are under promoted or not currently promoted.

We currently have a limited marketing staff and no sales staff. As a result of our acquisition of Vancocin, we need to build a commercial capability. Although our anticipated expenditures for Vancocin are expected to be modest, the development of a marketing and sales capability for our product candidates in clinical development could require significant expenditures, management resources and time. We may be unable to build a marketing and sales capability, the cost of establishing such a marketing and sales capability may exceed any product revenues, and our marketing and sales efforts may be unsuccessful. We may not be able to find a suitable sales and marketing partner for our other product candidates. 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 future revenues may be delayed.**

We do not have the internal capability to manufacture commercial quantities of pharmaceutical products under the FDA's current Good Manufacturing Practices, or 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 and product candidates. 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 and product candidates. 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 and product candidates. If we are required to find an additional or alternative source of supply, there may be additional costs and delays in the development or commercialization of our products and product candidates. Additionally, the FDA inspects all commercial manufacturing facilities before approving a new drug application, or 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 and product candidates may be delayed.

We will continue to buy Vancocin finished product from Lilly until the earlier of a date following the regulatory qualification of alternative supply sources or a date agreed to with Lilly, at which time Lilly will cease to manufacture and sell finished product and active pharmaceutical ingredients to us. Although Lilly has entered into agreements with third party contract manufacturers, we anticipate that it will take us approximately one year

to qualify these alternate sources. There is no guarantee that the contract manufacturers will be qualified in the time periods expected, or at all. Following qualification, we will be dependent upon a sole source supplier of active pharmaceutical ingredients and a sole finished product manufacturer. If our contract manufacturers are not qualified by regulatory authorities before the latest date that Lilly is required to supply us with Vancocin finished product, we will experience supply interruptions that may materially and adversely effect our sales and our business. If our contract manufacturers cannot provide us with our Vancocin requirements in a timely and cost-effective manner, or if the product they supply does not meet commercial requirements for shelf life, our sales of marketed products could be reduced.

Any commercial dispute with any of our suppliers could result in delays in the manufacture of our product, and affect our ability to commercialize our products. We cannot be certain that manufacturing sources will continue to be available or that we can continue to out-source the manufacturing of our products on reasonable or acceptable terms. Any loss of a manufacturer or any difficulties that could arise in the manufacturing process could significantly affect our inventories and supply of products available for sale. If we are unable to supply sufficient amounts of our products on a timely basis, our market share could decrease and, correspondingly, our revenues would decrease.

If our contract manufacturers fail to comply with cGMP regulations, our product commercialization could be delayed or subject to restrictions or we may be unable to meet demand for our products and may lose potential revenue.

All of our contract manufacturers must comply with the applicable FDA cGMP regulations, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. If our contract manufacturers do not comply with the applicable cGMP regulations and other FDA regulatory requirements, the availability of marketed products for sale could be reduced and we could suffer delays in the progress of clinical trials for products under development. We do not have control over our third-party manufacturers' compliance with these regulations and standards. 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 our supply of finished products is interrupted, our ability to maintain our inventory levels could suffer and future revenues may be delayed.**

We will try to maintain inventory levels that are no greater than necessary to meet our current projections, plus a reasonable safety stock. Any interruption in the supply of finished products could hinder our ability to timely distribute finished products. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose those orders and our customers may cancel other orders and stock and sell competing products. This in turn could cause a loss of our market share and negatively affect our revenues.

Supply interruptions may occur and our inventory may not always be adequate. Numerous factors could cause interruptions in the supply of our finished products, including failure to have a third party supply chain validated in a timely manner, shortages in raw material required by our manufacturers, changes in our sources for manufacturing, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials. Lilly experienced a supply interruption during 2002 due to changes in quality standards for Vancocin and its components and there is no assurance that we will not experience similar or dissimilar supply interruptions.

We obtained business interruption insurance which could mitigate some of our loss of income in the event of certain covered interruptions of supply. However, it will probably not completely mitigate the harm to our business from the interruption of the manufacturing of products. The loss of a manufacturer could still have a negative effect on our sales, margins and market share, as well as our overall business and financial results.

**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.

**Our future product revenues from sales of Vancocin could be reduced by imports from countries where Vancocin is available at lower prices.**

Vancocin has been approved for sale outside of the United States, including but not limited to Canada, Brazil and Europe, and Lilly will continue to market Vancocin outside of the United States. There have been cases in which pharmaceutical products were sold at steeply discounted prices in markets outside the United States and then re-imported to the United States where they could be resold at prices higher than the original discounted price, but lower than the prices commercially available in the United States. If this happens with Vancocin our revenues would be adversely affected. Additionally, there are non-U.S. internet based companies supplying Vancocin directly to patients at significantly reduced prices.

In recent years, various legislative proposals have been offered in Congress and in some state legislatures that would authorize re-importation of pharmaceutical products into the United States from other countries (including Canada). We cannot predict the outcome of such initiatives, and it is difficult to predict the future impact of the broad and expanding legislative and regulatory requirements affecting us.

**Orders for Vancocin may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.**

Our customers for Vancocin include some of the nation's leading wholesale pharmaceutical distributors. We monitor wholesaler inventory of our products using a combination of methods, including tracking prescriptions filled at the pharmacy level to determine inventory amounts sold from the wholesalers to their customers. However, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive inventory production, inadequate supplies of products in distribution channels, insufficient or excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. Forward-buying by

wholesalers, for example, may result in significant and unexpected changes in customer orders from quarter to quarter. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly.

**Our successful commercialization of our products will depend, in part, on the availability of third party reimbursement.**

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. Federal and state regulations govern or influence the reimbursement to health care providers of fees in connection with medical treatment of certain patients. In the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of drugs. Continued significant changes in the health care system could have a material adverse effect on our business. Decisions by state regulatory agencies, including state pharmacy boards, and/or retail pharmacies may require substitution of generic for branded products, may prefer competitors' products over our own, and may impair our pricing and thereby constrain our market share and growth. In addition, we believe the increasing emphasis on managed care in the United States could put pressure on the price and usage of our product candidates, which may in turn adversely impact future product sales.

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.

In recent years, various legislative proposals have been offered in Congress and in some state legislatures that include major changes in the health care system. These proposals have included price or patient reimbursement constraints on medicines and restrictions on access to certain products. We cannot predict the outcome of such initiatives, and it is difficult to predict the future impact of the broad and expanding legislative and regulatory requirements affecting us.

**Historically, Vancocin has been subject to limitations on the amount of payment and reimbursement available from third party payors.**

Historically, only a portion of the cost of Vancocin prescriptions is paid for or reimbursed by managed care organizations, government and other third-party payors. This reimbursement policy makes Vancocin less attractive, from a net-cost perspective, to patients, suppliers and prescribing physicians. For example, metronidazole is significantly less expensive than Vancocin. If adequate reimbursement levels are not provided for Vancocin, or if those policies increasingly favor other products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

**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 and HCV in clinical development. Schering-Plough is conducting the clinical development of pleconaril. We must complete significant laboratory, 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. For example, 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/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 a NDA is submitted, a 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 to service our debt requirements.

**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.**

Vancocin and any other 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, and with Vancocin, we currently 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 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, our Vice President and Chief Financial Officer, Vincent J. Milano, our Vice President and Chief Scientific Officer, Colin Broom and our Vice President Commercial Operations, Joshua Tarnoff. We are currently seeking to fill certain key positions, including persons to lead our supply chain logistics and regulatory compliance 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.

**Our restructuring plan may not achieve the intended benefits.**

We restructured in January 2004 as part of our effort to redefine 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 clinical development stage or commercial product opportunities as a means to accelerate our path toward becoming a profitable pharmaceutical company. 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 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 may need additional financing in order to acquire additional new products or product candidates. We are currently exploring alternatives to either reduce the outstanding principal amount or to restructure our convertible subordinated notes. Even if we are successful in such efforts, our outstanding indebtedness 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 periods described in this report may vary depending on a variety of factors, including:

- the level of revenue from sales of Vancocin actually received by us;
- our actual operating costs related to Vancocin;
- the cost of acquiring additional new product opportunities as a result of our business development efforts;
- the actual cost of conducting clinical trials;
- the outcome of clinical trials in our CMV and HCV programs;
- whether we receive any of the milestone payments and royalties contemplated by our license agreement with Schering-Plough relating to the development and commercialization of intranasal pleconaril;
- our resulting right to receive or obligation to pay milestone payments under agreements relating to our CMV, HCV and common cold programs;
- our ability to terminate our lease for our unused office and lab space; and
- whether we are able to maintain our listing on The NASDAQ Stock Market.

In addition to the points noted above, our ability to achieve and sustain 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), acquiring additional products through our business development efforts, 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.

**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 may not protect us from product liability claims.

We currently maintain product liability insurance in connection with our clinical development programs and marketing of Vancocin. We may not be able to obtain or maintain adequate protection against potential liabilities arising from clinical development or product sales. If we are unable to obtain sufficient levels of 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 may not have sufficient funds to purchase the senior convertible notes upon a repurchase event.**

We may not have the funds necessary to purchase the senior convertible notes at the option of the holders upon specified repurchase events, including a change in control or a delisting. If a repurchase event were to occur, we may not have sufficient funds to pay the purchase price for all tendered senior convertible notes, or restrictions in our outstanding debt may not allow those purchases. We are only obligated to offer to repurchase the senior convertible notes upon repurchase events specified in the indenture governing the terms of the senior convertible notes.

**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 pharmaceutical companies, has been volatile. For example, during the last twelve months, the market price for our common stock traded between \$1.40 and \$3.74 per share. The following factors, among others, could have a significant impact on the market for our common stock:

- period to period fluctuations in sales of Vancocin;
- results of clinical trials with respect to our product candidates in development or those of our competitors;
- developments with our collaborators;
- the existence of the senior convertible notes may encourage short selling by market participants because the conversion of the senior convertible notes could depress the price of our common stock;
- announcements of technological innovations or new products by our competitors;
- litigation or public concern relating to our products or our competitors' products;
- 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;
- 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 on our performance by securities analysts;
- market conditions applicable to our business sector; and
- general market conditions.

#### **Future sales of our common stock in the public market or the conversion of the senior convertible notes into shares of our common stock 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.

As of December 31, 2004, we had outstanding options to purchase 2,550,146 shares of our common stock at a weighted average exercise price of \$8.46 per share (1,147,376 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 152,025 shares of our common stock at a weighted average exercise price of \$1.27 per share (52,874 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, restricted stock grants and shares of common stock, 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 perception that such sales or issuances could occur, could adversely affect the prevailing market prices for our common stock.

The terms of our \$61.0 million in aggregate principal amount senior convertible notes outstanding as of March 1, 2005 will permit the holders thereof to voluntarily convert their senior convertible notes at any time into shares of common stock at \$2.50 per share, subject to adjustment. We will also have the option of auto-converting, on a quarterly basis, up to 25% of the total principal amount of any senior convertible notes issued, subject to certain conditions. As a result of these shares of our common stock being issued upon voluntary or auto-conversion of the senior convertible notes our stockholders may experience substantial dilution of their ownership interest, which could adversely affect our stock price. As of March 1, 2005, \$1.5 million in principal aggregate amount of our senior convertible notes have been converted to 600,000 shares of common stock. In addition, the existence of the senior convertible notes may encourage short selling by market participants because the conversion of the senior convertible notes could depress the price of our common stock.

**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 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, 2004, our stockholders' equity was below \$10.0 million. If our stockholders' equity remains below \$10.0 million, then to maintain our NASDAQ National Market listing we will be required to maintain a minimum bid price of \$1.00 per share and a \$50.0 million market value of our listed securities. In the second quarter of 2004 we were not in compliance with the NASDAQ continued listing requirements, however, in August 2004, we received a notice from NASDAQ that at such time we met all of the criteria for continued listing on the NASDAQ National Market.

**If our stock is delisted from The NASDAQ National Market, 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, 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.

**We previously used 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 radioactive and other materials that could be hazardous to human health, safety or the environment. In connection with our restructuring in January 2004, we decommissioned our discovery laboratories, which required 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 stored 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.

## **ITEM 2. PROPERTIES**

As of December 31, 2004, we leased 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. During February 2005, we reached a tentative agreement with the landlord to exit the lease that expires in 2008 in the second quarter of 2005. The facility under the lease that expires in 2008 represents 86,000 square feet of space. After this termination, we will have 33,000 square feet in one facility under an operating lease that expires in 2017.

## **ITEM 3. LEGAL PROCEEDINGS**

In March and May 2002, we and certain of our directors were named as defendants in purported class actions filed in the United States District Court for the Eastern District of Pennsylvania. In July 2002, these actions were consolidated into a single complaint, which also named certain of our officers as defendants. The plaintiffs in these actions have alleged that certain statements by us about oral pleconaril were misleading. We filed a motion to dismiss this action in August 2002. In April 2003, the court granted in part and denied in part our motion to dismiss the consolidated complaint.

In March 2004, we entered into an agreement in principle with plaintiffs' counsel to settle this litigation. The parties to the litigation then entered into a stipulation and agreement of the settlement dated June 29, 2004. Under the terms of the settlement, our insurance carriers assumed the obligation to pay the settlement amount of \$9 million from our insurance coverage. The settlement will therefore not result in the payment of any funds by us. In July 2004, the Court issued an order granting preliminary approval of the settlement and in November 2004, the Court issued an order granting final approval of the settlement of this litigation.

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

None.

## 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 2003 and 2004 and through March 1, 2005.

	<u>High</u>	<u>Low</u>
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
Year ended December 31, 2004		
First Quarter .....	\$3.74	\$2.24
Second Quarter .....	\$2.75	\$1.46
Third Quarter .....	\$2.61	\$1.40
Fourth Quarter .....	\$3.52	\$1.78
First Quarter 2005 (through March 1, 2005) .....	\$3.49	\$2.15

#### Holder and Dividends

There were approximately 740 record holders of our common stock as of March 1, 2005. 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, 2005, 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

To partially finance the acquisition of Vancocin, in October 2004 we issued \$62.5 million aggregate principal amount of 10% Senior Secured Bridge Notes due 2005 and warrants to purchase 5 million shares of our common stock. The offering was made to selected qualified institutional investors in a private placement conducted pursuant to Section 4(2) of, and Rule 506 of Regulation D under, the Securities Act of 1933.

The senior notes and the warrants were automatically exchanged for 6% Convertible Senior Secured Notes due October 2009 following stockholder approval of the issuance of the senior convertible notes in January 2005. The senior notes and the warrants are no longer outstanding. Interest on the senior convertible notes is payable semi-annually at an annual rate of 6% and the senior convertible notes have a maturity date of October 2009. One full year of interest payable on the senior convertible notes was placed into escrow and was released as interest payments became due. The remaining \$8.4 million was returned to us in January 2005.

The senior convertible notes rank senior in right of payment to our existing and future subordinated indebtedness and are secured by a first lien on our vancomycin assets which are primarily related to the manufacture, production, preparation, packaging or shipment of vancomycin products and all proceeds of such

assets, including accounts receivable generated from the sale of such vancomycin products. The holders will also have an option to purchase an additional \$12.5 million of the senior convertible notes on identical terms in April 2005.

Subject to certain limitations, the senior convertible notes are convertible into shares of common stock at the option of the holder at any time prior to maturity at a conversion rate of \$2.50 per share, subject to adjustment upon certain events. We may elect to automatically convert in any calendar quarter up to 25% of the principal amount of the senior convertible notes into shares of our common stock if the daily volume weighted average price of our stock exceeds \$3.75 per share, subject to adjustment upon certain events, for 20 trading days during any 30 trading day period, ending within 5 days of the notice of automatic conversion. If the holders voluntarily convert the senior convertible notes or if we effect an auto-conversion of the senior convertible notes prior to October 18, 2007, then we will make an additional payment on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date.

In accordance with Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended, or "Statement 133", the make-whole provision contained in the senior convertible notes is not clearly and closely related to the characteristics of the senior convertible notes. Accordingly, the make-whole provision is an embedded derivative instrument and is required by Statement 133 to be accounted for separately from the debt instrument.

Based upon relevant information available as of January 19, 2005, the date the senior notes and warrants were automatically exchanged for the senior convertible notes, we have estimated the fair value of the make-whole provision using a Monte Carlo simulation model to be \$7.9 million. The make-whole provision will be adjusted quarterly for changes in fair value during the first three years that any such senior convertible notes are outstanding, with the corresponding charge or credit to other expense or income. The estimated fair value of the make-whole provision of approximately \$7.9 million will be recorded as a discount on the senior convertible notes. The discount on the senior convertible notes will be accreted to par value through quarterly interest charges over through 2009, or approximately \$1.7 million of additional interest expense per year through October 2009, notwithstanding this separate adjustment of this derivative liability in other expense or income.

We subsequently filed a registration statement on Form S-3 with the SEC which registered the resale of \$62.5 million principal amount of the senior convertible notes and the shares of common stock issuable in accordance with the terms of the senior convertible notes indenture.

## ITEM 6. SELECTED FINANCIAL DATA

The selected financial data presented below under the caption "Consolidated Balance Sheet Data" as of December 31, 2004, 2003, 2002, 2001 and 2000 and under the caption "Consolidated Statement of Operations Data" for the years ended December 31, 2004, 2003, 2002, 2001 and 2000 are derived from our consolidated financial statements which have been audited. 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.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
<b>(in thousands, except per share amounts)</b>					
<b>Consolidated Statement of Operations Data:</b>					
Net product sales	\$ 8,348	\$ —	\$ —	\$ —	\$ —
License fee and milestone revenue	13,070	1,084	5,334	3,385	2,000
Other revenue	971	528	203	—	—
Total revenues	22,389	1,612	5,537	3,385	2,000
Operating expenses:					
Cost of sales	1,717	—	—	—	—
Research and development	16,388	23,043	39,823	43,013	38,038
Marketing, general and administrative	15,643	9,035	14,626	23,055	7,989
Intangible amortization and acquisition of technology	650	3,500	—	16,500	—
Total operating expenses	34,398	35,578	54,449	82,568	46,027
Gain on repurchase of debt	—	3,633	27,894	—	—
Gain on sale of non-core assets, net	1,715	—	—	—	—
Interest income	1,080	1,829	5,429	12,322	11,991
Interest expense	(10,320)	(8,438)	(11,034)	(11,620)	(9,781)
Net loss from continuing operations	(19,534)	(36,942)	(26,623)	(78,481)	(41,817)
Income (loss) from discontinued operations	—	—	10,817	(4,476)	—
Net loss	<u>\$ (19,534)</u>	<u>\$ (36,942)</u>	<u>\$ (15,806)</u>	<u>\$ (83,303)</u>	<u>\$ (42,545)</u>
Net loss per share from continuing operations:					
Basic and diluted	<u>\$ (0.73)</u>	<u>\$ (1.43)</u>	<u>\$ (1.11)</u>	<u>\$ (4.32)</u>	<u>\$ (2.75)</u>
Income (loss) per share from discontinued operations:					
Basic and diluted	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 0.45</u>	<u>\$ (0.25)</u>	<u>\$ —</u>
Net loss per share					
Basic and diluted	<u>\$ (0.73)</u>	<u>\$ (1.43)</u>	<u>\$ (0.66)</u>	<u>\$ (4.59)</u>	<u>\$ (2.80)</u>
Shares used in computing net loss/income per share:					
Basic and diluted	26,578	25,916	23,953	18,167	15,211
<b>As of December 31,</b>					
	2004	2003	2002	2001	2000
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments					
(1)	\$ 44,210	\$121,148	\$158,282	\$240,040	\$203,335
Working capital	42,497	113,096	152,772	220,621	196,280
Total assets	177,901	133,458	173,531	266,181	222,439
Long term obligations	190,400	127,900	134,908	180,125	180,325
Total stockholders' (deficit) equity	(26,138)	(7,509)	27,811	39,430	23,987

(1) Cash, cash equivalents and short-term investments includes \$9.0 million in restricted cash at December 31, 2004, of which \$8.4 million became unrestricted in January 2005.

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

### **Background**

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. In November 2004, we acquired the rights to market and sell Vancocin Pulvules, the oral capsule formulation of Vancocin (vancomycin hydrochloride), in the United States and its territories. We are focusing our current product development activities on product candidates to treat viral diseases, including those caused by cytomegalovirus (CMV) and hepatitis C virus (HCV) infections.

We have a significant level of indebtedness outstanding, which, as of March 1, 2005, consists of \$61.0 million principal amount of senior convertible notes due October 2009 and \$127.9 million of convertible subordinated notes due March 2007. In addition, the holders of our senior convertible notes have the option to purchase an additional \$12.5 million of the senior convertible notes on identical terms in April 2005. We have not been profitable from product sales since inception and have an accumulated deficit of \$277.1 million at December 31, 2004. Losses have resulted principally from costs incurred in research and development activities, write-off of acquired technology rights, general and administrative expenses, interest payments on our outstanding debt and sales and marketing expenses. We have financed our operations since inception in December 1994 primarily from equity and debt financing, funding pursuant to collaborative and partnering agreements and more recently, revenues from sales of Vancocin. We expect to incur additional net losses over the next several years and will require additional financing by 2007 when our convertible subordinated notes mature.

### **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 clinical development stage or commercial product opportunities as a means to accelerate our path toward becoming a profitable pharmaceutical company.

We intend to initially build two franchises. We are focusing on transplant and hospital settings and hepatologists and gastroenterologists, using Vancocin and our two core clinical programs in CMV infections related to hematopoietic stem cell/bone marrow transplantation, and HCV infection, as foundations for that effort. To expand further our product portfolio, we plan to seek additional products for diseases treated by our target audience of physician specialists and in hospital settings to complement the markets that we hope our CMV and HCV programs will serve. To build these franchises we intend to:

- focus on the development of our two current core clinical programs;
- market Vancocin; and
- expand our product portfolio.

### **2004 Key Events**

#### ***Acquisition of Vancocin Pulvules***

Our first significant step toward becoming a company focused on product development and commercialization by establishing franchises within narrowly focused prescribing groups was our acquisition of Vancocin. In November 2004, we acquired all rights in the United States and its territories to manufacture, market and sell Vancocin Pulvules, the oral capsule formulation of Vancocin (vancomycin hydrochloride), as well as rights to certain related vancomycin products, from Lilly. Oral Vancocin is a potent antibiotic approved

by the FDA to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Lilly will retain its rights to vancomycin outside of the United States and its territories.

We paid Lilly an upfront cash payment of \$116.0 million. In addition, we will pay Lilly royalties on annual net sales of Vancocin as set forth below:

2005 . . . . .	50% royalty on net sales between \$44-65 million
2006 . . . . .	35% royalty on net sales between \$46-65 million
2007 . . . . .	35% royalty on net sales between \$48-65 million
2008 through 2011 . . . .	35% royalty on net sales between \$45-65 million

No royalties are due to Lilly on 2004 net sales or net sales below or above the net sales levels reflected in the above table.

In the event we develop any product line extensions, revive discontinued vancomycin product lines (injectable or oral solutions), make improvements of existing products, or expand the label to cover new indications, Lilly would receive an additional royalty on net sales on these additional products for a predetermined time period.

In connection with the acquisition, we and Lilly entered into a supply agreement and a transition services agreement. The process of qualifying a third party supply chain will be ongoing during the term of the supply agreement. The transition period ended in January 2005 when we assumed responsibility for product inventory, sales, marketing and distribution of the Vancocin Pulvules brand in the United States.

#### *Acquisition—Liquidity impact*

We funded the \$116.0 million purchase price for the Vancocin acquisition through the use of \$53.5 million from our cash reserves and \$62.5 million of gross proceeds from the issuance of \$62.5 million aggregate principal amount of senior notes and warrants to purchase 5.0 million shares of our common stock. The senior notes and the warrants were automatically exchanged for 6% senior convertible notes following stockholder approval of the issuance of the senior convertible notes on January 19, 2005. For more information regarding the senior convertible notes, see the “Liquidity and Capital Resources” section.

We anticipate that revenues from this product will generate significant cash flows, and should allow us, over the next several years, to fund substantially all of our ongoing development and other operating costs.

#### **Restructuring**

In January 2004, we announced that we had restructured the company’s organization to focus our resources on the advancement and development of later stage products. As a result of this restructuring, we reduced our workforce by 70% from December 2003 levels. This reduction is the result of discontinuing our early stage activities, including discovery research and most internal preclinical activities, and reductions in clinical development and general and administrative personnel. During 2004, we included approximately \$9.2 million of severance and asset impairment costs related to this restructuring in our loss from continuing operations.

During the third quarter of 2004, we sold certain of our non-core assets, including compounds, assays and other intellectual property related to the development of antiviral drugs targeting the smallpox virus and viral hemorrhagic fever viruses, to SIGA Technologies, Inc. (SIGA), a company that focuses on the development of products for the prevention and treatment of infectious diseases, with an emphasis on products for biological warfare defense. As consideration for such assets, SIGA paid us \$1.0 million in cash and issued 1.0 million shares of SIGA common stock to us. We recognized a net gain of \$1.7 million on the date of the transaction, which was net of broker fees.

### ***Pleconaril / Schering-Plough Corporation***

In November 2004, we entered into a license agreement with Schering-Plough under which Schering-Plough has assumed responsibility for all future development and commercialization of pleconaril in the United States and Canada. Schering-Plough paid us an initial license fee of \$10 million in December 2004 and purchased our inventory of bulk drug substance for an additional \$6.0 million in January 2005. We are also eligible to receive up to an additional \$65 million in milestone payments upon achievement of certain targeted regulatory and commercial events, as well as royalties on Schering-Plough's sales of intranasal pleconaril in the licensed territories. Schering-Plough paid us an upfront option fee of \$3 million in November 2003. In August 2004, Schering-Plough exercised its option to enter into a full license agreement with us following its assessment of the product's performance in characterization studies. Other than transitioning the technology to Schering-Plough, we will have no further continuing operational involvement with the development and commercialization of the intranasal formulation of pleconaril for the treatment of the common cold. Sanofi-Synthelabo (now Sanofi-Aventis) has exclusive rights to market and sell pleconaril in countries other than the United States and Canada.

### **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. In implementing our strategic objectives, we expect to have sufficient cash available at the beginning of 2005 to fund our current business operations and debt service requirements until 2007 when our subordinated convertible notes mature. 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 annual report. 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 actual amount of cash flows generated from sales of Vancocin, and whether such sales will be sufficient to substantially fund all of our ongoing development and other operating costs over the next several years;
- our ability to continue to focus on business development opportunities in order to accelerate our path toward becoming a profitable pharmaceutical company by generating revenues, and achieve profitability, sooner;
- our ability to continue to build franchises in narrowly focused prescribing groups in transplant and hospital settings such as hepatologists and gastroenterologists through the acquisition of additional products;
- the timing of anticipated events in our CMV and HCV programs;
- the results of our product development efforts, including results from clinical trials;
- variations from our estimate of future direct and indirect expenses for 2005;
- our ability to raise additional financing and our ability to service or otherwise manage our debt obligations; and
- our ability to terminate our lease or, if necessary, sublease all unused office and lab space at the rates and/or timeframes that we have estimated, or at all.

Our actual results could differ materially from those results expressed in, or implied by, these forward-looking statements.

The commercial sale of approved pharmaceutical products, and conducting clinical trials for investigational pharmaceutical products, are subject to risks and uncertainties. There can be no assurance that future Vancocin sales will meet or exceed the historical rate of sales for the product, or will be sufficient to fund all of our

ongoing development and operational costs over the next several years, that planned clinical trials can be initiated, or that planned or ongoing clinical trials can be successfully concluded or concluded in accordance with our anticipated schedule and costs.

Also, we will face intense competition in acquiring additional products to expand further our product portfolio. Many of the companies and institutions that we will compete with in acquiring additional products to expand further 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. We may need additional financing in order to acquire new products in connection with our plans as described in this report.

Our outstanding indebtedness may make it more difficult for us to raise additional financing and we may not be able to service our debt obligations.

## Results of Operations

*Years ended December 31, 2004 and 2003*

### *Overview*

For the year ended December 31, 2004, we recorded revenues of \$22.4 million as a result of commencing sales of Vancocin in November 2004 and payments from our agreement with Schering-Plough related to intranasal pleconaril.

For the year ended December 31, 2004, we reported a net loss of \$19.5 million compared to a net loss of \$36.9 million for the year ended December 31, 2003. Net loss per share for the year ended December 31, 2004 was \$0.73 per share, basic and diluted, compared to net loss of \$1.43 per share, basic and diluted, for the year ended December 31, 2003. The 2004 net loss includes \$9.2 million of costs incurred as the result of the January 2004 restructuring. The decrease in net loss of \$17.4 million from the year ended December 31, 2003 to the same period in 2004 was due primarily to \$8.3 million of net sales of Vancocin which commenced in November 2004, \$12.5 million in revenue recognized in the year ended December 31, 2004 from the Schering-Plough agreements, reduction in headcount and operational costs resulting from our restructuring during January 2004, and a \$1.7 million gain on the sale of non-core assets in the year ended December 31, 2004. The net loss in 2003 included the write-off of \$3.5 million for the acquired technology rights for maribavir which was offset by a \$3.6 million gain, after the write-off of related debt issue costs, from our reduction of \$7.0 million in principal amount of our outstanding subordinated convertible notes.

### *Revenues*

Revenues were \$22.4 million for the year ended December 31, 2004, compared to \$1.6 million for the year ended December 31, 2003 and consisted of the following:

	For the year ended December 31	
	2004	2003
(in thousands)		
Net product sales .....	\$ 8,348	\$ —
License fees and milestones revenues .....	13,070	1,084
Grant and other revenues .....	971	528
Total revenues .....	<u>\$22,389</u>	<u>\$1,612</u>

#### Revenue—Vancocin product sales

For the year ended December 31, 2004, we recognized net sales of Vancocin of approximately \$8.3 million, which represents net sales from November 9, 2004 when we acquired the rights to Vancocin from Lilly. During this time period, Vancocin was sold under our transition services agreement to Lilly, who was our only customer. Following the termination of our transition agreement, which occurred in January 2005, we are selling directly to wholesalers.

#### Revenue—License fee and milestone revenue

For the year ended December 31, 2004, we recognized \$13.1 million of license fee and milestone payments comprised of \$10.0 million from Schering-Plough pursuant to the terms of our license agreement for intranasal pleconaril and approximately \$2.5 million from amortization of payments received under our agreements with Schering-Plough. Also in the year ended December 31, 2004, we recognized \$0.6 million from Wyeth under our collaboration agreement. 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-Plough that totaled \$0.6 million and \$0.5 million, respectively.

#### Revenue—Grant and other revenue

For the year ended December 31, 2004, we recognized grant and other revenue of approximately \$1.0 million, which increased by \$0.5 million from the \$0.5 million we recognized for the same period in 2003. During 2004, we received \$0.7 million for amounts agreed to be paid under our agreement with Schering-Plough that had no comparable payments in 2003 and received \$0.2 million less in grant payments in 2004 as compared to 2003 as the result of our January 2004 restructuring.

#### *Cost of sales and gross margin*

Our cost of sales for the year ended December 31, 2004 was \$1.7 million as compared with no cost of sales in the year ended December 31, 2003 as we acquired Vancocin in November 2004. Vancocin cost of sales include the cost of materials and distribution costs. We did not owe Lilly any royalty payments on net sales during 2004, however, our costs of sales during future periods may include royalties owed to Lilly on net sales of Vancocin between the dollar amounts established under our agreement with Lilly. Our gross margin (net product sales less cost of sales as a percent of net product sales) for Vancocin during 2004 was 79.4%.

We entered into a supply agreement with Lilly for the manufacture and supply of the active pharmaceutical ingredient (API) of Vancocin as well as the Vancocin finished product for an agreed upon time period. The process of qualifying a third party supply chain will be ongoing during the term of the supply agreement with Lilly. Upon completion of the preparation of these third party manufacturing facilities and the receipt of required regulatory approvals, Lilly will cease supplying us with Vancocin and we will purchase API directly from third parties. We anticipate that our gross margins will improve upon completion of the transition to the third party supply chain.

The cost to manufacture Vancocin can vary materially with production volume. To the extent that production levels increase or decrease in the future, we anticipate that the unit cost to manufacture Vancocin may decrease or increase, respectively. As a result, we would expect the cost of product sales of Vancocin, and accordingly, gross profit percentage, to fluctuate from year to year.

During 2004, we incurred product distribution expenses from Lilly pursuant to the terms of our transition services agreement. In January 2005, our transition services agreement with Lilly ended and we engaged a third party to manage our warehousing and inventory program and to handle fulfillment of customer orders. We anticipate that our product distribution expenses will be lower in future periods, as a percentage of sales, as a result of the transition from Lilly to the third party.

### *Research and development expenses*

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts, and preclinical and development costs. Indirect expenses include personnel, facility, and other overhead costs.

Research and development expenses decreased approximately \$6.6 million to \$16.4 million in the year ended December 31, 2004 from \$23.0 million in the year ended December 31, 2003 as a result of our reduction in headcount and operational costs resulting from our restructuring announced in January 2004. Our research and development expenses were divided between our research and development programs in the following manner:

	For the year ended December 31,	
	2004	2003
(in thousands)		
<b><i>Direct—Core programs</i></b>		
CMV .....	\$ 3,207	\$ 100
HCV .....	1,317	14
<b><i>Direct—Non-core programs</i></b>		
Common cold .....	106	801
CEMA .....	—	944
<b><i>Indirect</i></b>		
Development .....	8,239	10,291
Discovery research .....	3,519	10,893
Total .....	<u>\$16,388</u>	<u>\$23,043</u>

#### Direct—Core Programs

In the year ended December 31, 2004, we incurred \$3.2 million in direct expenses related to our CMV program. During the year ended December 31, 2004, we initiated two phase 1 clinical trials with maribavir to evaluate the potential for drug interactions and to evaluate the pharmacokinetics of maribavir in subjects with renal impairment, respectively, and we initiated one phase 2 clinical study involving CMV-seropositive subjects who have undergone allogeneic stem cell transplantation. We had no material expenses under this program in the year ended December 31, 2003, as we did not acquire the rights for its development and commercialization until August 2003.

During the year ended December 31, 2004, we incurred \$1.3 million of direct costs related to development activities of our HCV program, which increased \$1.3 million from the year ended December 31, 2003. These costs are net of payments from Wyeth made in accordance with our cost-sharing arrangement. During 2004, the primary drivers of these costs were phase 1 clinical trials for our former lead product candidate and predevelopment activities, including the preparation of an IND submission, on a follow-on compound to our lead product candidate. During the year ended December 31, 2003, the primary drivers of \$0.7 million in costs were phase 1 clinical trials for a previous lead product candidate and predevelopment activities on backup compounds, and were nearly offset by a \$0.7 million credit related to the 2003 amendment of our agreement with Wyeth.

#### Direct—Non-Core Programs

In the year ended December 31, 2004, we incurred \$0.1 million in direct costs related to our common cold program compared to \$0.8 million in direct costs during the year ended December 31, 2003. In the year ended December 31, 2004, all non-core program direct expenses were related to the intranasal formulation of

pleconaril, our only active product candidate in our non-core programs. The gross costs of \$1.1 million for the year ended December 31, 2004 were netted by a \$0.4 million credit from a revision of the estimated costs accrued for clinical development related to the oral formulation of pleconaril and a \$0.6 million credit related to the settlement of a disputed receivable with a former development partner that was written off in a prior year. During the year ended December 31, 2003, we incurred \$0.9 million of direct expenses related to clinical and regulatory activities related to our efforts to pursue the development of pleconaril for the treatment of serious and life-threatening diseases caused by enteroviral infections (CEMA). We ceased these development activities in connection with our January 2004 restructuring and have no comparable 2004 direct costs.

#### Indirect Expenses

In the year ended December 31, 2004, we incurred \$8.2 million of indirect expenses related to our development activities, which decreased \$2.1 million from \$10.3 million in the year ended December 31, 2003. The decrease of \$2.1 million was due primarily to the reduced headcount resulting from the January 2004 restructuring. Included in the costs recorded in 2004 are \$1.8 million in severance and transition costs from our January 2004 restructuring.

In the year ended December 31, 2004, we incurred \$3.5 million of indirect expenses related to our discovery research activities, which decreased from \$10.9 million in the same period of 2003. We exited our discovery research activities in January 2004. Included in the 2004 indirect costs is a \$1.8 million charge for severance and related costs of the January 2004 restructuring.

#### *Marketing, general and administrative expenses*

Marketing, general and administrative expenses for the year ended December 31, 2004 of approximately \$15.6 million increased \$6.6 million from \$9.0 million for the year ended December 31, 2003. Included in the expenses for the period in 2004 is \$5.6 million in severance and stock option modification costs and asset impairment costs that were the result of the January 2004 restructuring, \$1.1 million for a charge related to the exit of an operating lease, \$0.6 million in costs related to our terminated bond restructuring, an increase in expenses of \$0.9 million related to business development efforts undertaken during 2004, \$0.5 million in costs related to the Schering-Plough license agreement and \$0.6 million in increased accounting, public company and other expenses. Included in the expenses for the year ended December 31, 2003 is a \$1.7 million charge for lease commitments.

#### *Intangible amortization and acquisition of technology rights*

Intangible amortization was \$0.7 million for the year ended December 31, 2004. Intangible amortization is the result of the Vancocin product rights acquisition in the fourth quarter of 2004. We had a valuation study performed by a third party, based on information provided by management, to determine the allocation of the estimated purchase price of the Vancocin acquisition among the intangible assets acquired as well as their estimated amortization period. The following table represents the allocation of costs to the assets acquired, the related intangible assets useful lives and the amortization expense included in the 2004 consolidated statement of operations:

<b>(in thousands)</b>	<b>Fair value of intangibles</b>	<b>Estimated life (in years)</b>	<b>Amortization for the twelve months ended December 31, 2004</b>
<b>Assets acquired</b>			
Starting material inventory .....	\$ 1,022	—	\$ —
Trademarks .....	10,473	25	58
Know-how .....	73,308	25	407
Customer relationships .....	33,228	25	185
Total .....	<u>\$118,031</u>		<u>\$ 650</u>

On an ongoing periodic basis, we will evaluate the useful life of these intangible assets and determine if any economic, governmental or regulatory event has impaired the value of the assets or modified their estimated useful lives.

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

*Interest and other expenses (gains)*

Interest income for the year ended December 31, 2004 of \$1.1 million decreased \$0.7 million from interest income of \$1.8 million for the year ended December 31, 2003. This is due to lower invested balances. Interest expense for the year ended December 31, 2004 of \$10.3 million increased \$1.9 million compared to \$8.4 million in interest expense from the year ended December 31, 2003 due to the interest and amortization of financing costs from the issuance of the senior notes in October 2004.

If the holders of the senior convertible notes voluntarily convert the senior convertible notes or if we effect an auto-conversion of the senior convertible notes prior to October 18, 2007, then we will make an additional payment on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date. As of March 1, 2005, \$1.5 million in principal amount of the senior convertible notes have been converted and we paid \$0.2 million of additional interest on such conversions through March 1, 2005.

As the result of the exchange of the senior notes to the senior convertible notes in January 2005, we expect to have additional interest expense in 2005 due to the make whole provision of the senior convertible notes. Based upon relevant information available as of January 19, 2005, we have estimated the fair value of the make-whole provision using a Monte Carlo simulation model to be \$7.9 million. The make-whole provision will be adjusted quarterly for changes in fair value during the first three years that any such senior convertible notes are outstanding, with the corresponding charge or credit to other expense or income.

*Years ended December 31, 2003 and 2002*

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

The loss from continuing operations 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, we 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 our outstanding convertible subordinated notes. During the year ended December 31, 2002, we 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 our outstanding convertible subordinated notes.

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 in 2002, license fee and milestone revenue included an accelerated recognition of \$4.0 million of 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 amortization of 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 credit resulting from our June 2003 amendment to the collaboration agreement, 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 primary 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;
- 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 activities related to:

- manufacturing and development of pleconaril for the treatment of the common cold;
- pre-clinical activities in HCV being performed at Wyeth;
- the preparation of an 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 GSK a \$3.5 million license fee in connection with our agreement for the worldwide rights (excluding Japan) to maribavir, or VP41263, an inhibitor of 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 was 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 \$7.8 million from the same period in 2002. The increase was 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 were 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 2003 versus 2002.

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.

## **Liquidity**

We expect that our near term sources of revenue will arise from Vancocin product sales, milestone and license fee payments that we may receive from Wyeth and Schering-Plough if agreed upon events under our agreements with each of these companies are achieved, as well as from the sale of various non-core assets and programs. However, there are no assurances that sales of Vancocin will meet or exceed the historical rate of sales for the product, that the events that require payments to us under the Wyeth and Schering-Plough arrangements are achieved, or that we can sell any additional non-core assets and programs.

## ***Overall Cash Flows***

During the year ended December 31, 2004, we used \$20.2 million of cash in operating activities. For the year ended December 31, 2004, cash used in investing activities was \$28.7 million, primarily from the use of \$118.0 million to purchase the assets related to Vancocin and the funding of a restricted investment related to the interest payments on our Senior Notes of \$10.0 million. These uses of cash were offset by \$98.2 million provided by net maturities of short-term and restricted investments, \$0.7 million provided by the sale of non-core assets and \$0.4 million provided by net fixed asset sales. For the year ended December 31, 2004, we have received \$58.9 million of cash from financing activities, primarily related to the \$62.5 million provided by the issuance of our Senior Notes and \$0.2 million of cash received from employees exercising stock options and partially offset by the \$3.8 million of issuance costs related to the Senior Notes. At December 31, 2004, we had cash, cash equivalents and short-term investments of \$35.2 million. In addition, we had \$9.0 million in restricted cash, of which \$8.4 million became unrestricted in January 2005. Also, at December 31, 2004, the annualized weighted average nominal interest rate on our short-term investments was 1.3%.

## ***Operating Cash Inflows***

We began to receive cash inflows from the sale of Vancocin in January 2005. For the year ended December 31, 2004, which includes the period in which Vancocin was owned by Eli Lilly & Company, Vancocin had unaudited net sales of approximately \$54.0 million. However, there is no assurance that future sales of Vancocin will meet historical product sales. In addition, we cannot reasonably estimate the period in which we will begin to receive material net cash inflows from our product candidates currently under development. 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.

## ***Operating Cash Outflows***

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. 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 product candidates are currently in the clinical stage 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 to spend between \$16.0 million and \$21.0 million in 2005 in our drug development efforts and the most significant uses of our near-term operating development cash outflows are as described below.

For each of our development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts, and preclinical and clinical development costs. Indirect expenses include personnel, facility, and other overhead costs.

### *Direct expenses—Core Development Programs*

*CMV program*—From the date we in-licensed maribavir through December 31, 2004, we incurred \$6.8 million of direct costs in connection with this program, including the acquisition fee of \$3.5 million paid to GSK for the rights to maribavir.

During 2005, we expect maribavir related activities to include completion of the phase 2 study that we initiated during July 2004, as well as the initiation of several phase 1 clinical pharmacology studies to support subsequent phase 3 development. Depending on the outcome of the phase 2 study, additional clinical development activities may be pursued. The results of this phase 2 study will significantly impact the timing and the amount of expenses, including potential milestone payments to GSK, that we will incur related to this program in future periods. In addition, discussions with the FDA regarding these 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 GSK, the licensor of maribavir.

*HCV program*—From the date that we commenced predevelopment activities for compounds in this program that are currently active through December 31, 2004, we incurred \$1.9 million in direct expenses for the predevelopment and development activities relating to such compounds. These costs are net of contractual cost sharing arrangements between Wyeth and us. Wyeth pays a substantial portion of the collaboration's predevelopment and development expenses.

During 2005 the planned activities include activities to conduct phase 1 clinical trials with HCV 796 our HCV product candidate. 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 periods. In addition, discussions with the FDA regarding these future studies may impact the timing, nature and cost of future planned studies.

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 one of these milestones in 2005. However, there can be no assurances that we will be successful in achieving this milestone during this timeframe, or at all.

*Direct Expenses—Non-Core Development Programs (Active)*

*Common Cold*—From the date that we commenced predevelopment activities for the intranasal formulation of pleconaril through December 31, 2004, we incurred \$1.9 million in direct expenses. We will not incur any additional direct expenses in connection with this program as Schering-Plough has assumed responsibility for all future development and commercialization of pleconaril.

In November 2004, we entered into a license agreement with Schering-Plough under which Schering-Plough has assumed responsibility for all future development and commercialization of pleconaril. Schering-Plough paid us an initial license fee of \$10 million in December 2004 and purchased our existing inventory of bulk drug substance for an additional \$6 million in January 2005. We will also be eligible to receive up to an additional \$65 million in milestone payments upon achievement of certain targeted regulatory and commercial events, as well as royalties on Schering-Plough's sales of intranasal pleconaril in the licensed territories.

*Indirect development and discovery expenses*

During 2004, we incurred restructuring costs of approximately \$3.6 million that were related to our development and former discovery operations. Our indirect development expenses during 2004 totaled \$6.4 million. In addition, we spent \$1.8 million on our former discovery operations during 2004. We do not expect to incur additional material costs related to our former discovery operations in 2005.

*Business development activities*

Through December 31, 2004, we paid an acquisition price of \$116 million and incurred \$2.0 million of fees and expenses in connection with the Vancocin acquisition and an acquisition fee of \$3.5 million paid to GSK in 2003 for the rights to maribavir (VP 41263).

In addition, the costs associated with acquiring any additional product or 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, and actual and potential generic and non-generic competition for the product, 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, if any, however, the costs could be substantial.

*Marketing, general and administrative activities*

During the year ended December 31, 2004, we incurred restructuring costs of approximately \$5.6 million that are related to our general and administrative activities, of which \$5.0 million related to non-cash transactions. We do not anticipate incurring restructuring charges during 2005.

We expect to spend between \$10.0 million and \$14.0 million in cash on marketing, general and administrative activities in 2005. This assumes no additional costs related to unused office and research and development space.

*Restructuring and transition activities*

All restructuring and transition costs are properly reflected in either research and development or marketing, general and administrative expense in our consolidated statements of operations. During the year ended 2004, we incurred approximately \$9.2 million in costs related to our January 2004 restructuring, of which \$5.2 million related to non-cash transactions. Of these costs, \$4.5 million related to severance payments and stock option modification costs that were paid in 2004 and \$4.7 million related to asset impairments. In addition, we had transition related costs of \$2.5 million during 2004, most of which was compensation related expenses and were incurred and paid as of December 31, 2004. We do not anticipate incurring restructuring charges during 2005.

### Debt service requirements

Annual interest payments on our outstanding \$127.9 million principal amount of subordinated convertible notes total \$7.7 million. Interest accrues on the senior convertible notes at the annual rate of 6%. Annual interest payments on the outstanding \$61.0 million in principal amount of senior convertible notes, as of March 1, 2005, total \$3.7 million. The holders of the senior convertible notes have an option to acquire an additional \$12.5 million principal amount of senior convertible notes which option may be exercised in April 2005. If the holders of the senior convertible notes voluntarily convert the senior convertible notes or if we effect an auto-conversion of the senior convertible notes prior to October 18, 2007, then we will make an additional payment on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date. This interest make-whole can be paid in shares of our common stock or cash, at our option, upon an auto conversion or in cash upon a conversion by the holders. These notes are fully described below under the heading "Debt Financing".

### Contractual Obligations

Future contractual obligations and commercial commitments at December 31, 2004, are as follows:

<u>Contractual Obligations (1)</u>	<u>Total</u>	<u>Less than 1 year</u>	<u>2-3 years</u>	<u>4-5 years</u>	<u>More than 5 years</u>
Long-term debt (2) .....	\$190,400	\$ —	\$127,900	\$62,500	\$ —
Minimum purchase requirements (3) .....	7,700	7,700	—	—	—
Capital lease obligations .....	—	—	—	—	—
Operating leases (4) .....	12,283	1,796	3,616	2,478	4,393
Other long-term liabilities reflected on the registrant's balance sheet under GAAP .....	—	—	—	—	—
<b>Total .....</b>	<b><u>\$210,383</u></b>	<b><u>\$9,496</u></b>	<b><u>\$131,516</u></b>	<b><u>\$64,978</u></b>	<b><u>\$4,393</u></b>

(1) This table does not include any milestone payments under our agreement with GSK in relation to our in-licensed technology, as the timing and likelihood of such payments are not known. Similarly, we have excluded the royalty payments due to Lilly in connection with the Vancocin acquisition, as the amount and timing are not determinable. Under the terms of the agreement with Lilly, Lilly is entitled to royalty payments on net sales of Vancocin through 2011. The royalty payments to be paid to Lilly are calculated as follows:

2005 .....	50% royalty on net sales between \$44-65 million
2006 .....	35% royalty on net sales between \$46-65 million
2007 .....	35% royalty on net sales between \$48-65 million
2008 through 2011 .....	35% royalty on net sales between \$45-65 million

No royalties are due to Lilly on sales below or above the sales levels reflected in the above table. In the event we develop any product line extensions, revive discontinued vancomycin product lines (injectable or oral solutions), make improvements of existing products, or expand the label to cover new indications, Lilly would receive an additional royalty on net sales on these additional products for a predetermined time period.

(2) Subject to certain limitations, the senior convertible notes are convertible into shares of common stock at the option of the holder at any time prior to maturity at a conversion rate of \$2.50 per share, subject to adjustment upon certain events. At any time following the effectiveness of a registration statement related to the resale of the shares of common stock issuable upon the conversion of the senior convertible notes, we may elect to automatically convert in any calendar quarter up to twenty-five percent of the principal amount of the senior convertible notes into shares of our common stock if the daily volume weighted average price of our stock exceeds \$3.75 per share, subject to adjustment upon certain events, for 20 trading days during

any 30 trading day period, ending within 5 days of the notice of automatic conversion. If the holders voluntarily convert the senior convertible notes or if we effect an auto-conversion of the senior convertible notes prior to October 18, 2007, then we will make an additional payment on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date.

In addition, the holders of the senior convertible notes have an option to purchase an additional \$12.5 million of the senior convertible notes on identical terms in April 2005.

- (3) As part of our manufacturing agreement with Lilly, we have certain minimum purchase requirements of Vancocin for a period of time less than one year, on a rolling basis. We are not contractually obligated to any amount of purchases past this time period, and cannot reasonably estimate the amount which we may be obligated in the future.
- (4) As of December 31, 2004, we leased 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. Included in the table above is \$12.2 million related to these leases. During February 2005, we reached a tentative agreement with our landlord to exit the lease that expires in 2008. We recorded a \$1.1 million charge during 2004 related to this transaction, which is an estimate of the payment we will make to the landlord to exit the lease, which we expect to occur in the second quarter of 2005. Included in the table above is the total current obligation of \$4.0 million under this lease. The related facility we are exiting represented 86,000 square feet of space to which the lease expired in 2008. After the termination, we will have 33,000 square feet in one facility under an operating lease that expires in 2017, for which \$7.7 million is included in the table above. As of December 31, 2004, we had a \$1.5 million liability related to the expected termination of our lease on our consolidated balance sheet, including approximately \$0.5 million for the anticipated lease payments prior to termination and \$1.1 million related to the termination of the lease.

### ***Capital Resources***

We expect the cash, cash equivalents and short-term investments available at December 31, 2004, together with our expected cash flows from Vancocin sales, will be sufficient to fund our development, operating and debt service costs over the next several years. However, we believe we will require additional capital by March 2007 when our convertible subordinated notes mature. 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 equity or debt securities. Our outstanding indebtedness may make it more difficult for us to raise additional financing.

#### ***Equity financing***

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 equity financing, however, may not be available on acceptable terms from any source as a result of, among other factors, our outstanding indebtedness, our inability to achieve regulatory approval of any of our product candidates, our inability to generate revenue through our existing collaborative agreements, and our inability to file, prosecute, defend and enforce patent claims 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.

## *Debt Financing*

### Senior Notes

In October 2004, to partially finance the acquisition of Vancocin, we issued \$62.5 million aggregate principal amount of senior notes and the warrants. Our expenses related to this financing were approximately \$3.8 million. The offering was made to selected qualified institutional investors in a private placement under Regulation D of the Securities Act of 1933. We received approval from our stockholders to issue the senior convertible notes described below in exchange for the senior notes and the warrants on January 19, 2005. The senior notes and the warrants are no longer outstanding.

The senior notes were, and the senior convertible notes are, secured by a first lien on our vancomycin assets which are primarily related to the manufacture, production, preparation, packaging or shipment of vancomycin products and all proceeds of such assets, including accounts receivable generated from the sale of such vancomycin products.

### Senior Convertible Notes

On January 19, 2005, all of the outstanding senior notes and the warrants were automatically exchanged for \$62.5 million in principal amount of the senior convertible notes which was equal to the aggregate principal amount of the senior notes then outstanding. Interest on the senior convertible notes will be payable semi-annually at an annual rate of 6% and the senior convertible notes will have a maturity date of October 18, 2009. The senior convertible notes rank senior in right of payment to our existing and future subordinated indebtedness and are secured by a first lien on the vancomycin assets. The investors also have an option to purchase an additional \$12.5 million of the senior convertible notes on identical terms which may be exercised in April 2005.

Subject to certain limitations, the senior convertible notes are convertible into shares of common stock at the option of the holder at any time prior to maturity at a conversion rate of \$2.50 per share, subject to adjustment upon certain events. At any time following the effectiveness of a registration statement related to the resale of the shares of common stock issuable upon the conversion of the senior convertible notes, we may elect to automatically convert in any calendar quarter up to twenty-five percent of the principal amount of the senior convertible notes into shares of our common stock if the daily volume weighted average price of our stock exceeds \$3.75 per share, subject to adjustment upon certain events, for 20 trading days during any 30 trading day period, ending within 5 days of the notice of automatic conversion. If the investors voluntarily convert the senior convertible notes or if we effect an auto-conversion of the senior convertible notes prior to October 18, 2007, then we will make an additional payment, either in shares of our common stock or cash, on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date.

We have also agreed that until six months following the registration for resale of the senior convertible notes and shares of common stock underlying the senior convertible notes, we will not issue, sell, or contract to sell or issue more than 10 million shares of common stock plus an additional number of shares equal to the number of shares of common stock into which the senior convertible notes are actually converted, or securities convertible into common stock, without the consent of holders of a majority of the senior convertible notes. We also agreed that we would not issue any common stock, or securities convertible into common stock, at a price below \$2.75 per share during such period. The forgoing restrictions may expire sooner under certain circumstances, and are subject to certain exclusions as set forth in the indentures.

### Subordinated Convertible Notes

Through December 31, 2004 we have reduced the principal amount of our existing subordinated convertible notes by \$52.1 million and the outstanding balance of our subordinated convertible notes at December 31, 2004 is \$127.9 million. We have purchased an aggregate of \$50.1 million in principal amount of our subordinated

convertible notes for approximately \$18.5 million in cash through December 31, 2004. 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 subordinated convertible notes held by such third party. We are currently exploring alternatives to either reduce the outstanding principal amount or to restructure our subordinated convertible notes. Even if we are successful in such efforts, our outstanding indebtedness may make it more difficult for us to raise additional financing. In September 2004, our Board authorized the Notes Repurchase Committee of the Board to approve the issuance of up to 5,000,000 shares of our common stock in exchange for the surrender of the subordinated convertible notes from time to time. Our ability to issue these shares in exchange for the subordinated convertible notes is subject to the limitations described above under the heading "Senior Convertible Notes". There can be no assurance that we will purchase or otherwise acquire any of the subordinated convertible 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 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 consolidated financial statements included in Item 8 of this Form 10-K. 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 consolidated financial statements and that could impact our results of operations, financial position, and cash flows:

- **Revenue Recognition**—Our revenue includes both product sales from Vancocin and upfront fees and milestone payments from collaborative agreements. We recognize our revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition" (SAB 104). Revenue is recognized when all four of the following criteria are met: (1) we have persuasive evidence that an arrangement exists, (2) the price is fixed and determinable, (3) title has passed, and (4) collection is reasonably assured.

During the transition period with Lilly, all our product sales of Vancocin were to Lilly who then sold primarily to wholesalers. The transition period ended in January 2005, and we now sell directly to wholesalers. Product demand from wholesalers during a given period may not correlate with prescription demand for the product in that period. As a result, we may periodically evaluate the distributors inventory positions. If we believe these levels are too high based on prescription demand, we may either not accept purchase orders from or ship additional product to the distributor until these levels are reduced or defer recognition of revenue if we determine there is excess channel inventory for the product. During 2004, we did not defer any product sales. In addition, we established provisions for sales discounts and estimates for chargebacks, rebates, damaged product returns, and exchanges for expired product at the time such revenue is recognized based on historical data for the product acquired from Lilly.

In addition to product sales, we have collaborative agreements with several partners and can receive upfront and milestone payments from them. Upon receipt of payment or achievement of the related milestone, we evaluate the expected payment under the four criteria listed above. When non-refundable upfront fees are deferred, they are 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.

- **Intangible Assets**—We have in the past acquired products that have commercial sales and products that are in development phase and are unapproved to be sold commercially.

When we purchase products that have reached technological feasibility, we classify the purchase price, including expenses and assumed liabilities, as intangible assets. The purchase price may be allocated to product rights, trademarks, patents, and other intangibles based on the assistance of valuation experts. We estimate the useful life of the assets by considering remaining patent life, if any, competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review.

When we purchase the rights to products that have not reached technological feasibility, i.e. are in the development, we expense those costs in the period in which we acquire such rights.

- **Long-lived Assets**—We review our fixed and intangible assets for possible impairment whenever events occur or circumstances indicate that the carrying amount of an asset may not be recoverable. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include projections of future cash flows in determining whether an impairment exists and in measuring the current fair value of the asset.
- **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” as amended (SFAS 123). Had we applied SFAS 123 our net loss allocable to common stockholders for the years ended December 31, 2004, 2003 and 2002 would have been increased by approximately \$2.6 million, \$7.6 million, and \$11.7 million, respectively.
- **Restructuring Charges**—To the extent we have activities related to exit or disposal activities, we apply Statement of Financial Accounting Standards No. 146, “Accounting for Costs Associated with Exit or Disposal Activities” (SFAS 146). In determining the costs related to these activities, there is a significant amount of subjectivity and judgment applied by management. In addition, their impact on our financial condition could be material. Generally, we recognize and measure the costs associated with an exit or disposal activity at their fair value in the period in which it can be reasonably estimated. These costs include employee termination benefits, contract termination costs (including operating leases) and other associated costs.

As of December 31, 2004, we leased 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. During February 2005, we reached a tentative agreement with our landlord to exit the lease that expires in 2008. We recorded a \$1.1 million charge during 2004 related to this transaction, which is an estimate of the payment we will make to the landlord to exit the lease, which we expect to occur in the second quarter of 2005. The facility we are exiting represents 86,000 square feet of space to which the lease expires in 2008. After the termination date, we will have 33,000 square feet in one facility under an operating lease that expires in 2017. As of December 31, 2004, we had a \$1.5 million liability on our consolidated balance sheet related to the remaining leases payments through the termination date and the lease termination costs.

During 2003, we recorded a non-cash charge of approximately \$1.7 million in our marketing, general and administrative expenses relating to 33,000 square feet of leased space in the facility leased through 2017. This charge was an estimate of the then present value of the loss we might incur over the

remaining 13 years of the related lease and was net of assumed sublease income estimated at that time. During 2004, we moved to this facility and reversed the remaining accrual. As a result of this move, we no longer occupied the 86,000 square feet in the building with a lease expiring in 2008 and established a new provision based upon the new space requirements, which represented the value of the lease payments, net of expected future rental income.

As our business evolves, we may face additional issues that will require increased levels of management estimation and complex judgments.

### **Recently Issued Accounting Pronouncements**

In November 2004, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 151, *Inventory Costs, an Amendment of ARB No. 43, Chapter 4, "Inventory Pricing,"* to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. This statement requires those items be recognized as current-period charges. The provisions of this statement shall be effective for inventory costs incurred during fiscal periods beginning after June 15, 2005. We do not expect adoption of this statement to have a material impact on the consolidated financial statements.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-Monetary Assets, an Amendment of APB Opinion No. 29.* This statement eliminates the exception of non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. The provisions of this statement shall be effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. We do not expect adoption of this statement to have a material impact on the consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, a revision to SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123R). This statement replaces SFAS 123 and supercedes APB 25. This statement establishes standards for the accounting for which an entity exchanges its equity instruments for goods or services. This statement also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. SFAS 123R will require us to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost shall be recognized over the period during which an employee is required to provide service in exchange for the award – the requisite service period (vesting period). The grant-date fair value of employee share options will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. We must adopt SFAS 123R beginning no later than July 1, 2005. We are currently evaluating various implementation standards of SFAS 123R, including adoption methods and option pricing methodology. We expect that adoption of this statement will have a material impact on our consolidated financial statements. The pro forma impact on our net loss for the years ended December 31, 2004, 2003 and 2002 of \$2.6 million, \$7.6 million and \$11.7 million, respectively, may not be indicative of the results from the valuation methodologies ultimately adopted.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **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 U.S. 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 of less than one year. The carrying amount, which approximates fair value, and the annualized weighted average nominal interest rate of our investment portfolio at December 31, 2004 was approximately \$12.2 million and approximately 1.3%, respectively.

At March 1, 2004, we had outstanding \$127.9 million of our subordinated convertible notes. The subordinated convertible notes are convertible into shares of our common stock at a price of \$109 per share, subject to certain adjustments. The subordinated convertible 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 March 1, 2004, the market value of our convertible subordinated notes was approximately \$117.7 million, based on market prices. The fair value of our subordinated convertible notes is dependant upon, among other factors, the fair value of our common stock and prevailing market interest rates.

At March 1, 2005, we had outstanding \$61.0 million of senior convertible notes. The senior convertible notes bear interest at a rate of 6% per annum, payable semi-annual in arrears. Subject to certain limitations, the senior convertible notes are convertible into shares of common stock at the option of the holder at any time prior to maturity at a conversion rate of \$2.50 per share, subject to adjustment upon certain events. At any time following the effectiveness of a registration statement related to the resale of the shares of common stock issuable upon the conversion of the senior convertible notes, we may elect to automatically convert in any calendar quarter up to twenty-five percent of the principal amount of the senior convertible notes into shares of our common stock if the daily volume weighted average price of our stock exceeds \$3.75 per share, subject to adjustment upon certain events, for 20 trading days during any 30 trading day period, ending within 5 days of the notice of automatic conversion. If the investors voluntarily convert the senior convertible notes or if we effect an auto-conversion of the senior convertible notes prior to October 18, 2007, then we will make an additional payment, either in shares of our common stock or cash, on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date.

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

Our financial statements required by this item are attached to this Report beginning on page 65.

## **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 our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, of the effectiveness of our 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, 2004. Based on that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported as specified in Securities and Exchange Commission rules and forms.

(b) During the fourth quarter of 2004, as a result of the acquisition of Vancocin and the resulting commercial operations, we implemented new controls over net product sales, cost of sales and other commercial transactions. Other than these controls, there were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not Applicable.

## **PART III**

### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information concerning our directors and regarding compliance with Section 16 of the Securities Exchange Act of 1934 required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

The information concerning our executive officers required by this Item is incorporated by reference herein to the section of this Report in Part I entitled "Executive Officers of the Registrant".

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

### **ITEM 14. INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FEES AND SERVICES**

The information required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement.

## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

<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. (19) (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)
4.4	Senior Notes Indenture dated October 18, 2004 of ViroPharma Incorporated to U.S. Bank National Association as Trustee (including form of Senior Note). (22) (Exhibit 99.6)
4.5	Convertible Notes Indenture dated October 18, 2004 of ViroPharma Incorporated to U.S. Bank National Association as Trustee (including form of Convertible Note). (22) (Exhibit 99.7)
10.1*	Form of Employment Agreement. (1) (Exhibit 10.8)
10.2*	Form of Indemnification Agreement. (1) (Exhibit 10.9)
10.3	Lease, dated July 21, 1997, between the Company and The Hankin Group. (2) (Exhibit 10.23)
10.4	Purchase Option Agreement, dated July 21, 1997, between the Company and The Hankin Group. (2) (Exhibit 10.24)
10.5	Escrow Agreement, dated July 21, 1997, among the Company, The Hankin Group and Manito Abstract Company, Inc. (2) (Exhibit 10.25)
10.6	Investment Agreement among ViroPharma Incorporated and Perseus-Soros Biopharmaceutical Fund, L.P. dated May 5, 1999. (5) (Exhibit 10.21)
10.7†	Stock Purchase Agreement dated December 9, 1999 between American Home Products Corporation and ViroPharma Incorporated. (6) (Exhibit 10.26)
10.8	Severance Agreement dated August 21, 2000 between ViroPharma Incorporated and Michel de Rosen. (10) (Exhibit 10.31)
10.9†	First Amended and Restated Agreement dated February 27, 2001 between Sanofi-Synthelabo and ViroPharma Incorporated. (11) (Exhibit 10.32)
10.10	Stock Purchase Agreement dated as of September 9, 2001 between ViroPharma Incorporated and Aventis Pharma Inc. (12) (Exhibit 10.36)
10.11	Agreement of Lease dated as of September 24, 2001 between LV Associates, L.P. and ViroPharma Incorporated. (12) (Exhibit 10.37)
10.12††	2001 Equity Incentive Plan. (13) (Exhibit 10.33)
10.13	Letter Agreement between ViroPharma Incorporated and Wyeth dated May 29, 2002. (14) (Exhibit 10.35)

<u>Exhibit No.</u>	<u>Description</u>
10.14	Settlement Agreement and Release dated August 1, 2002 between ViroPharma Incorporated and Aventis Pharmaceuticals Inc. (15) (Exhibit 10.1)
10.15††	Amended and Restated ViroPharma Incorporated Employee Stock Purchase Plan. (16)
10.16	Form of Change of Control Agreement between ViroPharma and certain of its employees. (17) (Exhibit 10.32)
10.17†	First Amended and Restated Collaboration and License Agreement dated June 26, 2003 between ViroPharma Incorporated and Wyeth. (18) (Exhibit 10.33)
10.18†	Amendment to Stock Purchase Agreement dated June 26, 2003 between ViroPharma Incorporated and Wyeth. (18) (Exhibit 10.34)
10.19†	License Agreement dated August 8, 2003 by and between GlaxoSmithKline and ViroPharma Incorporated. (19) (Exhibit 10.35)
10.20	Third Amended and Restated Severance Agreement dated as of September 1, 2003 between Claude Nash and the Company. (20) (Exhibit 10.31)
10.21	Exchange Agreement dated as of October 2, 2003 between Everspring Master Fund Ltd. and ViroPharma Incorporated. (20) (Exhibit 10.32)
10.22†	Option Agreement dated November 25, 2003 between Schering Corporation and the Company. (20) (Exhibit 10.33)
10.23†	Letter Agreement dated November 24, 2003 between Sanofi-Synthelabo and the Company. (20) (Exhibit 10.34)
10.24	Exchange Agreement dated as of November 26, 2003 between Everspring Master Fund Ltd. and ViroPharma Incorporated. (20) (Exhibit 10.35)
10.25	Securities Purchase Agreement dated October 18, 2004 by and among ViroPharma Incorporated and the Buyers. (21) (Exhibit 99.2)
10.26	Convertible Notes Registration Rights Agreement dated October 18, 2004 by and among ViroPharma Incorporated and the Buyers. (21) (Exhibit 99.4)
10.27	Senior Notes Registration Rights Agreement dated October 18, 2004 by and among ViroPharma Incorporated and the Buyers. (21) (Exhibit 99.3)
10.28	Pledge and Collateral Agreement to U.S. Bank National Association as Trustee, and U.S. Bank National Association, as Collateral Agent for the Secured Parties. (21) (Exhibit 99.5)
10.29	Form of Warrant to Purchase shares of Common Stock. (21) (Exhibit 99.8)
10.30†	Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004.(22) (Exhibit 2.1)
10.31†	Amendment No. 1 to the Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated November 8, 2004.(22) (Exhibit 2.2)
10.32†	Manufacturing Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004. (22) (Exhibit 10.1)
10.33†	Transition Services Agreement between ViroPharma Incorporated and Eli Lilly and Company dated November 8, 2004. (22) (Exhibit 10.2)
10.34†	Security Agreement between ViroPharma Incorporated and U.S. Bank National Association dated November 8, 2004. (22) (Exhibit 10.3)
10.35†	Cooperation Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004. (22) (Exhibit 10.4)

<u>Exhibit No.</u>	<u>Description</u>
10.36†	License Agreement between ViroPharma Incorporated and Schering Corporation dated November 3, 2004. (23) (Exhibit 2.1)
10.37*	ViroPharma Severance Plan
10.38††	ViroPharma Cash Bonus Plan (24) (Exhibit 10.1)
10.39††	ViroPharma Board Compensation Policy (26) (Exhibit 10.1)
10.40††	Amended and Restated ViroPharma Stock Option and Restricted Share Plan. (27)
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, Independent Registered Public Accounting Firm.
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 related to Convertible Subordinated Notes due 2007. (8) (Exhibit 25.1)
25.2	Form of T-1 Statement of Eligibility of Trustee for Indenture Under the Trust Indenture Act of 1939 related to Senior Convertible Notes due 2009. (28) (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.
- (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 Annex to Registrant's Proxy Statement filed with the Commission on March 27, 2003.

- (17) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2003.
- (18) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2003.
- (19) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2003.
- (20) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2004.
- (21) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on October 19, 2004.
- (22) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 24, 2004.
- (23) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 29, 2004.
- (24) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on January 25, 2005.
- (26) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 15, 2005.
- (27) Filed as an Annex to Registrant's Proxy Statement filed with the Commission on April 8, 2002.
- (28) Filed as an Exhibit to Registration Statement on Form S-3 (File No. 333-30005) filed on January 26, 2005.

**Copies of the exhibits are available to stockholders from Thomas F. Doyle, Vice President, General Counsel and Secretary, ViroPharma Incorporated, 397 Eagleview Boulevard, Exton, Pennsylvania 19341. There will be a fee to cover the Company's expenses in furnishing the exhibits.**

## 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 14, 2005
<u>/s/ VINCENT J. MILANO</u> Vincent J. Milano	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 14, 2005
<u>/s/ MICHEL de ROSEN</u> Michel de Rosen	Chairman of the Board	March 14, 2005
<u>/s/ FRANK BALDINO, JR., PH.D.</u> Frank Baldino, Jr., Ph.D.	Director	March 14, 2005
<u>/s/ PAUL A. BROOKE</u> Paul A. Brooke	Director	March 14, 2005
<u>/s/ WILLIAM CLAYPOOL, M.D.</u> William Claypool, M.D.	Director	March 14, 2005
<u>/s/ MICHAEL R. DOUGHERTY</u> Michael R. Dougherty	Director	March 14, 2005
<u>/s/ ROBERT J. GLASER</u> Robert J. Glaser	Director	March 14, 2005

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

The Board of Directors and Stockholders  
ViroPharma Incorporated:

We have audited the accompanying consolidated balance sheets of ViroPharma Incorporated and subsidiary as of December 31, 2004 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, 2004. 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ViroPharma Incorporated and subsidiary as of December 31, 2004 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, 2004, in conformity with U.S generally accepted accounting principles.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
March 11, 2005

**ViroPharma Incorporated**  
**Consolidated Balance Sheets**  
**December 31, 2004 and 2003**

(in thousands, except share and per share data)	December 31,	
	2004	2003
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,993	\$ 12,969
Short-term investments	12,184	108,179
Restricted cash equivalent	9,033	—
Accounts receivable, net	8,711	—
Inventory	1,022	—
Other current assets	1,630	3,094
Total current assets	55,573	124,242
Intangible assets, net	116,359	—
Equipment and leasehold improvements, net	1,503	7,213
Debt issue costs, net	4,372	1,909
Other assets	94	94
Total assets	\$ 177,901	\$ 133,458
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 791	\$ 658
Due to partners	412	—
Accrued expenses and other current liabilities	11,309	7,414
Deferred revenue—current	564	3,074
Total current liabilities	13,076	11,146
Long-term debt	190,400	127,900
Deferred revenue—noncurrent	563	1,127
Other liabilities	—	794
Total liabilities	204,039	140,967
Stockholders' 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 26,758,495 shares at December 31, 2004 and 26,462,738 shares at December 31, 2003	54	53
Additional paid-in capital	250,776	250,320
Deferred compensation	(10)	(210)
Accumulated other comprehensive income (loss)	147	(101)
Accumulated deficit	(277,105)	(257,571)
Total stockholders' deficit	(26,138)	(7,509)
Total liabilities and stockholders' deficit	\$ 177,901	\$ 133,458

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**  
**Consolidated Statements of Operations**  
**Years ended December 31, 2004, 2003 and 2002**

	<u>Year ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
(in thousands, except per share data)			
<b>Revenues:</b>			
Net product sales .....	\$ 8,348	\$ —	\$ —
License fee and milestone revenue .....	13,070	1,084	5,334
Grant and other revenue .....	971	528	203
Total revenues .....	<u>22,389</u>	<u>1,612</u>	<u>5,537</u>
<b>Cost and Expenses:</b>			
Cost of sales .....	1,717	—	—
Research and development .....	16,388	23,043	39,823
Marketing, general and administrative .....	15,643	9,035	14,626
Intangible amortization and acquisition of technology rights .....	650	3,500	—
Total costs and expenses .....	<u>34,398</u>	<u>35,578</u>	<u>54,449</u>
Operating loss .....	(12,009)	(33,966)	(48,912)
<b>Other Income (Expense):</b>			
Gain on repurchase of debt, net .....	—	3,633	27,894
Gain on sale of non-core assets, net .....	1,715	—	—
Interest income .....	1,080	1,829	5,429
Interest expense .....	(10,320)	(8,438)	(11,034)
Net loss from continuing operations .....	<u>(19,534)</u>	<u>(36,942)</u>	<u>(26,623)</u>
<b>Discontinued Operations:</b>			
Income from discontinued sales operations .....	—	—	10,817
Net loss .....	<u>(19,534)</u>	<u>(36,942)</u>	<u>(15,806)</u>
Basic and diluted loss per share from continuing operations .....	<u>\$ (0.73)</u>	<u>\$ (1.43)</u>	<u>\$ (1.11)</u>
Basic and diluted income per share from discontinued sales operations .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 0.45</u>
Basic and diluted net loss per share .....	<u>\$ (0.73)</u>	<u>\$ (1.43)</u>	<u>\$ (0.66)</u>
Shares used in computing basic and diluted income (loss) per share amounts ..	<u>26,578</u>	<u>25,916</u>	<u>23,953</u>

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**  
**Consolidated Statements of Comprehensive Loss**  
**Years ended December 31, 2004, 2003 and 2002**

	<u>Year ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
(in thousands)			
<b>Net loss</b> .....	<u>\$(19,534)</u>	<u>\$(36,942)</u>	<u>\$(15,806)</u>
<b>Other comprehensive income (loss):</b>			
Unrealized holding gains (losses) arising during period .....	147	(101)	(2,087)
Reclassification adjustment for gains (losses) included in net loss .....	101	(41)	1,012
Adjustment to unrealized loss on available for sale securities .....	<u>—</u>	<u>2,127</u>	<u>—</u>
Unrealized gains (losses) on available for sale securities .....	<u>248</u>	<u>1,985</u>	<u>(1,075)</u>
Comprehensive loss .....	<u>\$(19,286)</u>	<u>\$(34,957)</u>	<u>\$(16,881)</u>

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**  
**Consolidated Statements of Stockholders' Equity (Deficit)**  
**For the years ended December 31, 2004, 2003 and 2002**

(in thousands)	Preferred stock		Common stock		Additional paid-in capital	Deferred Comp	Accumulated other comprehensive income (loss)	Accumulated Deficit	Total stockholders' equity (deficit)
	Number of shares	Amount	Number of shares	Amount					
Balance, December 31, 2001	—	\$—	22,741	\$ 46	\$244,035	\$(943)	\$(1,012)	\$(202,696)	\$ 39,430
Issuance of common stock to partner	—	—	3,000	6	4,584	—	—	—	4,590
Employee stock purchase plan	—	—	181	—	226	—	—	—	226
Issuance of stock options to non-employees	—	—	—	—	25	(25)	—	—	—
Exercise of common stock options	—	—	19	—	39	—	—	—	39
Forfeiture of restricted stock	—	—	(8)	—	(126)	126	—	—	—
Amortization of deferred compensation	—	—	—	—	—	407	—	—	407
Unrealized loss on available for sale securities	—	—	—	—	—	—	(1,075)	—	(1,075)
Net loss	—	—	—	—	—	—	—	(15,806)	(15,806)
Balance, December 31, 2002	—	\$—	25,933	\$ 52	\$248,783	\$(435)	\$(2,087)	\$(218,502)	\$ 27,811
Issuance of common stock for note and accrued interest reduction	—	—	473	1	1,173	—	—	—	1,174
Employee stock purchase plan	—	—	49	—	80	—	—	—	80
Exercise of common stock options	—	—	8	—	3	—	—	—	3
Issuance of stock options to non-employee	—	—	—	—	281	—	—	—	281
Amortization of deferred compensation	—	—	—	—	—	225	—	—	225
Unrealized loss on available for sale securities	—	—	—	—	—	—	(141)	—	(141)
Adjustment to unrealized loss on available for sale securities	—	—	—	—	—	—	2,127	(2,127)	—
Net loss	—	—	—	—	—	—	—	(36,942)	(36,942)
Balance, December 31, 2003	—	\$—	26,463	\$ 53	\$250,320	\$(210)	\$( 101)	\$(257,571)	\$ (7,509)
Employee stock purchase plan	—	—	16	—	26	—	—	—	26
Exercise of common stock options	—	—	279	1	252	—	—	—	253
Stock option accelerations	—	—	—	—	178	—	—	—	178
Amortization of deferred compensation	—	—	—	—	—	200	—	—	200
Unrealized gain on available for sale securities	—	—	—	—	—	—	248	—	248
Net loss	—	—	—	—	—	—	—	(19,534)	(19,534)
Balance, December 31, 2004	—	\$—	26,758	\$ 54	\$250,776	\$( 10)	\$ 147	\$(277,105)	\$(26,138)

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**  
**Consolidated Statements of Cash Flows**  
**Years ended December 31, 2004, 2003 and 2002**

(in thousands)	Year ended December 31,		
	2004	2003	2002
<b>Cash flows from operating activities:</b>			
Net loss	\$ (19,534)	\$ (36,942)	\$ (15,806)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash gain on sale of sales force	—	—	(15,410)
Gain on sale of non-core assets, net	(1,715)	—	—
Non-cash gain on repurchase of convertible subordinated notes	—	(3,725)	(28,725)
Non-cash settlement of interest payable related to note reduction	—	24	0
Write-off of deferred financing costs on note repurchase	—	92	830
Non-cash charge for lease costs	—	1,650	0
Non-cash write-off of fixed assets	4,782	—	1,517
Non-cash compensation expense	378	507	407
Non-cash interest expense	1,369	612	786
Depreciation and amortization expense	1,176	2,287	2,132
Changes in assets and liabilities:			
Accounts receivable	(8,711)	—	—
Other current assets	1,464	354	852
Other assets	—	49	(97)
Accounts payable	141	(330)	(1,678)
Due (to) from partners	412	(694)	8,206
Accrued expenses and other current liabilities	3,895	(4)	(9,414)
Deferred revenue and other liabilities	(3,868)	1,919	(5,333)
Net cash used in operating activities	(20,211)	(34,201)	(61,733)
<b>Cash flows from investing activities:</b>			
Purchase of Vancocin assets and inventory	(118,031)	—	—
Purchase of equipment and leasehold improvements	(1,005)	(984)	(4,034)
Proceeds from sale of equipment	1,407	—	197
Proceeds from sale of non-core assets, net	700	—	—
Purchase of restricted investment	(10,000)	—	—
Maturities of restricted investments	967	—	—
Purchases of short-term investments	(208,430)	(141,812)	(178,628)
Maturities of short-term investments	305,688	176,138	266,668
Net cash provided by (used in) investing activities	(28,704)	33,342	84,203
<b>Cash flows from financing activities:</b>			
Net proceeds from issuances of common stock	279	83	265
Gross proceeds from issuance of senior notes	62,500	—	—
Issuance costs related to senior notes	(3,832)	—	—
Payment of loans payable	(8)	(117)	(200)
Repurchase of convertible subordinated notes	—	(2,125)	(16,375)
Net cash provided by (used in) financing activities	58,939	(2,159)	(16,310)
Net increase (decrease) in cash and cash equivalents	10,024	(3,018)	6,160
Cash and cash equivalents at beginning of period	12,969	15,987	9,827
Cash and cash equivalents at end of period	\$ 22,993	\$ 12,969	\$ 15,987
<b>Supplemental disclosure of non-cash transactions:</b>			
Deferred compensation	\$ —	\$ —	\$ 26
Forfeiture of restricted stock	—	—	127
Unrealized gains (losses) on available for sale securities	248	(142)	(1,075)
Stock received from sale of non-core assets	(1,015)	—	—
Issuance of common stock in note reduction	—	1,151	—
Issuance of common stock to Aventis Pharmaceuticals Inc.	—	—	4,590
Settlement of milestone advances to Aventis Pharmaceuticals Inc.	—	—	20,000
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest	\$ 8,661	\$ 7,944	\$ 10,812

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements**

**1. Organization and Business Activities**

ViroPharma Incorporated (“ViroPharma” or “the Company”) is a pharmaceutical company dedicated to the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings. The Company is focused on the marketing and selling of its only commercialized product Vancocin® Pulvules®, the development of later stage opportunities and to expand its product portfolio through the acquisition of complementary development stage or commercial product opportunities. As a result of the revenues earned on product sales during 2004, the Company is no longer considered a development stage company as it was in prior years and all cumulative information reported in prior years is no longer reported.

ViroPharma markets and sells Vancocin Pulvules, the oral capsule formulation of Vancocin (vancomycin hydrochloride) in the United States and its territories. Oral Vancocin is a potent antibiotic approved by the U.S. Food and Drug Administration to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). ViroPharma acquired Vancocin from Eli Lilly & Company (“Eli Lilly”) in November 2004 for \$116 million in cash, excluding transaction costs of \$2.0 million. ViroPharma is focusing its current product development activities on viral diseases, including cytomegalovirus (CMV) infection and hepatitis C (HCV). The Company intends to continue to evaluate products in clinical development and marketed products that are under-promoted or not currently promoted, to expand its current product portfolio.

The Company plans to continue to finance its operations with a combination of revenues from product sales, 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 revenues from currently unapproved development products, if and when such product candidates are ultimately approved for marketing. 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 and servicing of its debt.

**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 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 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. Net unrealized holding gains and losses are included in accumulated other comprehensive income (loss). For

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

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 in the years ended December 31, 2004, 2003 and 2002.

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' deficit, 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 accumulated deficit in the consolidated balance sheet in 2003. The effect of this charge on loss from continuing operations for each of the years ended December 31, 2003 and 2002 and on accumulated deficit as of December 31, 2003 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.

The Company has an exposure to credit risk in its trade accounts receivable from sales of Vancocin. The Company began selling Vancocin in November 2004 under a transition services agreement with Eli Lilly where Eli Lilly was the Company's only customer. However, Eli Lilly sold Vancocin primarily through wholesale distributors and therefore, wholesaler distributors account for a large portion of their Vancocin accounts receivable.

*Accounts Receivable*

Accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company determines the allowance based on specific review of its accounts receivable. At December 31, 2004, there is no allowance for doubtful accounts. The Company does not have any off-balance sheet exposure related to its customer.

*Inventories*

Inventories are stated at the lower of cost or market using the first-in, first-out method. At December 31, 2004 inventory only consists of a certain starting material required to produce inventory of Vancocin (see Note 6).

*Equipment and leasehold improvements*

Equipment and leasehold improvements are recorded at cost. Depreciation and amortization are 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.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

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.

*Intangible Assets*

Intangible assets, net of accumulated amortization, includes the allocation of the cost to acquire the rights to Vancocin Pulvules, the oral formulation of Vancocin, as well as rights to certain vancomycin related Vancocin products, from Eli Lilly (see note 6). The Company bases its intangible assets' valuation and related estimated useful life on third party evaluations of the assets. Each intangible asset acquired as part of the Vancocin acquisition is being amortized on a straight-line basis over the estimated useful life of 25 years. The Company estimates the useful life of the assets by considering remaining patent life, if any, competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review.

*Impairment or Disposal of Long-Lived Assets*

The Company assesses the recoverability of long-lived assets for which an indicator of impairment exists. Specifically, the Company determines if a long-lived asset or asset group is impaired by comparing the carrying value of these assets to their estimated undiscounted future operating cash flows. If an impairment is indicated, a charge is recognized for the difference between the asset's carrying value and fair value. Although the Company's current and historical negative cash flows are indicators of impairment, the Company believes the future cash flows to be received from its long-lived assets will exceed the assets' carrying value. Accordingly, the Company has not recognized any impairment losses through December 31, 2004.

*Revenue recognition*

Revenue is recognized when all four of the following criteria are met (1) the Company has persuasive evidence of an arrangement exists, (2) the price is fixed and determinable, (3) title has passed, and (4) collection is reasonably assured. Generally, product revenue is recognized when shipped. The company's credit and exchange policy includes provisions for return of its product when it (1) has expired, or (2) was damaged in shipment. The return allowance is determined based on analysis of the historical rate of returns associated with Vancocin and applied to its sales.

During the transition period with Eli Lilly, the Company sold Vancocin directly to Eli Lilly, who in turn sold the product to wholesalers. Product demand from wholesalers during a given period may not correlate with prescription demand for the product in that period. As a result, the Company may periodically evaluate the distributors inventory position. If the company believes these levels are too high based on prescription demand, it will either not accept purchase orders from or ship additional product to the distributor until these levels are reduced or it may defer recognition of revenue if it determines there is excess channel inventory for the product. During 2004, the Company did not defer any product sales.

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.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

*Research and development expenses*

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*

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary difference are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

*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 APB 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, if any, of the current market price of the underlying common 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 SFAS No. 123, "Accounting for Stock-Based Compensation," as amended (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.

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.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

If 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 and net loss per share would have been increased as indicated below:

<i>(in thousands, except per share data)</i>	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net loss:			
As reported .....	\$(19,534)	\$(36,942)	\$(15,806)
Add: stock-based employee and directors compensation expense included in net loss) .....	378	507	407
Deduct: total stock-based employee and directors compensation expense determined under the fair value-based method for all employee and director awards .....	<u>(2,992)</u>	<u>(8,143)</u>	<u>(12,147)</u>
Pro forma net loss .....	<u>\$(22,148)</u>	<u>(44,578)</u>	<u>(27,546)</u>
Net loss per share—basic and diluted:			
As reported .....	<u>\$ (0.73)</u>	<u>\$ (1.43)</u>	<u>\$ (0.66)</u>
Pro forma .....	<u>(0.83)</u>	<u>(1.72)</u>	<u>(1.15)</u>

*Financial Instruments*

The Company's financial instruments, principally short-term investments, are carried at fair value. Cash and cash equivalents, restricted cash equivalents, due to partners, accounts payable, accrued expenses, other current liabilities and Senior Notes are carried at cost which approximate fair value due to their short-term nature. The Company's Subordinated Convertible Notes have a fair value of approximately \$115.1 million and \$86.3 million at December 31, 2004 and 2003, respectively.

*Earnings (loss) / per share*

Basic earnings per share ("EPS") is calculated by dividing earnings (loss) by the weighted average shares of common stock outstanding. Diluted EPS would also include the effect of dilution to earnings of convertible securities, stock options and warrants. The Company has convertible debt and options 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, 2004 are outstanding options exercisable for 2.7 million shares of common stock and convertible debt securities that are convertible into 1.2 million shares of common stock. In January 2005, the Senior Notes were exchanged for the Senior Convertible Notes. The Senior Convertible Notes are potentially dilutive and are potentially convertible into 25.0 million shares of common stock. Potentially dilutive to EPS as of December 31, 2003 were outstanding options exercisable into 3.8 million shares of common stock and convertible debt securities that are convertible into 1.2 million shares of common stock. Potentially dilutive to EPS as of December 31, 2002 were outstanding options exercisable into 3.4 million shares of common stock and convertible debt securities that are convertible into 1.2 million shares of common stock.

*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 products or product candidates and all of its product sales are within the United States. Accordingly, the Company does not prepare discrete financial

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

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".

*Comprehensive income (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.

*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.

*New Accounting Standards*

In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, *Inventory Costs, an Amendment of ARB No. 43, Chapter 4, "Inventory Pricing,"* to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. This statement requires those items be recognized as current-period charges. The provisions of this statement shall be effective for inventory costs incurred during fiscal periods beginning after June 15, 2005. The Company does not expect adoption of this statement to have a material impact on its consolidated financial statements.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-Monetary Assets, an Amendment of APB Opinion No. 29.* This statement eliminates the exception of non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. The provisions of this statement shall be effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The Company does not expect adoption of this statement to have a material impact on its consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment,* a revision to SFAS No. 123, *Accounting for Stock-Based Compensation.* This statement replaces SFAS 123 and supercedes APB No. 25. This statement establishes standards for the accounting for which an entity exchanges its equity instruments for goods or services. This statement also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. SFAS 123R will require the Company to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award.

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**Notes to the Consolidated Financial Statements (continued)**

That cost shall be recognized over the period during which an employee is required to provide service in exchange for the award – the requisite service period (vesting period). The grant-date fair value of employee share options will be estimated using option-pricing models adjusted for the unique characteristics of those instruments. The Company must adopt SFAS 123R beginning no later than July 1, 2005. The Company is currently evaluating various implementation standards of SFAS 123R, including adoption methods and option pricing methodology. The Company expects that adoption of this statement will have a material impact on its consolidated financial statements. The pro forma impact on the Company's net loss for the years ended December 31, 2004, 2003 and 2002 of \$2.6 million, \$7.6 million and \$11.7 million, respectively, may not be indicative of the results from the valuation methodologies ultimately adopted.

**3. Short-Term Investments**

Short-term investments consist of fixed income securities with original maturities of greater than three months at the date of purchase including U.S. treasury instruments of agencies of the U.S. Government and high-grade commercial paper. At December 31, 2004 and 2003, all of the short-term investments were deemed as "available for sale" investments.

The following summarizes the "available-for-sale" investments at December 31, 2004 and 2003:

(in thousands)	<u>Cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Fair value</u>
<b>2004</b>				
Certificate of deposit .....	\$ 11,022	\$ —	\$ —	\$ 11,022
Marketable securities (see note 9) .....	1,015	147	—	1,162
December 31, 2004 .....	<u>\$ 12,037</u>	<u>\$ 147</u>	<u>\$ —</u>	<u>\$ 12,184</u>
At December 31, 2004, maturities of investments were as follows:				
Less than 1 year .....	<u>\$ 11,022</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,022</u>
<b>2003</b>				
Certificate of deposit .....	\$ 11,704	\$ —	\$ —	\$ 11,704
Obligations of the U.S. Government and agencies of the U.S. ....	51,247	3	28	51,222
Commercial paper .....	45,329	—	76	45,253
December 31, 2003 .....	<u>\$108,280</u>	<u>\$ 3</u>	<u>\$ 104</u>	<u>\$108,179</u>

**4. Inventory**

Inventory as of December 31, 2004 consist of a certain starting material used in the manufacturing process of Vancocin. The Company has no work in process or finished goods inventory at December 31, 2004 as the result of its transition agreement with Eli Lilly.

In January 2005, the transition period with Eli Lilly ended and ViroPharma purchased an initial supply of finished goods inventory that totaled \$2.2 million.

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**Notes to the Consolidated Financial Statements (continued)**

**5. Equipment and Leasehold Improvements**

Equipment and leasehold improvements consist of the following at December 31, 2004 and 2003:

(in thousands)	<u>2004</u>	<u>2003</u>
Computers and equipment .....	\$ 895	\$ 9,463
Leasehold improvements .....	<u>1,332</u>	<u>5,751</u>
	2,227	15,214
Less: accumulated depreciation and amortization .....	<u>724</u>	<u>8,001</u>
	<u>\$1,503</u>	<u>\$ 7,213</u>

Included in leasehold improvements is \$0.1 million related to construction in progress (CIP) at December 31, 2003. There was no CIP balance at December 31, 2004.

**6. Intangible Assets**

On November 9, 2004, the Company acquired the rights to Vancocin Pulvules, the oral formulation of Vancocin, as well as rights to certain related Vancocin products, from Eli Lilly (see note 9).

(in thousands)	
Cash consideration, including \$62.5 million aggregate principal amount of the Company's	
Senior Notes .....	\$116,000
Transaction costs and fees .....	<u>2,031</u>
Total purchase price and acquisition costs .....	<u>\$118,031</u>

The Company had a valuation study performed by a third party to determine the allocation of the purchase price of the Vancocin acquisition among the intangible assets acquired as well as their estimated amortization period. The following table represents the allocation of costs to the assets acquired including an estimate of the value of starting material inventory acquired, the intangible assets acquired, the related intangible assets useful lives and the amortization expense included in the 2004 consolidated statement of operations:

(in thousands)	<u>Fair value of</u>	<u>Estimated life</u>	<u>Amortization</u>
<u>Assets acquired</u>	<u>intangibles</u>	<u>(in years)</u>	<u>for the year ended</u>
			<u>December 31,</u>
			<u>2004</u>
Starting material inventory .....	\$ 1,022	—	\$ —
Trademarks .....	10,473	25	58
Know-how .....	73,308	25	407
Customer relationships .....	<u>33,228</u>	25	<u>185</u>
Total .....	<u>\$118,031</u>		<u>\$ 650</u>

On an ongoing periodic basis, the Company will evaluate the useful life of these intangible assets and determine if any economic, governmental or regulatory event has impaired the value of the assets or modified their estimated useful lives.

The Company estimated the useful life of the assets by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review.

**7. Accrued expenses and other current liabilities**

Accrued expenses and other current liabilities consist of the following at December 31, 2004 and 2003:

(in thousands)	December 31,	
	2004	2003
Interest payable . . . . .	\$ 2,818	\$2,558
Other current liabilities . . . . .	2,126	933
Lease exit costs (See note 14) . . . . .	1,546	680
Finished goods purchased . . . . .	1,482	—
Payroll, bonus and employee benefits . . . . .	1,289	1,832
Insurance financing . . . . .	923	613
Clinical development and research . . . . .	891	798
Distribution fees to Eli Lilly . . . . .	234	—
	\$11,309	\$7,414

**8. Long Term Debt**

On December 31, 2004 and 2003, the Company's long-term indebtedness includes the following:

(in thousands)	December 31,	
	2004	2003
Convertible Subordinated Notes, 6% interest paid semi-annually, due March 2007 . . . . .	\$127,900	\$127,900
Senior Notes, 10% interest paid monthly . . . . .	62,500	—
	\$190,400	\$127,900

*Convertible Subordinated Notes*

The Company made a private offering of \$180.0 million of convertible subordinated notes due March 2007 ("convertible subordinated notes"), which closed on March 8, 2000. Gross proceeds from the issuance of convertible subordinated notes were \$180.0 million. Debt issuance costs of \$5.7 million 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. At December 31, 2004, the market value of the Company's convertible subordinated notes was approximately \$115.1 million, based on quoted market prices.

Through December 31, 2004, the Company has reduced \$52.1 million in principal amount of its convertible subordinated notes. 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, 2004. 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

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**Notes to the Consolidated Financial Statements (continued)**

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. There were no comparable reductions in the Company's outstanding convertible subordinated notes during 2004.

*Senior Notes*

To partially finance the acquisition of Vancocin, ViroPharma issued \$62.5 million aggregate principal amount of Senior Secured Bridge Notes due October 2005 (the "Senior Notes") and warrants to purchase 5 million shares of the Company's common stock at \$0.01 per share (the "Warrants") in October 2004. The Senior Notes and the Warrants were automatically exchanged for 6% Convertible Senior Secured Notes due October 2009 (the "Senior Convertible Notes") following stockholder approval of the issuance of the Senior Convertible Notes in January 2005.

Interest on the Senior Notes was payable monthly at an annual rate of 10% until shareholder approval of the exchange into the Senior Convertible Notes in January 2005. One full year of interest payable of \$10.0 million on the Senior Notes was also placed into escrow and released as interest payments became due. The Company incurred approximately \$3.8 million in fees related to this financing that was capitalized and is being amortized over the life of the Senior Notes, which until exchanged into the Senior Convertible Notes was one year.

In accordance with SFAS No. 6 "Classification of Short-Term Obligations Expected to be Refinanced", the Company has recorded the Senior Notes as long-term debt as of December 31, 2004. Upon the exchange of Senior Notes for Senior Convertible Notes in January 2005, the remaining \$8.4 million balance of the unpaid escrowed interest for the Senior Notes was released to the Company.

*Senior Convertible Notes*

The Senior Notes and the Warrants were automatically exchanged in January 2005 for 6% Convertible Senior Secured Notes due October 2009 following stockholder approval of the issuance of the Senior Convertible Notes. The \$62.5 million value of the Senior Convertible Notes is in an amount equal to the aggregate principal amount of the Senior Notes then outstanding. The Senior Convertible Notes will rank senior in right of payment to the Company's existing and future subordinated indebtedness and will be secured by a first lien on the vancomycin assets which are primarily related to the manufacture, production, preparation, packaging or shipment of vancomycin products and all proceeds of such assets, including accounts receivable generated from the sale of such vancomycin products. The carrying value of the Vancocin assets as of December 31, 2004 that secure the Senior Convertible Notes was \$116.4 million. The investors will also have an option to purchase an additional \$12.5 million of the 6% Senior Convertible Notes on identical terms which may close in April 2005.

Subject to certain limitations, the Senior Convertible Notes will be convertible into shares of common stock at the option of the holder at any time prior to maturity at a conversion rate of \$2.50 per share, subject to adjustment upon certain events. At any time following the effectiveness of a registration statement related to the resale of the shares of common stock issuable upon the conversion of the Senior Convertible Notes, the Company may elect to automatically convert in any calendar quarter up to twenty-five percent of the principal amount of the Senior Convertible Notes into shares of its common stock if the daily volume weighted average price of the Company's stock exceeds \$3.75 per share, subject to adjustment upon certain events, for 20 trading days during any 30 trading day period, ending within 5 days of the notice of automatic conversion. If the investors voluntarily

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**Notes to the Consolidated Financial Statements (continued)**

convert the Senior Convertible Notes or if the Company effects an auto-conversion of the Senior Convertible Notes prior to October 18, 2007, then the Company will make an additional payment on the principal amount converted equal to three full years of interest, less any interest actually paid or provided for prior to the conversion date. In the case of a voluntary conversion by the investors, the Company must make this payment in cash. If the Company effects an auto-conversion, the Company may, at its option and if certain conditions are satisfied, make the additional payment with shares of its common stock. If the Company elects to pay the additional payment in common stock, then the stock will be valued at 90% of the volume weighted average price of the stock for the 10 days preceding the automatic conversion date.

In accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended, or "Statement 133", the make-whole provision contained in the senior convertible notes is not clearly and closely related to the characteristics of the senior convertible notes. Accordingly, the make-whole provision is an embedded derivative instrument and is required by Statement 133 to be accounted for separately from the debt instrument.

Based upon relevant information available as of January 19, 2005, the date the Senior Notes and Warrants were automatically exchanged for the Senior Convertible Notes, the Company has estimated the fair value of the make-whole provision using a Monte Carlo simulation model to be \$7.9 million. The make-whole provision will be adjusted quarterly for changes in fair value during the first three years that any such senior convertible notes are outstanding, with the corresponding charge or credit to other expense or income. The estimated fair value of the make-whole provision of approximately \$7.9 million will be recorded as a discount on the Senior Convertible Notes. The discount on the Senior Convertible Notes will be accreted to par value through quarterly interest charges through 2009, or approximately \$1.7 million of additional interest expense per year through October 2009, notwithstanding this separate adjustment of this derivative liability in other expense or income or the effects of conversions or redemptions.

The Company will be able to redeem some or all of the Senior Convertible Notes at any time on or after October 18, 2007 at 100% par value plus accrued and unpaid interest. The investors will be able to cause the Company to redeem the Senior Convertible Notes upon a fundamental change or, after June 30, 2005, the delisting of the Company's common stock from trading on any national securities exchange or the Nasdaq National Market or Nasdaq Small Cap Market. In the event the investors cause a redemption as a result of a fundamental change or a delisting prior to October 2007, the redemption will be at a premium to the par value of the Senior Convertible Notes.

The repayment of the principal amount of the Senior Convertible Notes and all unpaid interest can be accelerated in the event of a failure to pay any installment of interest, principal of or premium upon the Senior Convertible Notes as and when the same shall become due and payable; breaches of covenants in the Senior Convertible Notes, the Senior Convertible Notes Indenture and certain related agreements; failure to pay any installment of interest, principal of or premium upon, and other defaults under, the Company's outstanding Senior Convertible Notes and Subordinated Convertible Notes; defaults under any other indebtedness of the Company in excess of \$25 million; upon final judgments involving, in the aggregate, liability (to the extent not covered by independent third-party insurance) of the Company in excess of \$25 million; or upon a bankruptcy event.

The Company has also agreed that until six months following the registration for resale of the Senior Convertible Notes and shares of common stock underlying the Senior Convertible Notes, the Company will not, subject to certain exceptions: (1) issue, sell, or contract to sell or issue more than 10 million shares of common stock, or securities convertible into common stock, without the consent of holders of a majority of the Senior Convertible Notes, (2) the Company also agreed that it would not issue any common stock, or securities convertible into common stock, at a price below \$2.75 per share.

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**Notes to the Consolidated Financial Statements (continued)**

As of March 1, 2005, the outstanding balance of the Senior Convertible Notes is \$61.0 million after the conversions of \$1.5 million in Senior Convertible Notes into shares of the Company's common stock.

**9. Acquisition, License and Research Agreements**

*Vancocin Acquisition*

In November 2004, the Company acquired all rights in the United States and its territories to manufacture, market and sell Vancocin Pulvules, the oral capsule formulation of Vancocin, as well as rights to certain related Vancocin products, from Eli Lilly. Oral Vancocin is a potent antibiotic approved by the U.S. Food and Drug Administration to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Eli Lilly will retain its rights to vancomycin outside of the United States and its territories.

Through this acquisition, the Company acquired certain know-how related to manufacturing of the product, the Vancocin trademark, starting material inventory, the active New Drug Application (NDA) for Vancocin Pulvules, as well as additional rights relating to the injectable and oral solution formulations of vancomycin. In addition, the Company received certain related intellectual property and other information and materials required to continue marketing the brand in the United States and its territories.

At closing, the Company and Eli Lilly entered into a supply agreement and a transition services agreement. The process of qualifying a third party supply chain will be ongoing during the term of the supply agreement. Following the transition period, the Company will assume responsibility for product inventory, sales, marketing and distribution of the Vancocin Pulvules brand.

To acquire the rights to Vancocin, the Company paid an upfront cash payment of \$116.0 million, comprised of \$53.5 million from the Company's existing cash and \$62.5 million from the issuance of \$62.5 million aggregate principal amount of Senior Notes and Warrants (see note 8). In addition, the Company will pay Eli Lilly royalties on annual net sales of Vancocin within certain defined levels of sales occurring between 2005 and 2011. The Company spent approximately \$2.0 million in fees related to this transaction.

The Company recorded this transaction as an asset purchase with the purchase price and related transaction costs allocated to specific tangible and intangible assets acquired. The assets will be amortized over their related useful lives (see note 6).

*Schering Plough Agreement*

In November 2003, the Company entered into an agreement granting Schering-Plough Corporation ("Schering-Plough") 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-Plough paid the Company an upfront option fee of \$3 million, which was recognized over its estimated performance period, which ended in August 2004.

In November 2004, the Company announced that Schering-Plough and it entered into a license agreement under which Schering-Plough has assumed responsibility for all future development and commercialization of pleconaril. Other than transitioning the technology to Schering-Plough, the Company will have no further continuing operational involvement with the development and commercialization of the intranasal formulation of pleconaril for the treatment of the common cold. Upon the effective date of the agreement, Schering-Plough paid the Company an initial license fee of \$10.0 million, which was recorded as license fee and milestone revenue in

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**Notes to the Consolidated Financial Statements (continued)**

2004 consistent with the Company's revenue recognition policy. As part of the agreement, Schering-Plough also purchased the Company's existing inventory of bulk drug substance for an additional \$6.0 million during January 2005. The Company reviewed the factors surrounding this purchase and determined that since title had not passed until 2005, the related revenue will be recognized in the first quarter of 2005. The Company will also be eligible to receive up to an additional \$65 million in milestone payments upon achievement of certain targeted regulatory and commercial events, as well as royalties on Schering-Plough's sales of intranasal pleconaril in the licensed territories.

*SIGA Agreement*

During the third quarter of 2004, the Company sold certain of its non-core assets, including compounds, assays and other intellectual property related to the development of antiviral drugs targeting the smallpox virus and viral hemorrhagic fever viruses, to SIGA Technologies, Inc. ("SIGA"), a company that focuses on the development of products for the prevention and treatment of infectious diseases, with an emphasis on products for biological warfare defense. As consideration for such assets, SIGA paid the Company \$1.0 million in cash and issued ViroPharma 1.0 million shares of SIGA common stock. The shares received were accounted for as available-for-sale securities and recorded at fair value as part of short-term investments as of December 31, 2004. The gain on sale of these assets recognized by the Company was \$1.7 million on the date of this transaction, net of broker fees.

*GlaxoSmithKline Agreement*

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

Under the terms of the agreement, the Company 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. The Company 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. The Company paid GSK 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 GSK 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 revenue is being recognized as certain activities are performed by the Company over the estimated performance period. The original performance 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

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**Notes to the Consolidated Financial Statements (continued)**

Company recognized \$0.6 million as revenue in 2004, \$0.6 million as revenue in 2003, \$0.7 million as revenue in 2002, and \$1.1 million is recorded as deferred revenue on the consolidated balance sheet at December 31, 2004. 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 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 the Company's 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 the Company (subject to the Company's 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 parties would cease screening compounds against HCV under the 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.

*Sanofi-Aventis Agreement*

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

In February 2001, the Company revised its agreement with Sanofi-Aventis. 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 Sanofi-Aventis on future sales of products, if any, under certain conditions, in exchange for a reduction of royalty rate obligations by Sanofi-Aventis 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.

The Company further amended its agreement with Sanofi-Aventis in November 2003 in connection with its entry into the option agreement with Schering-Plough in respect of intranasal pleconaril. Upon Schering-Plough exercising 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-Aventis.

*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.

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**Notes to the Consolidated Financial Statements (continued)**

**10. Stockholder's Equity**

*Preferred Stock*

The Company's 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.

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 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, 2004, 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.

*Common Stock*

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, 2004. 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. 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. In August 2002, the Company sold Aventis Pharmaceuticals 3,000,000 shares of the Company's common stock with a fair value of \$4.59 million.

**11. Equity Compensation Plans**

*Employee 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 Company's common 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. Since inception of the plan, the stockholders of the Company have approved amendments to increase the number of shares eligible to grant under the 1995 Plan by 1,750,000 shares. In addition, the shareholders have voted to allow for the issuance of restricted shares of the Company's common stock.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

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. 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.

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 common stock at the time of grant.

There are 5,000,000 combined shares of common stock in the aggregate reserved under the 1995 Plan and the 2001 Plan (together, the "Plans"). Stock option activity for the Plans for the three years ended December 31, 2004 is as follows:

	Share Options	Weighted average exercise price per share
Balance, December 31, 2001 .....	2,592,841	\$19.80
Granted .....	1,885,175	5.77
Exercised .....	(18,412)	2.11
Canceled .....	<u>(1,104,467)</u>	<u>16.16</u>
Balance, December 31, 2002 .....	3,355,137	13.22
Granted .....	807,000	2.11
Exercised .....	(8,150)	0.35
Canceled .....	<u>(328,227)</u>	<u>16.36</u>
Balance at December 31, 2003 .....	3,825,760	10.63
Granted .....	1,007,800	3.01
Exercised .....	(279,480)	0.90
Canceled .....	<u>(1,851,909)</u>	<u>11.72</u>
Balance at December 31, 2004 .....	<u><u>2,702,171</u></u>	<u><u>\$ 8.05</u></u>

At December 31, 2004, there were 1,533,566 shares available for grant under the Plans. Stock options outstanding and exercisable as of December 31, 2004 under the plans are as follows:

Exercise Price Range of Options	Options Outstanding			Options Exercisable	
	Share Options	Weighted average remaining contractual life (Years)	Weighted average exercise price per share	As of December 31, 2004	Weighted average exercise price
\$ 0.20-2.09	802,194	7.99	\$ 1.50	428,270	\$ 1.29
2.16-3.55	893,544	9.03	3.14	169,952	3.06
3.93-8.38	189,125	5.75	4.55	155,838	4.67
8.75-81.75	817,308	5.33	20.66	747,861	20.56
<u><u>\$ 0.20-81.75</u></u>	<u><u>2,702,171</u></u>	<u><u>7.37</u></u>	<u><u>\$ 8.05</u></u>	<u><u>1,501,921</u></u>	<u><u>\$11.43</u></u>

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

The weighted average fair value of option grants during 2004, 2003, and 2002 was \$2.68, \$1.86, and \$5.48 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>2004</u>	<u>2003</u>	<u>2002</u>
Expected dividend yield: .....	—	—	—
Risk free interest rate: .....	3.9 %	3.7 %	3.4 %
Volatility: .....	141 %	149 %	155 %
Expected option life (in years): .....	5.8	5.4	5.7

*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. Since inception of the plan, 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 16,273, 48,438, 181,370 shares were sold to employees during 2004, 2003 and 2002, respectively. As of December 31, 2004 there are approximately 338,182 shares remaining under this plan. The plan qualifies under Section 423 of the Internal Revenue Code.

*Restricted Common Stock*

In 2000, the Company issued 50,000 of restricted common stock to Chief Executive Officer 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. This amount is reflected in deferred compensation and is being amortized to operations over the vesting period. During 2004 and 2003, the Company issued no shares of restricted common stock. Compensation expense related to this issuance for the years ended December 31, 2004, 2003 and 2002 was \$0.2 million, \$0.2 million, and \$0.3 million, respectively.

**12. Income Taxes**

As of December 31, 2004, the Company has approximately \$155.0 million of Federal and \$149.0 million of state net operating loss carry forwards available to offset future taxable income. In addition, the Company has approximately \$7.8 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 a preliminary analysis of the “change in ownership” provisions of the Tax Reform Act of 1986, net operating loss carry forwards will be subject to annual limitations that will reduce the Company’s ability to utilize these carry forwards in the future.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2004 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, 2004 and 2003. The change in the valuation allowance for 2004 and 2003 was an increase of approximately \$5.8 million and \$7.8 million, respectively. Additionally, at December 31, 2004, approximately \$1.9 million of gross deferred tax assets will increase equity to the extent such assets are realized.

(in thousands)	December 31,	
	2004	2003
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 60,688	\$ 49,998
Research and development credits .....	7,789	7,442
Capitalized research and development costs .....	47,777	51,891
Income recorded for tax but not recorded on books, net .....	1,505	2,604
Total gross deferred tax assets .....	117,759	111,935
Valuation allowance .....	\$(117,759)	\$(111,935)
Net deferred taxes .....	—	—

**13. 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 \$0.1 million, \$0.1 million and \$0.2 million to the 401(k) Plan in 2004, 2003 and 2002, 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.

**14. Commitments and Contingencies**

As of December 31, 2004, the Company leased an aggregate of 119,000 square feet in two facilities located in Exton, Pennsylvania for its corporate and development activities under operating leases expiring in 2008 and 2017, respectively. The total remaining obligation under these leases total \$12.2 million. During February 2005, the Company reached a tentative agreement with its landlord to exit the lease that expires in 2008. The Company recorded a \$1.1 million charge during 2004 related to this transaction, which is an estimate of the payment it will make to the landlord to exit the lease, which it expects to occur in the second quarter of 2005. Should the Company finalize this agreement, the total remaining obligation it will owe under these leases will be \$9.2 million, which includes the expected termination charge. The facility the Company is exiting represents 86,000 square feet of space to which the lease expires in 2008. After the termination, the Company will have 33,000 square feet in one facility under an operating lease that expires in 2017. As of December 31, 2004, the Company had a \$1.5 million liability on its consolidated balance sheet related to the remaining lease payments and the expected termination payment.

During the third quarter of 2003, the Company recorded a non-cash charge of approximately \$1.7 million in its marketing, general and administrative expenses relating to 33,000 square feet of leased space in the facility leased through 2017. This charge was an estimate of the then present value of the loss it might incur over the remaining 13 years of the lease and was net of assumed sublease income estimated at that time. During July

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

2004, it moved to this facility and reversed the remaining accrual. As a result of this move, it no longer occupied the 86,000 square feet in the building with a lease expiring in 2008 and established a new provision in July 2004 based upon the new space requirements, which represented the value of the lease payments, net of expected future rental income.

As part of the Company's manufacturing agreement with Eli Lilly & Company, it has certain minimum purchase requirements of Vancocin for a period of time less than one year, on a rolling basis, which at December 31, 2004 totaled \$7.7 million. The Company is not contractually obligated to any amount of purchases past this time period, and cannot reasonably estimate the amount of Vancocin which it may be obligated to purchase in the future.

The Company's future minimum lease payments under the aforementioned leases, including the entire contractual amounts for the lease the Company expects to terminate in 2005, and other operating leases related to equipment for years subsequent to December 31, 2004 are as follows (in thousands):

<u>Year ending December 31,</u>	<u>Commitments</u>
2005 .....	\$ 1,796
2006 .....	1,801
2007 .....	1,815
2008 .....	1,795
2009 .....	683
Thereafter .....	<u>4,393</u>
Total minimum payments .....	<u>\$12,283</u>

Rent expense for the years ended December 31, 2004, 2003, and 2002 aggregated \$0.9 million, \$1.8 million and \$1.1 million, 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.

**15. Litigation**

In March and May 2002, the Company and certain of its directors were named as defendants in purported class actions filed in the United States District Court for the Eastern District of Pennsylvania. In July 2002, these actions were consolidated into a single complaint, which also named certain of the Company's officers as defendants. The plaintiffs in these actions have alleged that certain statements by the Company about oral pleconaril were misleading. The Company filed a motion to dismiss this action in August 2002. In April 2003, the court granted in part and denied in part the Company's motion to dismiss the consolidated complaint.

In March 2004, the Company entered into an agreement in principle with plaintiffs' counsel to settle this litigation. The parties to the litigation then entered into a stipulation and agreement of the settlement dated June 29, 2004. Under the terms of the settlement, the Company's insurance carriers assumed the obligation to pay the settlement amount of \$9.0 million from its insurance coverage. The settlement therefore resulted in no payment

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

of any funds by the Company. In July 2004, the Court issued an order granting preliminary approval of the settlement and in November 2004, the Court issued an order granting final approval of a settlement of this litigation.

**16. Restructuring**

*2004 Restructuring*

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. As a result of this restructuring, the Company has reduced its workforce by 70% from December 2003 levels. This reduction is the result of the Company discontinuing its early stage activities, including discovery research and most internal preclinical activities, and reductions in clinical development and general and administrative personnel. During 2004, the Company included approximately \$9.2 million of severance and asset impairment costs related to this restructuring in its loss from continuing operations. The following table reflects the charges recorded, and payments made through December 31, 2004 (in thousands):

	<u>Research and Development</u>	<u>G&amp;A</u>	<u>Total</u>
<b>Restructuring charges:</b>			
Severance .....	\$3,579	\$ 922	\$ 4,501
Asset impairments .....	—	5,169	5,169
Additional proceeds from the sale of unused fixed assets .....	—	(422)	(422)
Total .....	<u>\$3,579</u>	<u>\$5,669</u>	<u>\$ 9,248</u>
<b>Activity related to restructuring charges through December 31, 2004:</b>			
Severance payments .....			\$(4,501)
Asset impairments recorded to accumulated depreciation .....			<u>(4,747)</u>
<b>Remaining payments as of December 31, 2004</b> .....			<u><u>\$ —</u></u>

As of December 31, 2004, there was no restructuring accrual remaining.

*2002 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, 2004.

*Discontinued Operations*

On September 1, 2002, Aventis acquired the Company's sales force, which totaled nearly 200 people, for \$15.4 million, which was recorded as a gain in 2002. There were no costs related to this transaction.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

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 net loss for the year ended December 31, 2002, was \$19.2 million in sales operations costs. As of December 31, 2004, 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, 2004.

*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 non-refundable \$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 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 related marketing and commercialization efforts: 55 percent by Aventis and 45 percent by The Company. 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.

**ViroPharma Incorporated**  
**Notes to the Consolidated Financial Statements (continued)**

**17. Quarterly Financial Information (unaudited)**

This table summarizes the unaudited consolidated financial results of operations for the quarters ended (amounts in thousands except per share data):

	<u>March 31,</u>	<u>June 30,</u>	<u>September 30,</u>	<u>December 31,</u>
<b>2004 Quarter Ended</b>				
Revenues .....	\$ 1,737	\$ 1,765	\$ 398	\$18,489
Gross Margin (1) .....	—	—	—	6,631
Operating Expenses .....	(16,610)	(5,359)	(3,718)	(8,711)
Net Income (Loss) .....	(16,616)	(5,378)	(3,331)	5,791
Basic net (loss) income per share (2) .....	<u>\$ (0.63)</u>	<u>\$ (0.20)</u>	<u>\$ (0.13)</u>	<u>\$ 0.22</u>
Diluted net (loss) income per share (2) .....	<u>\$ (0.63)</u>	<u>\$ (0.20)</u>	<u>\$ (0.13)</u>	<u>\$ 0.22</u>
<b>2003 Quarter Ended</b>				
Revenues .....	\$ 202	\$ 141	\$ 218	\$ 1,051
Gross Margin (1) .....	—	—	—	—
Operating Expenses .....	(8,014)	(6,066)	(14,262)	(7,236)
Net Loss .....	(6,847)	(7,235)	(15,762)	(7,098)
Basic and diluted net loss per share (2) .....	<u>\$ (0.27)</u>	<u>\$ (0.28)</u>	<u>\$ (0.61)</u>	<u>\$ (0.27)</u>

(1) Gross margin is calculated as net product sales less cost of sales

(2) Net (loss) income per share amounts will not agree to the per share amounts for the full year due to the use of weighted average shares for each period

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## DIRECTORS



From left, William D. Claypool, M.D., Frank Baldino, Jr., Ph.D., Michel de Rosen, Robert J. Glaser, Paul A. Brooke, Michael R. Dougherty

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Corporation

**Robert J. Glaser**<sup>(2)</sup>  
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(1) Member of Audit Committee  
(2) Member of Compensation Committee

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Director, Corporate Communications  
(610) 321-6288

### Business Development

Clayton Fletcher  
Director, Business Development and  
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Accounting Firm**  
KPMG LLP  
1601 Market Street  
Philadelphia, PA 19103

**Annual Shareholders' Meeting**  
The next annual shareholders'  
meeting will be held on Friday,  
May 20, 2005, at 10:00 a.m.  
at The Desmond, Great Valley Hotel,  
One Liberty Boulevard,  
Malvern, Pennsylvania

**Securities Information**  
NASDAQ National Market System  
Symbol: VPHM

**Transfer Agent**  
For shareholder questions regarding  
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