# TOGETHER

VIROPHARMA INCORPORATED
2008 ANNUAL REPORT

# Together in 2008 we ...

- *Launched Cinryze™ C1 Inhibitor (human) for routine prophylaxis against attacks of Hereditary Angioedema (HAE), a potentially life-threatening, genetic inflammatory condition*
- *Submitted a supplemental biologics license application for Cinryze to treat acute attacks of HAE*
- *Advanced two of the largest clinical trials ever to study the prevention of cytomegalovirus disease in transplant recipients*
- *Ensured that patients suffering from C. difficile infections had access to Vancocin®*
- *Advanced our Non-toxigenic C. difficile program closer to clinical development*

Together, the people of ViroPharma represent an international biopharmaceutical company devoted to developing and commercializing innovative products that address life-threatening unmet medical needs.

We are committed to working together to meet physician and patient needs as we strive to bring new products to markets where there are few, if any, therapeutic options. Our clear mission is to improve the lives of patients suffering from serious diseases.

Today we are executing on our programs to deliver these life-saving medicines to patients desperately seeking them; tomorrow we will provide hope for more effective medicines. Together our team can and will make a difference in the lives of patients and their families.

***Management Team:***
*(from left to right)*

*Thomas F. Doyle*
*Vice President, Strategic Initiatives*

*Daniel B. Soland*
*Vice President, Chief Operating Officer*

*Vincent J. Milano*
*President, Chief Executive Officer and Chairman of the Board of Directors*

*Colin Broom*
*Vice President, Chief Scientific Officer*

*Robert G. Pietrusko*
*Vice President, Global Regulatory Affairs and Quality*

*Charles A. Rowland*
*Vice President, Chief Financial Officer*

# TO our shareholders,

**While it is likely no secret to those of you who've met me in the past, one of my core principles is that no group will perform at its peak without a high level of teamwork.** And whether we are describing athletic teams or biotechnology companies, a fundamental truth is that the most successful teams are those composed of selfless individuals all working together to achieve a common goal. Our team at ViroPharma has a clear common goal of providing solutions to patients long-suffering from life-threatening unmet medical needs. Working together in 2008, we made a number of great strides to deliver on that goal.

One of our key advancements in 2008 was the diversification of our business through the acquisition of Lev Pharmaceuticals and Cinryze™ C1 Inhibitor (human), which is approved to prevent attacks of Hereditary Angioedema, or HAE, a potentially life-threatening swelling disorder that affects a small, though long-suffering, population of patients. The diversification of our business creates opportunities for us to generate and achieve long-term success. Beyond the positive impact that Cinryze has on patients, the product also represents an additional revenue driver to help fund our team's efforts to advance our clinical products and provide for further growth through additional strategic acquisitions.

Before spending time on each of our key initiatives, I'd like to comment on the recent news that our anti-CMV compound maribavir ultimately did not meet the primary endpoint in our Phase 3 study in stem cell transplant patients. We also made the difficult decision to discontinue our second Phase 3 study in liver transplant patients. This was a clear disappointment to every member of our team. We had high hopes that we would be able to provide maribavir to improve the likelihood of successful transplants by reducing CMV infections and disease. However, drug development is a risky business, and setbacks will occur. More important is what we learn from these setbacks and how we move forward to achieve our common goals. If there is a path forward for maribavir, I am confident that we have the team in place to find it. But, in doing so, we will not lose momentum in the execution of the rest of our business.

Now, let's reflect our team's accomplishments throughout 2008 in more depth:

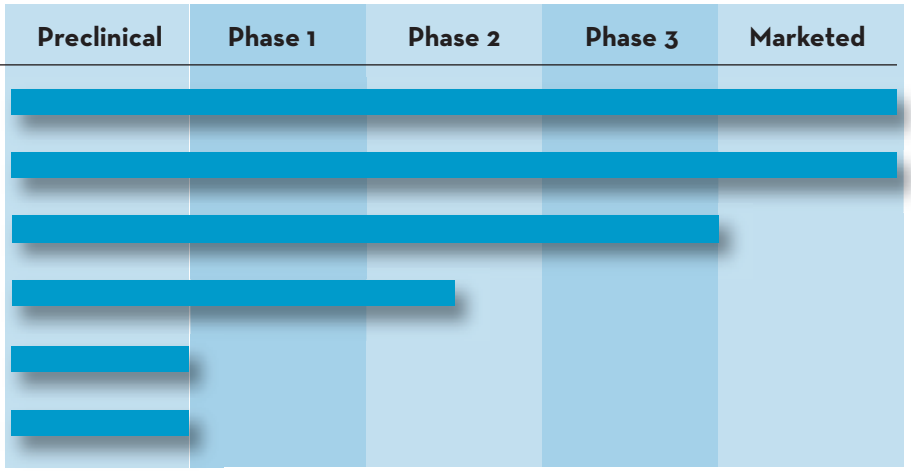
**Hereditary Angioedema (HAE)**
HAE is a rare inherited disorder that is characterized by painful swelling that can appear in any part of the body. It most commonly affects the hands, feet, face, abdomen, urogenital tract, and upper respiratory tract. The inflammation can be disfiguring and debilitating, or in the case of a laryngeal attack, life-threatening.

HAE is estimated to occur in at least 6,000 people in the U.S. As it is a genetic disorder, the disease can span multiple generations. Children of HAE patients have a 50% chance of inheriting the disease. HAE is caused by decreased production, or production of functionally impaired levels, of a critical protein called C1 inhibitor, which regulates the inflammatory process in the body. Cinryze™, which was approved by the FDA in October of this past year, increases the constituent levels of that very protein. By providing that missing protein to HAE patients, Cinryze helps them avoid these painful and often disabling inflammation.

Our goal is to assure that every patient who needs Cinryze has access to it. To support this goal, and to provide the best possible HAE patient service, we launched CINRYZE*Solutions*™, our patient access program. The program provides individualized case management, assistance in navigating the maze of reimbursement and managing co-pays, patient assistance, and delivery of the drug, whether in the physician's office or in the patient's home. Thus far, we are heartened with the positive feedback from treating physicians and HAE patients who've enrolled into the program, seeking the opportunity for a more normal life, reducing the worry over attacks of HAE. Our commercial efforts were launched late in 2008, and so far, we are pleased with our progress. Finally, our medical affairs and regional medical science teams have done a

**PRODUCT PORTFOLIO**

| Compound | Disease |
|---|---|
| Vancocin® (1) | *C. difficile* |
| Cinryze™ (2) | *HAE Prophylaxis* |
| Cinryze | *Acute HAE Treatment* |
| Maribavir* | *CMV* |
| NTCD | *C. difficile* |
| Cinryze | *life-cycle management* |




* *Under review*

*(1) VANCOCIN is approved for oral administration for treatment of antibiotic-associated pseudomembranous colitis caused by C. difficile and enterocolitis caused by Staphylococcus aureus including methicillin-resistant strains.*

*(2) CINRYZE is a C1 inhibitor indicated for routine prophylaxis against angioedema attacks in adolescent and adult patients with Hereditary Angioedema (HAE).*

phenomenal job working together with the physician community to broaden the awareness of HAE and appropriate patient management practices.

In December, our team filed a supplemental Biologics License Application (sBLA) to the FDA for Cinryze™ in the treatment of acute attacks of Hereditary Angioedema. While we are confident in the merits of the application, it is now up to the FDA to decide. We look forward to the FDA's decision in June of 2009.

**C. *difficile* Infections (CDI)**

Since our 2004 acquisition of Vancocin®, the only approved product to treat *C. difficile* infections (CDI), we have treated well over 1 million patients suffering from this life-threatening infection. In 2008 we launched our first-ever sales efforts for Vancocin, deploying 5 sales representatives into the field with a focus on reaching major hospitals in the Northeast corridor, to increase awareness of physicians and medical staff on established benefits of Vancocin.

We continue to take very seriously our role as stewards of CDI. We remain focused on meeting demand for the drug, as well as providing effective educational programs to the physician community on management of disease. Regarding our efforts towards the proposed methods for demonstrating bioequivalence to Vancocin, we remain steadfast in our belief that until a method can be proven, patients' lives cannot be placed at risk. Patients deserve better. As with everything we do at ViroPharma, patients come first to us, and we will continue to fight for their best interests.

Vancocin's continued strong performance – in 2008 net sales of the drug were $232 million – helps enable our company to fund our clinical development programs, acquire new product opportunities to save lives and execute significant physician and patient education programs in all of the therapeutic areas we serve.

We have not spent much time speaking of Non-toxigenic *C. difficile*, or NTCD. However, this is a program about which we are very excited and have a goal of bringing into clinical development in 2009. While Vancocin is an effective treatment for CDI, its one Achilles' heel is recurrent CDI infections, which remain a serious unmet medical need. Our NTCD program offers hope that we might someday be able to provide a solution to reduce the rate of such recurrent infections. We look forward to speaking with you more about this program in the months ahead.

**Cytomegalovirus (CMV)**

During 2008, our clinical development team continued conducting the two largest studies ever in the management of cytomegalovirus in transplant patients. While we did not meet our objectives in these studies, they will provide a wealth of data to help us assess any potential future for maribavir, and help others by significantly expanding the scientific knowledge of the disease. We still have additional data mining ahead of us. If a path forward is to be found, we have the team in place to find it.

It's clear to me that 2008 was a year of execution, advancement and diversification by our team, which has laid the foundation for success in 2009 and beyond.

**2008 FINANCIAL HIGHLIGHTS**

| *(in thousands, except per share amounts)* | **2008** | 2007 | 2006 | 2005 | 2004 |
|---|---|---|---|---|---|
| **Consolidated Statement of Operations Data** | | | | | |
| Net Product Sales | $ 232,307 | $203,770 | $166,617 | $125,853 | $ 8,348 |
| Total Revenues | $ 232,307 | 203,770 | 167,181 | 132,417 | 22,389 |
| Total Operating Expenses | 153,652 | 87,974 | 68,375 | 44,272 | 34,398 |
| Operating Income (Loss) | 78,655 | 115,796 | 98,806 | 88,145 | (12,009) |
| Income (Loss) Before Income Tax Expense (Benefit) | 87,099 | 135,666 | 108,528 | 75,900 | (19,534) |
| Net Income (Loss) | 67,617 | 95,353 | 66,666 | 113,705 | (19,534) |
| Diluted Earnings (Loss) Per Share | $ 0.83 | $ 1.21 | $ 0.95 | $ 2.02 | $ (0.73) |
| **Consolidated Balance Sheet Data** | | | | | |
| Cash, Cash Equivalents | $ 275,839 | $ 179,691 | $ 51,524 | $232,195 | $ 32,026 |
| Short-term Investments | – | 404,637 | 203,885 | 1,218 | 12,184 |
| Working Capital | 317,413 | 594,403 | 266,443 | 166,666 | 42,918 |
| Total Assets | $ 1,053,684 | 776,066 | 429,694 | 435,525 | 178,360 |
| Long-term Debt | 250,000 | 250,000 | – | – | 190,400 |
| Total Stockholders' Equity (Deficit) | 661,024 | 496,563 | 411,899 | 326,977 | (26,138) |

On that note, let's spend a few moments on how we intend to achieve our goals in 2009.

With Cinryze™, we are early in the launch of this product. We are very excited by our progress thus far, and we are extremely encouraged with the level of enthusiasm among HAE patients and physicians towards Cinryze and our patient access program CINRYZE*Solutions*™. We also look forward to the potential additional indication of treating acute attacks of HAE. The FDA action date for our sBLA is June 3, 2009.

With Vancocin® and CDI, we will continue to provide first class medical education programs to the physician community and remain steadfast in our dedication to patient safety. We are also focused on initiating human clinical trials in 2009 with NTCD and discussing the opportunity and how it may contribute to the long-term growth of ViroPharma.

Finally, our cash management strategies will not change. We ended the year with $276 million in cash, which enables us to fully fund our business and assess other business development opportunities. Today's financial market environment favors companies like us with cash, strong business development acumen, and conservative cash management practices.

On a personal note, this letter marks the conclusion of my first year as chief executive officer of ViroPharma. As I expected, it has been rewarding to work with such a great team of gifted individuals who collaborate together towards common team goals. There's often not much of which you can be certain in drug development. However, there is one fact of which I am absolutely certain – The team we have assembled at ViroPharma is capable of accomplishing amazing things to promote patient health. Thank you to all my teammates for your dedication and commitment. We will continue towards that promise in 2009.

We always consider you, our shareholders, as an integral part of our team and appreciate the input you contribute to help us reach our goals. We thank you for your continued support and look forward to working towards our common goal. Together.

Vincent J. Milano
*President, Chief Executive Officer and Chairman of the Board of Directors*

# TODAY

## EXECUTION. EXECUTION ON OUR PROGRAMS TO DELIVER LIFE-SAVING MEDICINES TO PATIENTS DESPERATELY SEEKING THEM.

> ***"The approval and availability of Cinryze™ provides the HAE patient community with hope that the pain, suffering and disability experienced by so many can finally be addressed."***
>
> *Anthony J. Castaldo*
> *President*
> *United States HAE Association (HAEA)*

The greatest measure of the work we do today will be the outcomes of the patients who benefit from and rely on the medicines we provide. It is never lost on the ViroPharma team that the important work we do may lead to a life being saved; patients leaving the hospital and returning to their families; patients for the first time being able to lead a normal life, with reduced fear of their genetic inflammatory disorder. Every day since November 9, 2004, ViroPharma has worked to ensure that patients suffering from cases of C. *difficile* infections have had access to Vancocin®. For U.S. patients with Hereditary Angioedema (HAE), a potentially deadly genetic inflammatory disease, we have launched Cinryze™ C1 Inhibitor (human), the first therapy of its kind used to prevent attacks of Hereditary Angioedema (HAE). Today, through our patient access program, CINRYZE*Solutions*™, we are ensuring that any patient who can benefit from Cinryze will have access to the product. Today, we are providing the medical community with world-class medical education through our many symposia and webinars regarding life-threatening diseases, including C. *difficile* and HAE, and deploying our regional medical scientists in the field to share their knowledge and discuss new data. We are working together with these physicians in an effort to control and prevent the spread of C. *difficile* in their institutions. Today, we are mining the data that have come from our two large Phase 3 studies of maribavir in transplant patients. While these studies did not yield the desired results, they do represent a large bank of information that may lead to answers for tomorrow's cytomegalovirus (CMV) care. Our team is working to identify other areas of unmet medical need where, ultimately, ViroPharma can advance potential cures. Our goal today is to execute on all of our programs so that we can continue to build the foundations for growth.

# TOMORROW

## HOPE. HOPE FOR A HEALTHIER TOMORROW. HOPE FOR MORE EFFECTIVE MEDICINES. HOPE FOR A CURE.

> ***"ViroPharma's Non-toxigenic C. difficile (NTCD) has the potential to prevent recurrence of C. difficile infections which can cause devastating pain, suffering and death. I am delighted to be collaborating with ViroPharma on development of this biotherapeutic agent."***
>
> *Dale N. Gerding, MD*
> *Division of Infectious Diseases*
> *Edward Hines Jr. VA Hospital*

The core goal of the biotechnology industry is to provide new, safe, and effective drugs to meet the needs of patients who have hopes for better therapies. At ViroPharma, we seek to accomplish this goal for patients who need it the most – those suffering from a myriad of diseases with few, if any, treatment options. Tomorrow, we hope to provide Cinryze™ to patients suffering acute attacks of HAE. Our goals also include expanding the use of Cinryze to patients in additional countries; assessing new formulations of Cinryze, such as subcutaneous versions, to expand its usage; and to identify and target additional unmet medical needs perpetuated by C1 Inhibitor deficiency. Another major unmet medical need that ViroPharma seeks to address in the future is that of recurrent C. *difficile* infection, a dangerous problem for patients at risk of this notorious healthcare-associated infection. Once a patient has been infected with C. *difficile,* there is a 15% to 25% chance of recurrence; and once it has recurred the first time, there is a 50% chance or greater of multiple recurrences. Tomorrow, our preclinical product candidate Non-toxigenic C. *difficile* (NTCD) may address this medical need in a unique way: by preventing infection with disease-carrying bacteria until restoration of a healthy gastrointestinal bacterial flora and protecting the patient from recurrent disease. ViroPharma has yet another advantage in that we are well capitalized, and we have great experience in evaluating and acquiring new product opportunities. We will continue to assess such new opportunities, keeping the best interests of our shareholders in mind. However, when the time is right and the medical need great, we will act decisively to bring these new drugs into our pipeline and to the patients who critically need them. Turning hope into reality. Tomorrow's innovations start today and every day at ViroPharma.

# TOGETHER

## CAN A SINGLE COMPANY CHANGE LIVES? CAN ONE TEAM MAKE A DIFFERENCE TO PATIENTS AND THEIR FAMILIES?

Does a group of scientists have the ability to develop safer and more effective drugs for patient populations with limited options? The answer for ViroPharma is a resounding 'yes,' so long as we make the effort and endeavor to achieve such measures of success **together**. We understand that we have the loftiest of goals: to search for cures for the difficult-to-treat patient populations and the unmet medical needs that few others have chosen to pursue. The path is not always straight, and the risks of failure are many – but together, our chances of success are great.

It takes a driven team to bring to market the first drug of its kind to prevent attacks of a debilitating and often deadly genetic inflammatory disorder called Hereditary Angioedema (HAE). For these patients, before the launch of Cinryze™ C1 Inhibitor (human) and its complementary patient access program CINRYZE*Solutions*™, their opportunities for successfully preventing these potentially dangerous attacks were minimal, and their lives were lived in fear that their next attack could be deadly. Together, we are changing such lives. It takes a cohesive team of scientists to design and execute the

***"Teamwork is so much more than an ideal at ViroPharma; it resides at the very core of everything we do. I've never before seen a group of individuals work together so cohesively to achieve common goals."***

*Karen Chalmers, Executive Assistant, Legal*

largest clinical program in CMV disease, elucidating the rate of cytomegalovirus infection and disease in transplant patients, and to evaluate an anti-cytomegalovirus agent. Though the outcome was not what we expected, our scientific team was efficient and well organized to quickly complete the study and analysis. It takes a strong team of medical professionals to be the stewards of medical education on one of the most notorious healthcare-associated infections – *Clostridium difficile* infection, or CDI – and to work with physicians to control outbreaks of this deadly infection in their institutions. Together, we are working with these doctors to save lives and advance the knowledge around these infections. Similarly, it takes a unique team of visionaries to believe in a world without recurrent CDI and to develop novel prevention paradigms like Non-toxigenic C. *difficile* (NTCD) to reduce the rate of reccurrence. Together, such a future is coming into focus. The team we have assembled at ViroPharma is second to none. We are a world class biopharmaceutical company that invests in the future of each of our employees with the expectation that they will work selflessly towards a future of better and safer drugs for patients with few if any treatment options. Together, we can make a difference and positively impact the world of medicine. The goals of the teams within this organization will stay focused on improving patient outcome, expanding medical education, driving shareholder value, and working to ensure a healthier future for this generation and the next. These are our mandates, and we aim to accomplish them all. **Together.**

*(from left to right)*

Thomas Mancini
*Intellectual Property Attorney*

Karen Chalmers
*Executive Assistant, Legal*

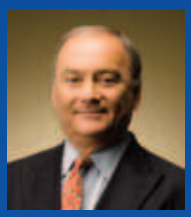
Chad Mohr
*Systems Engineer, IT*

Jian Xi
*Director, Market Research*

Deborah Franklin
*Manager, Commercial Analysis*

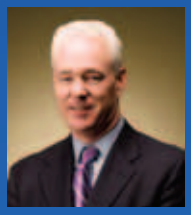
William Roberts
*VP, Corporate Communications*

## Board of Directors



Paul A. Brooke [1]
*Chairman of the Board of Directors of Alsius Corporation; Managing Member of PMSV Holdings LLC; Senior Advisor of Morgan Stanley & Co.*

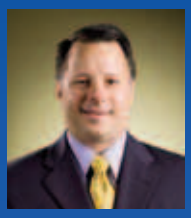
William D. Claypool, M.D. [2]
*Senior Partner, Pennmark Associates, LLC*



Michael B. Dougherty [1][3]
*President and Chief Executive Officer of Adolor Corporation*

Robert J. Glaser [2]
*Senior Partner, Pennmark Associates, LLC*

John R. Leone [1]
*Partner, Paul Capital Partners*



Vincent J. Milano
*Chairman of the Board of Directors of ViroPharma Incorporated; President and Chief Executive Officer of ViroPharma Incorporated*

Howard H. Pien [3]
*Lead Independent Director of Board of Directors of ViroPharma Incorporated; President and Chief Executive Officer of Medarex*

(1) Member of Audit Committee
(2) Member of Compensation Committee
(3) Member of Nominating and Governance Committee

## Management

Richard P. Bax, MBBS, FRCP, FFRM, MRGP
*Vice President, Clinical Development and Medical Affairs, ViroPharma Europe*

Colin Broom, M.D.
*Vice President and Chief Scientific Officer*

John C. Carlisle
*Vice President, Plasma Operations*

Thierry J. P. Darcis, M.D.
*Vice President and General Manager, ViroPharma Europe*

Thomas F. Doyle, J.D.
*Vice President, Strategic Initiatives*

Paul E. Firuta
*Vice President and Director, Reimbursement and Managed Care*

R. Clayton Fletcher
*Vice President, Business Development*

Peter A. Galiano
*Vice President, Sales*

Steven P. Gelone, Pharm. D.
*Vice President, Clinical Development Programs*

Judith A. Johnson M.S., M.B.A.
*Vice President, Clinical Pharmacology and Non-Clinical Development*

Thomas R. B. Lembck
*Vice President, Information Technology*

Thomas G. MacNamara
*Vice President, Human Resources*

Vincent J. Milano
*Chairman of the Board of Directors; President and Chief Executive Officer*

James A. Nash
*Vice President, Technology Development and Operations*

Robert G. Pietrusko, Pharm. D.
*Vice President, Global Regulatory Affairs and Quality*

William C. Roberts
*Vice President, Corporate Communications*

Charles A. Rowland Jr.
*Vice President and Chief Financial Officer*

Daniel B. Soland
*Vice President and Chief Operating Officer*

Stephen A. Villano, M.D.
*Vice President, Clinical Research and Development*

J. Peter Wolf, J.D.
*Vice President, General Counsel and Secretary*

This annual report contains forward-looking statements relating to goals of developing and commercializing innovative products addressing life-threatening unmet medical needs and improving the lives of patients suffering from serious diseases. Forward-looking statements include, but are not limited to, those related to our ability to find a path forward to develop maribavir, the goals, timing, and potential markets of our clinical and preclinical development programs; our ability to conduct a successful commercial launch of Cinryze™; our ability to assure that every patient who needs Cinryze will have access; regulatory approval timelines, including our ability to receive regulatory approval for an acute treatment indication for Cinryze in the time we anticipate, or at all; our opposition to changes to OGD recommendations regarding the path for approval of a generic oral vancomycin; and our plans regarding business development. There can be no assurance that our efforts related to our clinical and preclinical development programs will occur on our estimated timelines, will yield positive results, that the FDA or EMEA would approve any of our product candidates. We may not conduct additional studies with maribavir. The FDA or other regulatory authorities may prohibit any future studies with maribavir or alternatively may require additional or unanticipated studies or clinical trial outcomes before granting regulatory approval of maribavir or Cinryze. There can be no guarantee that ViroPharma will be successful in gaining regulatory approval of maribavir for any indications or for Cinryze for acute treatment of HAE. Our ability to successfully launch Cinryze is dependent upon many factors, including: the number of patients with HAE that may be treated with Cinryze; our ability to effectively market and distribute Cinryze; patients' ability to obtain sufficient coverage or reimbursement by third-party payors; and the timing of the approval of competitive products including another C1 esterase inhibitor for the acute treatment of HAE. There can be no assurance that our efforts to oppose the FDA's bioequivalence guidance for Vancocin® will be successful. If the FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor may enter the market would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly asset valuations. We cannot assure you that our current cash, cash equivalents and short-term investments or cash flows from Vancocin and Cinryze sales will be sufficient to fund all of our ongoing development and operational costs. Additionally, we may require additional financing in connection with a business development opportunity. These statements are based on management's current expectations, but the development and commercialization of pharmaceutical products are subject to many risks and uncertainties. Our actual results could differ materially from those results expressed in, or implied by, these forward-looking statements. Factors that could cause our actual results to differ significantly from these expectations are described in detail in our annual report on Form 10-K filed with the Securities and Exchange Commission. The forward-looking statements contained in this annual report may become outdated over time. We do not assume any responsibility for updating any forward-looking statements.

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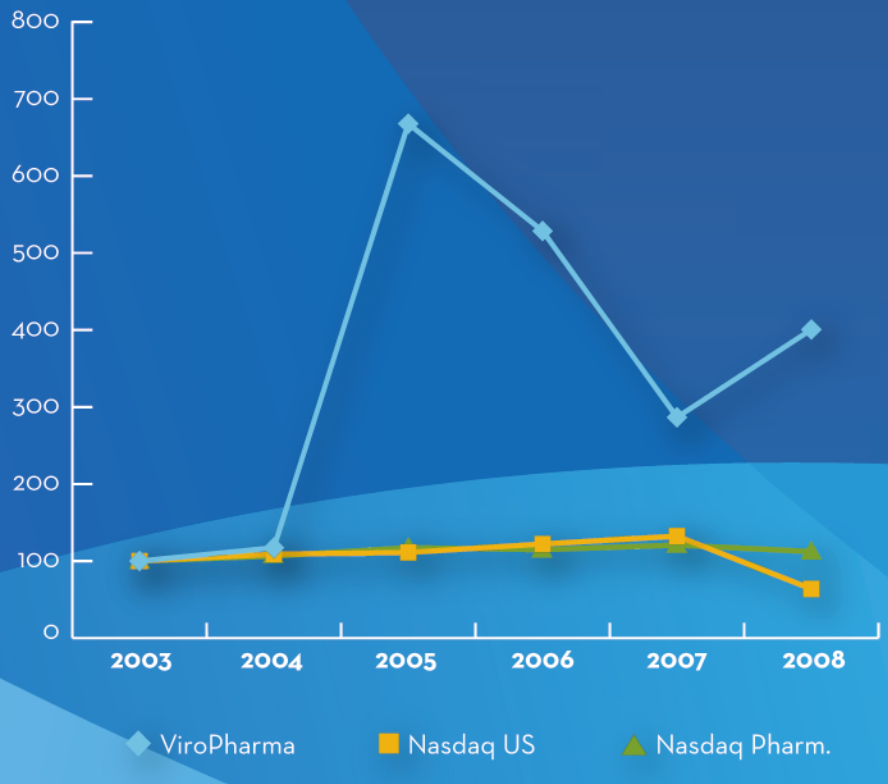
## COMPARATIVE STOCK PERFORMANCE GRAPH




The graph compares the cumulative total stockholder return on the Common Stock with the cumulative total stockholder return of (i) the NASDAQ Stock Market (U.S.) Index (the "NASDAQ Index"), and (ii) the NASDAQ Pharmaceutical Stocks Total Return Index (the "Pharmaceutical Index"), assuming an investment of $100 on December 31, 2003 in each of the Common Stock of ViroPharma; the stocks comprising the NASDAQ Index; and the stocks comprising the Pharmaceutical Index. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices over the five-year period extending through the end of fiscal 2008.

# UNITED STATES
# 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, 2008**

**OR**

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
**For the transition period from to**

**Commission File Number: 000-21699**

# VIROPHARMA INCORPORATED

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **23-2789550** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **730 Stockton Drive, Exton, Pennsylvania** | **19341** |
| **(Address of principal executive offices)** | **(Zip Code)** |

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

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

| **Title of each class:** | **Name of each exchange on which registered:** |
|---|---|
| **Common Stock, par value $0.002** | **The NASDAQ Stock Market LLC** |

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

**Title of each class: None**

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large Accelerated Filer ☒ Accelerated Filer ☐

Non-accelerated filer ☐ Smaller Reporting Company ☐

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

The approximate aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $764.5 million as of June 30, 2008, based upon the closing sale price per share of the Common Stock as quoted on the Global Market segment of the NASDAQ Stock Market on that date.

The number of shares of the registrant's Common Stock outstanding as of February 20, 2009 was 77,406,908 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 2009 Annual Meeting of Stockholders scheduled to be held on May 22, 2009 are incorporated by reference in Part III of this Annual Report on Form 10-K.

**VIROPHARMA INCORPORATED**

**FORM 10-K ANNUAL REPORT**
**For Fiscal Year Ended December 31, 2008**
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## PART I

### ITEM 1. BUSINESS

As used in this Annual Report on Form 10-K, all references in this report to "ViroPharma," the "Company," "we," "us," or "our" refer to ViroPharma Incorporated and its subsidiaries as a single entity unless the context otherwise requires.

ViroPharma is an international biopharmaceutical company dedicated to the development and commercialization of products that address serious diseases, with a focus on products used by physician specialists or in hospital settings. We intend to grow through sales of our marketed products, Vancocin® and Cinryze™, through continued development of our product pipeline and through potential acquisition or licensing of products or acquisition of companies. We have two marketed products, and three development programs.

We market and sell Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is a potent antibiotic approved by the U.S. Food and Drug Administration, or the FDA, to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* infection (CDI), or *C. difficile*, and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On October 21, 2008, we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev), a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. As a result of the merger, we obtained Cinryze, a C1 inhibitor, which has been approved by the FDA for routine prophylaxis of hereditary angioedema (HAE) also known as C1 inhibitor deficiency, a rare, severely debilitating, potentially life-threatening genetic disorder. In December 2008, we submitted a supplemental Biologics Application (sBLA) for Cinryze as a treatment for acute attacks of HAE based on a re-analysis and resubmission of data from a pivotal Phase 3 acute treatment study of Cinryze and interim data from an ongoing open label acute study of the drug. In February 2009, the sBLA was granted priority review with a Prescription Drug User Fee Act (PDUFA) date of June 3, 2009.

ViroPharma is developing two new product candidates, maribavir for the prevention and treatment of cytomegalovirus, or CMV disease; and non-toxigenic strains of C. *difficile* (NTCD) for the treatment and prevention of CDI. On February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant (SCT) patients did not achieve its primary endpoint. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. Additionally, on February 13, 2009, we announced that enrollment in our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to current standard of care.

We have licensed the U.S. and Canadian rights for a third product development candidate, an intranasal formulation of pleconaril, to Schering-Plough for the treatment of picornavirus infections.

We intend to continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious medical conditions which require modest sales and marketing infrastructure, or to complement the markets that we hope our CMV and NTCD programs will serve or in which Vancocin and Cinryze are prescribed.

We were incorporated in Delaware in September 1994 and commenced operations in December 1994. Our executive offices are located at 730 Stockton Drive, Exton, Pennsylvania 19341, our telephone number is 610-458-7300 and our website address is www.viropharma.com. Information contained on our website is not incorporated into this Annual Report on Form 10-K or any other filings we make with the SEC.

#### Vancocin

In November 2004, we acquired all rights in the U.S. and its territories to manufacture, market and sell Vancocin, as well as rights to certain related vancomycin products, from Eli Lilly and Company (Lilly). Lilly retained its rights to Vancocin outside of the U.S. and its territories. Vancocin is approved by the FDA for treatment of enterocolitis caused by *S. aureus* (including methicillin-resistant strains) and antibiotic associated pseudomembranous colitis caused by *C. difficile*. Both are potentially serious infections of the gastrointestinal (GI) tract. *S. aureus* enterocolitis is rare; however, infection with *C. difficile* is the indication that accounts for the majority of Vancocin's use.

CDI is an infection of the GI tract. The clinical manifestations, ranging from diarrhea to toxicmegacolon and sometimes death, are a result of toxins produced by the bacterium that cause inflammation in the colon. Hospitalized patients, those residing in long-term care centers, those greater than 65 years of age, and patients that have received broad-spectrum antibiotic therapy, are at greatest risk to acquire CDI.

CDI is not a nationally reportable disease and as such it is difficult to estimate the actual incidence of disease with precision. Based on reports from the Centers for Diseases Control and Prevention (CDC) and peer-reviewed publications, we estimate that at least 500,000 patients were affected by CDI in 2008. Many clinicians report treating increasing numbers of patients with severe CDI and increased mortality rates. Clinicians have also noted that some patients are progressing from mild/moderate disease to severe disease or death more rapidly than previously observed. The incidence of CDI appears to have plateaued in 2008 relative to previous years.

Although the causes for this change in CDI remain under active investigation, the CDC has postulated that a combination of changes in antibiotic use and infection control practices, along with the emergence of a hypervirulent strain of *C. difficile*, are likely contributors. As of late 2008, this strain (referred to as the toxinotype III, BI, or NAP1/027 strain) has been identified in at least 40 states in the U.S.

Vancocin is the only drug approved by the FDA for the treatment of antibiotic-associated pseudomembranous colitis caused by *C. difficile*. Historically metronidazole has been commonly used as first-line treatment for CDI, while Vancocin has been reserved for those patients who have failed metronidazole, have recurrent disease, or who are suffering from severe CDI. We believe that changes in the epidemiology of CDI, in particular the increasing frequency of severe disease, and data suggesting that failure or relapse occur more commonly in patients treated with metronidazole have led to an increase in the use of Vancocin. In October of 2007, the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of American (IDSA) presented draft management guidelines for CDI at the IDSA annual meeting. Key points from the draft evidenced-based guidelines include:

- A recommendation supporting the use of metronidazole for the treatment of initial episodes of mild-to-moderate CDI;
- The definition of severe CDI is proposed to be patients with a peripheral white blood count (WBC) greater than 15,000/mm3 or a rising serum creatinine greater than 50% above the pre-morbid CDI level;
- An evidence-based recommendation supporting the use of Vancocin as first line therapy for initial episodes of severe or severe-complicated CDI;
- The recommended duration of therapy of 10 – 14 days for the treatment of all initial episodes of CDI regardless of severity;
- A recommendation to treat a first episode of a recurrence of CDI with the same agent used to treat the initial episode;
- The recommended use of metronidazole only in the management of a first episode of recurrent CDI, with Vancocin being recommended for the management of all second episodes of recurrent CDI.

On March 17, 2006, we learned that the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research ("OGD") permitted a generic drug applicant to request a waiver of in-vivo bioequivalence testing for copies of Vancocin if the generic applicant could show that its product was rapidly dissolving. In December 2008, FDA changed OGD's 2006 bioequivalence recommendation by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin ("Q1 and Q2 the same") to demonstrate bioequivalence through comparative dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. The comment period for this proposed change is scheduled to expire on March 19, 2009. We are opposing both the substance of the FDA's bioequivalence method and the manner in which it was developed. However, if FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor may enter the market would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations.

**Cinryze**

In October 2008, we completed our acquisition of Lev. Lev was a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration in the aggregate amount of $453.1 million, or $2.75 per Lev share, comprised of $2.25 per share in cash and $0.50 per share in ViroPharma common stock, and contingent consideration (CVRs) of up to $1.00 per share which may be paid upon the achievement of certain regulatory and commercial milestones.

The FDA granted approval for Cinryze in October 2008 for routine prophylaxis against attacks in adolescent and adult patients with hereditary angioedema (HAE). HAE is a genetic disorder characterized by episodes of edema (swelling) in the extremities, face, abdomen, and airway passages. The majority of patients have episodes of severe abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Attacks that involve the face and throat must be taken seriously and medical treatment should be sought without delay. Swelling of the throat can close the air passage and cause death by suffocation. The mortality rate from untreated airway obstruction has been reported to be over 30% with death most frequently caused by asphyxiation due to airway closure. The course of the disease is diverse and unpredictable, even within a single patient over his or her lifetime. Swelling caused by HAE usually lasts for 24-72 hours, but the length of an attack can range from four hours to four days. On average, patients experience approximately one attack per month, but the frequency is highly variable. As many as 5% to 10% of patients are severely affected, experiencing attacks one to three times per week. HAE affects between 1 in 10,000 and 1 in 50,000 individuals worldwide and there are believed to be 4,600-6,000 people with HAE in the United States.

HAE is caused by a defective gene for C1 inhibitor (C1-INH), and this defect is passed on in families, such that—a child has a 50% chance of inheriting this disease if one parent is affected. The absence of family history, however, does not rule out HAE diagnosis, and as many as 20% of HAE cases involve patients who appear to have had a spontaneous mutation of the C1-INH gene at conception. This genetic defect results in the production of either inadequate or nonfunctioning C1-INH protein.

C1-INH is known to inhibit three key biochemical pathways underlying inflammation and/or coagulation as follows: (i) the complement system; (ii) the contact pathway of intrinsic coagulation; and (iii) the fibrinolytic system. Excessive activity of each of these systems has been demonstrated in HAE, as evidenced by increased levels of components of the complement system, kallikrein, coagulation Factors XIa and XIIa, and plasmin. The biochemical imbalance that results from reduced levels of functional C1-INH leads to the production of proteins and peptides that cause fluids to be released from the capillaries into surrounding tissues thereby causing edema.

In the absence of C1-INH activity, activated C1 and plasmin generate certain inflammatory mediators that are thought to be causal factors of the angioedema observed in patients with HAE. C1-INH concentrate replaces the missing or non-functional protein and inhibits the catalytic subunits of the first component of the classic complement pathway (C1r and C1s), and also inhibits the function of kallikrien, plasmin, and coagulation factors XIa and XIIa.

Because HAE is rare and has a wide variability in disease expression, it is not uncommon for patients to remain undiagnosed or misdiagnosed for many years. Many patients report that their frequent and severe abdominal pain was inappropriately diagnosed as psychosomatic. Although rare, HAE is a disease with potentially catastrophic consequences for those affected. Aside from the potentially fatal acute respiratory compromise, unnecessary exploratory surgery has been performed on patients experiencing gastrointestinal edema because abdominal HAE attacks mimic conditions requiring surgery.

Traditionally, HAE has been classified into two types (I and II). The most common form of the disease, Type I, is characterized by low levels of C1-INH and affects about 85% of patients, whereas Type II HAE affects 15% of patients and is characterized by non-functional C1-INH. A third type of HAE has been identified in which the abnormal C1-INH protein binds to albumin, effectively reducing the amount of functional C1-INH.

*Current Treatments of HAE*

Treatment of HAE can be categorized as: (i) mitigation or acute treatments to remedy the symptoms of infrequent episodic acute attacks; and (ii) preventive or prophylactic treatments for patients severely affected by HAE.

There are currently no approved treatments for acute attacks of HAE available in the United States. Rather, current therapies primarily focus upon treating the symptoms of an acute attack. For swelling of the intestinal wall, which can cause debilitating pain, narcotics such as morphine and antiemetics for nausea are given, but these medications only address the symptoms and not the underlying cause. For severe laryngeal swelling, which can be life threatening, rescue therapy such as intubation or tracheotomy may be required. The use of fresh frozen plasma, which contains C1-INH but which also contains a wide variety of other factors that may activate multiple inflammatory pathways and exacerbate an attack, is also used in some instances. Facial and extremity attacks are usually left to resolve on their own. To address this unmet medical need, in the period following our acquisition of Lev, we resubmitted the portion of the Cinryze BLA referring to the data for the acute treatment of HAE attacks along with additional data from the ongoing open label acute studies of Cinryze.

Cinryze is the only FDA approved product for prevention of HAE attacks. Prior to the approval of Cinryze, patients who experience more than one attack per month have historically been treated with anabolic steroids that reduce the frequency of attacks of edema. The most commonly used steroids are alpha-alkylated androgens. Use of such anabolic steroids can have numerous side effects ranging from hepatotoxicity (liver toxicity), virilization (development of male sexual characteristics in a female), weight gain, acne and hirsutism (unwanted hair growth).

The FDA granted Cinryze seven years of marketing exclusivity for routine prophylaxis of HAE upon FDA approval pursuant to the Orphan Drug Act. The Office of Orphan Products Development originally granted orphan drug designation for Cinryze on July 16, 2004.

As part of the merger consideration payable to the former stockholders of Lev, we agreed to make up to two CVR payments upon the achievement of regulatory and commercial targets. The first CVR payment of $0.50 per share (or $87.5 million) would become payable when either (i) Cinryze is approved by the FDA for acute treatment of HAE and the FDA grants orphan exclusivity for Cinryze encompassing the acute treatment of HAE to the exclusion of all other human C1 inhibitor products or, (ii) orphan exclusivity for the acute treatment of HAE has not become effective for any third party's human C1 inhibitor product by October 21, 2010. The second CVR payment of $0.50 per share ($87.5 million) would become payable when Cinryze reaches at least $600 million in cumulative net product sales within 10 years of closing of the acquisition.

**Product Pipeline**

We currently have three development programs. Our first program is for the acute treatment of HAE. Our second clinical development program targets CMV with an initial focus on CMV disease in recipients of hematopoietic stem cell and solid organ transplants. This program is within the transplant and hospital setting and focuses on diseases treated by physician specialists. Our third program is in preclinical development and targets the treatment and prevention of CDI utilizing the spore form of a non-toxin producing strain of *C. difficile* (NTCD).

In addition, we have licensed intranasal pleconaril to Schering-Plough who has assumed responsibility for all development and commercialization of pleconaril in the U.S. and Canada.

The following chart generally describes our research and development programs:

| Product Candidate | Disease | Program Indication | Development Status | ViroPharma Commercialization Rights |
|---|---|---|---|---|
| Cinryze | HAE | Acute treatment | sBLA filed | All countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel |
| Maribavir | CMV | Treatment and prevention | Evaluating Phase 3 Data | Worldwide, other than Japan |
| Non-toxigenic strain of C. difficile (NTCD) | CDI | Treatment and prevention | Preclinical | Worldwide rights |

**Cinryze**

In December 2008, we submitted a supplemental Biologics Application (sBLA) for Cinryze as a treatment for acute attacks of HAE based on a re-analysis and resubmission of data from a pivotal Phase 3 acute treatment study of Cinryze and interim data from an ongoing open label acute study of the drug. In February 2009, the sBLA was granted priority review with a PDUFA date of June 3, 2009. The phase 3 study was a randomized, double blind, placebo controlled multi-center trial in 71 patients evaluating the safety and efficacy of Cinryze for the treatment of HAE attacks. The primary efficacy measure in the pivotal phase 3 acute treatment study was the time from initial treatment to the start of unequivocal relief from the defining symptom. Based on the primary efficacy variable, in the All Randomized (ITT) Dataset, the likelihood of a patient having the start of unequivocal relief of the defining symptom was 2.048 times greater in the Cinryze treatment group than in the placebo treatment group (p=0.048). The median time to the start of unequivocal relief of the defining symptom was shorter in subjects in the Cinryze treatment group (two hours) than in subjects in the placebo treatment group (greater than four hours).

In the open label study of Cinryze as a treatment for acute attacks of HAE, no patients who had acute laryngeal edema attacks required hospitalization or intubation. Cinryze was generally well tolerated. There were no deaths or serious adverse reactions related to Cinryze administration, or discontinuations due to treatment-emergent adverse events. In the analysis of 447 acute attacks in 82 patients, open label Cinryze administration provided substantial relief of the defining symptom in 93.4 percent of the attacks within four hours of injection, with a median time to onset of relief of 30 minutes. There was no observed loss of effectiveness over multiple administrations of Cinryze for subsequent HAE attacks.

In addition, we are currently evaluating the feasibility of additional indications or other formulations for Cinryze.

**CMV Program**

On February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant (SCT) patients did not achieve its primary endpoint. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. In addition, the study failed to meet its key secondary endpoints. Maribavir was generally well tolerated in this clinical study.

The primary endpoint of this Phase 3 study was the incidence of CMV disease, confirmed by an independent endpoint committee, within 6 months post-transplant. The incidence of CMV disease within 6 months was 4.4 percent for maribavir compared to 4.8 percent for placebo (P=0.79). The first of four key secondary endpoints was the rate of initiation of anti-CMV treatment within 6 months, which was 37.9 percent for maribavir compared to 40.5 percent for placebo (P=0.49). In addition, the incidence of graft-versus-host disease, mortality and CMV disease-free survival was comparable between the groups. We are continuing to analyze the study results.

The SCT study is a randomized, double-blind, placebo-controlled, multicenter pivotal Phase 3 study in 681 patients who have undergone allogeneic stem cell transplantation. Following transplantation and transplant engraftment, eligible patients were randomized to receive maribavir or matching placebo in a 2:1 randomization ratio. All patients received maribavir 100 mg BID or placebo for a maximum duration of 12 weeks, and followed for an additional 12 weeks to reach the 6-month post-transplant analyses for regulatory filing purposes. All patients were then to be followed for an additional 24 weeks.

Enrolled subjects underwent testing for CMV infection at least weekly. CMV surveillance included weekly testing at a central laboratory for the presence of CMV pp65 antigenemia and for the presence of CMV DNA in plasma using a polymerase chain reaction (PCR). If CMV infection was detected during the study drug administration period (or if CMV organ disease was diagnosed), study drug was discontinued and the subject was managed according to standard CMV treatment practices at the transplant center.

On February 13, 2009, we announced that enrollment in our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to current standard of care. This decision was made based on the results of the Phase 3 study of maribavir in stem cell transplant patients, and the recommendation from our independent Data Monitoring Committee who considered the rate of viremia in both arms of the study.

We have completed several phase 1 clinical trials with maribavir to evaluate the potential for drug interactions, to evaluate the pharmacokinetics of maribavir in subjects with renal impairment and in subjects with hepatic impairment, and to evaluate the relative bioavailability of different tablet formulations. Additional clinical studies will be considered following additional analysis of the SCT study results. We completed a phase 2 clinical trial with maribavir for the prevention of CMV infections in allogeneic stem cell transplant patients, which demonstrated that maribavir significantly reduced CMV reactivation in this population.

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 40% and 85% of adults in North America and Europe. 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 or solid organ transplantation remain at high risk of CMV infection. In these patients, CMV can lead to severe conditions such as pneumonitis, gastroenteritis, or even death.

We are evaluating our maribavir program in light of the Phase 3 clinical trial results and discontinuing dosing any patients with maribavir in any clinical trials.

**CDI Program**

In February 2006, we announced that we had entered into a licensing agreement with Dr. Dale Gerding, of the Hines VA for the rights to develop non-toxigenic strains of C. *difficile* (NTCD) for the treatment and prevention of CDI. We plan to initially focus our efforts on the opportunity to prevent recurrence of CDI, using oral administration of spores of non-toxin producing C. *difficile*. The underlying concept of this approach is to first treat the disease with an effective product like Vancocin and eradicate the dangerous toxin-producing *C. difficile* which causes severe CDI. The treated patient could potentially then be dosed with oral NTCD to re-colonize the GI tract and prevent the pathogenic C. *difficile* bacteria from re-infecting the colon until normal GI flora returns and the patient is no longer susceptible to disease. We expect to commence a Phase 1 clinical trial with NTCD in 2009.

**Business Development**

We intend to continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious medical conditions which require modest sales and marketing infrastructure, or to complement the markets that we hope our CMV and NTCD programs will serve or in which Vancocin or Cinryze is prescribed.

Competition for products currently in clinical development, or that are currently on the market, 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 expand our sales and marketing infrastructure both in the US and internationally. There is no assurance that we would be successful in expanding our commercial capabilities, that we would be able to penetrate the markets for any such products or that we could achieve market acceptance of our products. There are also no assurances that we will be able to obtain financing for acquiring such products or to expanding our operations to realize the products potential.

**Strategic Relationships**

*Vancocin Capsules and Lilly*

In November 2004, we acquired all rights in the U.S. and its territories to manufacture, market and sell Vancocin, the oral capsule formulation of vancomycin hydrochloride, as well as rights to certain related vancomycin products, from Lilly. Vancocin is a potent antibiotic approved by the FDA to treat antibiotic-associated pseudomembranous colitis caused by *C. difficile* and enterocolitis caused by *S. aureus*, including methicillin-resistant strains. Lilly retained its rights to vancomycin outside of the U.S. and its territories.

We paid Lilly an upfront cash payment of $116.0 million. We are obligated to pay additional purchase price consideration based on annual net sales of Vancocin through 2011. As of December 31, 2008, we have paid an aggregate of $30.1 million to Lilly in additional purchase price consideration, as our net sales of Vancocin surpassed the maximum obligation level of $65 million in 2005 through 2008. The $30.1 million paid was based upon 35% of $20 million in 2008, 35% of $17 million in 2007, 35% of $19 million in 2006 and 50% of $21 million in 2005.

For annual net sales during 2009 through 2011, we are obligated to pay additional amounts of 35% on net sales between $45 and $65 million. No additional payments are due to Lilly on net sales of Vancocin below or above the net sales levels. We account for additional purchase price consideration as contingent consideration and record an adjustment to the carrying amount of the related intangible assets and a cumulative adjustment to the intangible amortization upon achievement of the related sales milestones. See Note 7 of the Consolidated Financial Statements for additional information regarding intangible assets and amortization.

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 a royalty on net sales on these additional products for a predetermined time period.

*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, 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.

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 milestone payments based upon defined clinical development and regulatory events. In the third quarter of 2006, we recorded a $3.0 million milestone payment due to GSK associated with the initiation of the phase 3 study of maribavir, which was paid in February 2007. No additional amounts were recorded in 2007. We also will pay royalties to GSK and its licensor on product sales in the U.S. 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 consent from GSK.

*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 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 U.S. 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 April 2008, we announced that ViroPharma and Wyeth, have jointly discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. We also announced that ViroPharma and Wyeth do not expect to continue to collaborate on future development of hepatitis C treatment candidates.

Our agreement with Wyeth terminates, country-by-country, in the U.S. and Canada, if the parties are no longer co-promoting any product developed under the agreement, and outside the U.S. 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 U.S. and Canada. 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 a full license agreement with us following its assessment of the product's performance in characterization studies. 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 is now responsible for the development and commercialization of the intranasal formulation of pleconaril for the treatment of the common cold. Sanofi-Aventis has exclusive rights to market and sell pleconaril in countries other than the U.S. and Canada.

*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 U.S. and Canada, as well as a right of first refusal for any other indications in the U.S. 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, amongst other things, the royalty rate payable to Sanofi-Aventis was reduced. Pleconaril is covered by one of the licensed U.S. 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 U.S. 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, if any, which extends indefinitely. We are entitled to royalties from Sanofi-Aventis on sales of products by Sanofi-Aventis outside the U.S. 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 U.S. 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 and Distribution**

We currently utilize a virtual supply manufacturing and distribution chain in which we do not have our own facilities to manufacture commercial or clinical trial supplies of drugs and we do not have our own distribution facilities. Additionally, we do not intend to develop such facilities for any product in the near future. Instead, we contract with third parties for the manufacture, warehousing, order management, billing and collection and distribution of our products and product candidates. This virtual approach allows us the flexibility to adapt as our pipeline advances.

**Vancocin**

In December 2005 we entered into a toll manufacturing agreement with NPI Pharmaceuticals (formerly OSG Norwich Pharmaceuticals, Inc.) to produce finished Vancocin product. The qualification process required to transfer Vancocin manufacturing from Lilly to NPI Pharmaceuticals was completed in February 2006. All approvals were finalized in the second quarter of 2006 and, since June 30, 2006, all of our finished product has been supplied from NPI Pharmaceuticals. In April 2006, we also entered into an agreement with Alpharma, Inc. for the manufacturing of API for Vancocin. In October, 2007, we amended this agreement with Alpharma to extend the agreement until December 2011 and identified an additional production facility that will produce API in the future. Prior to our agreement with NPI, we purchased Vancocin from Lilly from November 2004 until the second quarter 2006.

**Cinryze**

In conjunction with the Lev acquisition, we acquired a Distribution and Manufacturing Services Agreement with Sanquin as of January 16, 2004. Under this agreement, Sanquin has granted us (i) the exclusive right to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma manufactured by Sanquin for the treatment of HAE in Israel and in all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil), and (ii) a right of first refusal to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma manufactured by Sanquin for the treatment of HAE in certain other geographic regions and under certain conditions.

Under the distribution agreement, it was Lev's responsibility to conduct the Phase III clinical trials of C1-INH for the treatment of HAE and to prepare and file all regulatory applications necessary to register the product candidate. In exchange, Sanquin agreed to provide Lev with the technical data and support necessary to assist Lev in preparing and filing all such regulatory applications.

Furthermore, Sanquin agreed to supply C1-INH for Lev's Phase III clinical trials. Upon receipt of FDA approval for our product candidate for the treatment of HAE, upon commercial launch of this product and thereafter during the term of the agreement, Sanquin will supply us with our commercial requirements for C1-INH for the treatment of HAE in each country where we have received regulatory approval subject to minimum annual purchase requirements in Euros equal to approximately $20.6 million per year. The term of this agreement is through December 31, 2010. We have the right to extend this agreement for up to eighteen additional years by way of six three year renewal periods.

On October 10, 2007, we entered into an amendment, dated as of September 24, 2007, to the Distribution and Manufacturing Services Agreement with Sanquin. Pursuant to this amendment, we initiated a construction project to scale-up the production facilities of Sanquin to be used for the purpose of meeting our anticipated ongoing requirements for the commercial use of the C1-Inhibitor product. Pursuant to the terms and conditions of the amendment, ViroPharma and Sanquin jointly developed a project plan for the construction to the production facilities with Sanquin. Subject to the terms of the final project plan, we provided Sanquin with a loan, of €7.5 million (approximately US $10.9 million, based on the exchange rate as of December 31, 2008), to finance the construction project. This construction project is currently in the planning phases and is expected to be complete in 2010 or 2011. This loan will be due July 1, 2014 and Sanquin agreed to repay the principal amount of the loan by providing us with a discount to the per unit purchase price of product. In addition, in the event the agreement is terminated before July 1, 2014 because of a default by us or if by such date the volume of product we ordered is less than the required volume for Sanquin to repay the loan, then we shall waive the then outstanding balance of the loan. In the event the agreement is terminated because of a default of Sanquin prior to the loan being repaid in full, then Sanquin shall pay us the entire outstanding principal balance of the loan as of the date of termination within 60 days from such date.

Pursuant to the amendment, Sanquin shall manufacture the product for us on a toll-manufacturing basis using the blood plasma we supply. We are required to purchase a specified amount of product from Sanquin until the scale up is complete. In addition, we agreed to an annual minimum purchase commitment of product (32 million units). Our contractual purchase commitments are subject to annual adjustments based on market conditions and do not include the cost of storage, handling and testing services that Sanquin will provide for us. We currently believe that Sanquin has enough capacity to fill our production requirements for the foreseeable future.

Further, pursuant to the amendment, Sanquin agreed to transfer to us and/or one or more third parties, all necessary rights and interests to its technology for manufacturing the product to enable a third party to serve as a second supplier of product under certain circumstances. The terms and conditions of this transfer are subject to negotiation among Sanquin, ViroPharma and a mutually agreed-upon third party. In addition, Sanquin agreed that in the event of a change in control of Sanquin (as defined in the amendment), we shall have the right to acquire from Sanquin a joint ownership right to the technology to enable us to exploit the technology, including to transfer the technology to a third party for the purpose of manufacturing product (and terminating or reducing its obligation to purchase from Sanquin). If we exercise this right, we would pay Sanquin a down payment against future annual license fees and royalties and be obligated to pay such future fees and royalties as provided for in the amendment. As provided for in the amendment, the agreement between ViroPharma and Sanquin shall be effective through December 31, 2010, and thereafter, we shall have the sole right to extend the initial term for up to an additional 18 years by providing for six consecutive renewal terms of three years each; and thereafter, the Distribution and Manufacturing Services Agreement may be extended by the mutual consent of the parties.

**Plasma**

In connection with our acquisition of Lev, we became party to a supply agreement for the purchase and sale of plasma with DCI Management Group, LLC pursuant to which we will purchase quantities of U.S. Source Plasma to be utilized in the production of product under our Distribution and Manufacturing Services Agreement with Sanquin Blood Supply Foundation. Under the agreement, the supplier agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices. We expect our annual purchase commitment to be between $12.1 million and $12.9 million for the balance of the term of the agreement. Our contractual purchase commitments are subject to annual percentage increases based on market conditions and do not include the cost of additional pre-delivery testing which we may require the supplier to undertake. We estimate our remaining commitment under this agreement to be approximately $37.3 million.

The agreement expires December 31, 2011, unless sooner terminated in accordance with its terms. Either party may terminate the agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. Subject to the supplier's ability to mitigate damages, in the event we are in default of our payment obligation under the contract, we will be liable to purchase the minimum quantities of plasma specified under the contract for the balance of the term. Upon expiration of the agreement, or in the event the agreement is terminated for reasons other than as set forth above, we will be obligated to purchase a closing inventory of plasma in the quantity specified in the agreement. We expect to obtain plasma for our production of Cinryze following the expiration of this contract through our plasma centers discussed below.

*Intermediate Supply Agreement with Biotest AG*

On April 9, 2008, we entered into an intermediate supply agreement with Biotest AG (Biotest) pursuant to which we will sell to Biotest all of our excess output of specific intermediate plasma products (the "Residuals") derived from the plasma processed by Sanquin on behalf of the Company. In addition, we offered Biotest a right of first refusal to purchase unprocessed plasma in the event we elect to sell unprocessed plasma to a third party. Biotest also agreed to provide us with a right of first refusal, subject to certain exceptions, to repurchase certain by products derived from the Residuals. The supply agreement has an initial term expiring December 31, 2012, unless sooner terminated. Either party may terminate the supply agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. In the event of a breach of the agreement by Biotest, Biotest shall be liable to purchase all amounts of Residuals deliverable under the supply agreement during its remaining term.

*Purchase Agreement with Plasma Centers of America, LLC*

On April 9, 2008, we entered into a purchase agreement with Plasma Centers of America, LLC (PCA) pursuant to which we and PCA will, subject to the terms and conditions of the purchase agreement, consummate the following transactions: (1) construction of three new plasma collection centers (New Centers) by PCA; (2); the acquisition by us of a maximum of three new of the plasma collection centers, assuming the satisfaction of certain performance targets by PCA and (3) purchase by us of source plasma from each of these new collection centers in accordance with the terms of the purchase agreement. Pursuant to the purchase agreement, PCA shall construct and operate the three New Centers in accordance with the schedule agreed upon by the parties. We expect site selection of these centers and construction to begin in 2009. In connection with PCA's obligations, we will make certain performance payments to PCA upon their achievement of agreed upon milestones relating to the construction and operation of each New Center. Further, during the period commencing on each New Center opening date and until the first to occur of the twelve month anniversary of such date, the closing date of our acquisition of such New Center or the election by the parties not to sell a qualified New Center, PCA shall exclusively sell the plasma generated at the New Centers to us. The purchase agreement also provides that upon the achievement by PCA of the following operating benchmarks, PCA shall have the right to cause us to acquire one or more New Centers up to the maximum of three: (a) PCA secures all regulatory approvals for each New Center with an agreed upon time frame and (b) PCA achieves and maintains an agreed-upon average collection level of plasma units. In the event PCA does not cause us to acquire a New Center, the Company shall have the right to require PCA to proceed with the sale of the New Center. In addition, in the event that the operating benchmarks are not achieved for a New Center, then we shall also have the right to acquire such New Center for a reduced purchase price.

Our commitments under this purchase agreement are comprised of three variable cost inputs: performance payments based on milestones achieved by PCA, costs of purchasing source plasma generated from each New Center and costs of acquiring the New Centers in the event that the contractual benchmarks are satisfied. The aggregate amount of the performance payments required under the purchase agreement for all New Centers is estimated at approximately $0.9 million. Further, we estimate that, if all three New Centers become operational in the time frames specified in the purchase agreement, our total pre-acquisition purchase commitment for plasma generated from such New Centers would be approximately $10.2 million. This assessment is based on management's estimate of the volume of plasma collections at each New Center. However, plasma collections may be highly variable at each location, and therefore our actual obligations may be significantly higher or lower. In the event the contractually specified benchmarks are satisfied and we acquire one or more New Centers, our acquisition cost for each New Center will be based on the volume of collections generated at each New Center multiplied by our per unit cost of plasma purchases from such New Center. We estimate that our cost for acquiring all three New Centers will be approximately $11.4 million. However, as this commitment is based on the plasma collections generated at each New Center, our actual acquisition cost may differ.

The purchase agreement commenced on April 3, 2008 and continues until December 31, 2010, unless sooner terminated. We shall have the right to terminate the purchase agreement upon written notice in the event that (a) we are unable to obtain any regulatory approvals necessary for us to take title to any of the New Centers; (b) PCA does not satisfy the operating benchmarks within the required timeframes; or (c) the parties are unable to consummate an acquisition of a New Center within the required time period. All performance payments for a given New Center and, to the extent applicable, payments for pre-licensed plasma collected at a particular New Center shall be reimbursed in the event that our obligation to acquire such New Center is terminated due to the non-performance of PCA of any of its obligations, in the event the operating benchmarks for such New Center are not timely achieved or in the event the parties do not consummate the sale of a qualified center.

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.

We expect to continue to rely solely on our collaborators and third-party manufacturers to manufacture drug substance and final drug products for both clinical development and commercial sale.

**Customers**

We sell our products directly to wholesale drug distributors and specialty pharmacies/ specialty distributors who then distribute the product to pharmacies, hospitals, patients, physicians and long term care facilities, among others. Net product sales to customers who accounted for 10% or more of our net product sales during the years ended December 31, 2008, 2007 and 2006 are as follows:

| | Percentage of total revenues | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| Customer A | 39% | 37% | 38% |
| Customer B | 38% | 40% | 35% |
| Customer C | 17% | 16% | 19% |
| Total | 94% | 93% | 92% |

In 2008, three wholesalers represented 94% of our total net product sales. We do not believe that the loss of any one of these wholesalers would have a material adverse effect on product sales because product sales would shift to other wholesalers or alternative forms of distribution. However, the loss of a wholesaler could increase our dependence on a reduced number of wholesalers.

In recent years, there have been numerous mergers and acquisitions among wholesale distributors as well as rapid growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. Some wholesale distributors are demanding that pharmaceutical manufacturers, including us, enter into what are referred to as distribution service agreements pursuant to which the wholesale distributors provide the pharmaceutical manufacturers with specific services, including the provision of periodic retail demand information and current inventory levels and other information. To date, we have entered into three such agreements with the parties identified in the table above.

**Marketing and Sales**

Our initial sales organization was established in 2008 to target doctors and hospitals to promote Vancocin. The Vancocin sales force is located solely in the Northeastern United States. With the commercial launch of Cinryze, we have expanded this sales force to target doctors who treat patients who have been diagnosed with HAE. We expect to focus our sales efforts for Cinryze towards hospitals, allergists, immunologists and home healthcare.

**Foreign Operations**

We conduct business in European countries through wholly-owned subsidiaries. Our international businesses are subject to risks customarily encountered in foreign operations, including fluctuations in foreign currency exchange rates and controls, import and export controls and other economic, political and regulatory policies of local governments. We currently have operations in Belgium, the United Kingdom, France and Switzerland.

**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 U.S. and abroad. The last core patent protecting Vancocin expired in 1996. There are no core patents protecting Cinryze. 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, and regulatory barriers to competitive products. We own four pending U.S. patent applications covering vancomycin related technology. We have one issued U.S. patent and two pending U.S. patent applications describing compounds, compositions and methods for treating respiratory syncytial virus (RSV) diseases. We have one issued U.S. patent and two pending U.S. patent applications covering compounds, compositions and methods of treating and preventing picarnovirus disease and one pending U.S. patent application covering methods of reducing rhinovirus contagion. We have four issued U.S. patents, nine non-U.S. patents, eleven pending U.S. patent applications that we co-own with a single development collaborator, and one pending U.S. patent application that we co-own with multiple development collaborators describing compounds and methods for treating hepatitis C and related virus diseases, including a patent application family that covers HCV-796 and claims related compounds, compositions and methods of use for the treatment of HCV infections. We have one pending U.S. patent application on compositions and methods for identifying inhibitors of HCV, and related technology. We have one pending U.S. patent application describing compounds and methods for treating hepatitis C and related virus diseases. We have three pending U.S. patent applications covering benzimidazole related technology. We also have filed international, regional and non-U.S. national patent applications in order to pursue patent protection in major foreign countries. Related patent applications were filed under the Patent Cooperation Treaty (PCT), as well as other non-U.S. national and/or regional patent applications. These patent applications describe compounds and methods for treating hepatitis C and related virus diseases, 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 the PCT and related foreign filings.

As patent applications in the U.S. 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 U.S. 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 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 U.S. 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 products and drug candidates.

**Government Regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements on the clinical development, licensure, 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 FDA 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 U.S. 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 the FDA of an Investigational New Drug Application, including the results of preclinical evaluations and tests, along with manufacturing information and analytical data plus any clinical data if the product previously was administered to humans including outside the US;
- 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, adequate, well-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 basic research, including pharmacology and mechanisms of action animal 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 or BLA;
- 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 generally takes 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 or efficacy issues. 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 take several years to complete, and there is no guarantee that an IND we submit will result in a submission of an NDA within any specific time period, if at all. Similar risks and uncertainties apply to the conduct and approval for licensure and marketing a product in non-U.S. markets around the world.

The FDA has issued regulations intended to expedite 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 streamline the traditional product development process in the U.S. Similarly, products that represent a substantial improvement over existing therapies may be eligible for priority review and a FDA expedited review 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 such as in a Risk Evaluation and Mitigation Strategy (REMS) requirement, including restricted access to the product and potential registries in the US and to a greater extent in Europe, formalized requirements to access pediatric safety and effectiveness. The Agency has the power to prevent or limit further marketing of a product based on the results of these post-approval commitments. 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 possible 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 with these 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 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 regulations, manufacturers must continue to spend time, money and effort on facilities and equipment, process control, recordkeeping, personnel training, quality control validation, 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 enforcement action, such as untitled letters, Warning Letters, suspension of manufacturing operations, seizure of the product, voluntary or mandatory recall of a product, injunctive action, consent decrees and/or suspension or revocation of product approval, as well as possible civil and criminal 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 U.S. for distribution abroad will be subject to FDA regulations regarding export, as well as 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 possible 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 U.S. also must register their establishments and 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 primary prescription drug benefit under the MMA, the new Medicare Part D coverage, began in January 2006. The new Part D prescription drug benefit is 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. 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 additional 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 regarding the percentage of needy population served).

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. Several states have also enacted laws requiring recordkeeping, compliance requirements, and reporting of gifts and other value given to healthcare providers. 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 other 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 U.S. 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.

In the United States, the Orphan Drug Act provides incentives to drug manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the United States, or for a disease that affects more than 200,000 individuals in the United States, where the sponsor does not realistically anticipate its product becoming profitable. The FDA has granted Cinryze seven years of marketing exclusivity to Cinryze C1 inhibitor (human) for routine prophylaxis of hereditary angioedema (HAE) pursuant to the Orphan Drug Act. Lev originally received orphan drug designation for Cinryze by the Office of Orphan Products Development on July 16, 2004. Additionally, the FDA has granted maribavir orphan drug status for prevention of cytomegalovirus (CMV) viremia and disease in the populations at-risk. Under the Orphan Drug Act, a manufacturer of a designated orphan product can seek certain tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication unless the subsequent sponsors could demonstrate clinical superiority or a market shortage occurs, it would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. The U.S. Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug and, thus, we cannot be sure that the benefits of the existing statute will remain in effect. Additionally, we cannot be sure that other governmental regulations applicable to our products will not change. We rely on the marketing exclusivity provided by the Orphan Drug Act for Cinryze as there are no core patents protecting Cinryze.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the European Union. The orphan legislation in the European Union is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. On November 12, 2007, the Company was granted Orphan Drug designation for maribavir by the Committee for Orphan Medicinal Products of the European Medicines Agency.

**Competition**

The last core patent protecting Vancocin expired in 1996. As a result, there is a potential for significant competition from generic versions of Vancocin. Such competition would result in a significant reduction in sales of Vancocin. We believe that regulatory hurdles (notwithstanding the recent actions taken by the OGD, described below), as well as product manufacturing trade secrets, know-how and related non-patent intellectual property may impact market entry of generic competition. However, there can be no assurance that these barriers will actually impact generic competition.

On March 17, 2006, we learned that the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research ("OGD") permitted a generic drug applicant to request a waiver of in-vivo bioequivalence testing for copies of Vancocin if the generic applicant could show that its product was rapidly dissolving. In December 2008, FDA changed OGD's 2006 bioequivalence recommendation by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin ("Q1 and Q2 the same") to demonstrate bioequivalence through comparative dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. The comment period for this proposed change is scheduled to expire on March 19, 2009. We are opposing both the substance of the FDA's bioequivalence method and the manner in which it was developed. However, if FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor may enter the market would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly asset valuations.

Vancocin sales for treatment of antibiotic-associated pseudomembranous colitis caused by *C. difficile* have increased over the past 12 months; however, Vancocin's share of the U.S. market for this indication may decrease due to competitive forces and market dynamics. Metronidazole, a generic product, is regularly prescribed to treat CDI at costs which are substantially lower than for Vancocin. In addition, products which are currently marketed for other indications by other companies may also be prescribed to treat this indication.

We do not have patent protection for the composition of Cinryze and we rely on the exclusivity provided by the Orphan Drug Act. The FDA granted Cinryze seven years of marketing exclusivity to Cinryze C1 inhibitor (human) for routine prophylaxis of HAE pursuant to the Orphan Drug Act and we are seeking approval to market Cinryze for the acute treatment of HAE. Acute treatment of HAE is a disease that fits within the definition of the Orphan Drug Act, and therefore any company that develops a therapy for this indication could, upon licensure, obtain a seven year marketing exclusivity in the United States for the licensed indication. We believe CSL Behring and Pharming Group N.V. are currently developing therapy for the acute treatment of HAE that the FDA may consider the same as ours under the Orphan Drug Act. In the event that these companies obtain FDA product licensures before us, we could be prevented from obtaining FDA licensure and marketing our C1-INH product for the acute treatment of HAE for up to seven years.

Stem cell and solid organ transplant patients at risk for CMV infection or with active CMV disease are most likely to receive ganciclovir or valganciclovir (prodrug of ganciclovir), each of which were developed and are marketed by F. Hoffmann-La Roche. Ganciclovir and valganciclovir 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 toxicity. Other broad-spectrum antiviral agents including valacyclovir and acyclovir (GSK) are marketed in several countries, and may also be 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.

In addition to approved products, other companies are developing treatments for infectious diseases, including compounds in preclinical and clinical development for *C. difficile*, CMV, HAE and rhinovirus infections. These companies include both public and private entities, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions. For example, Optimer Pharmaceuticals, Salix Pharmaceutical and Cubist Pharmaceuticals have clinical development programs with therapeutic agents for the treatment of *C. difficile* infection that could be found to have competitive advantages over Vancocin. Approval of new products, or expanded use of currently available products, to treat CDI, and particularly severe disease caused by *C. difficile* infection, could materially and adversely affect our sales of Vancocin. We believe that there is at least one vaccine product in clinical trials for the prevention of CMV infection and other companies may have research and development programs with molecules active against CMV. In addition, several other companies, including Dyax Corp., Shire Pharmaceuticals,

Pharming Group N.V. and CSL Behring, are developing compounds to treat acute attacks of HAE. 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 continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious medical conditions which require modest sales and marketing infrastructure, or to complement the markets that we hope our CMV and NTCD programs will serve or in which Vancocin and Cinryze 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.

**Employees**

As of February 20, 2009, we had 201 employees of which 172 were employed in the United States and 29 were located in Europe. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical products companies. None of our employees are 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**

| Name | Age | Position |
|---|---|---|
| Vincent J. Milano | 45 | President, Chief Executive Officer and Chairman of the Board of Directors |
| Charles A. Rowland, Jr. | 50 | Vice President, Chief Financial Officer |
| Colin Broom, M.D. | 53 | Vice President, Chief Scientific Officer |
| Thomas F. Doyle | 48 | Vice President, Strategic Initiatives |
| Daniel B. Soland | 50 | Vice President, Chief Operating Officer, Chief Commercial Officer |
| Robert G. Pietrusko | 60 | Vice President, Regulatory Affairs and Quality |
| J. Peter Wolf | 39 | Vice President, General Counsel and Secretary |
| Richard S. Morris | 35 | Controller and Chief Accounting Officer |

Vincent J. Milano joined the company in 1996, and has served as President and Chief Executive Officer since March 31, 2008. He became Chairman of the Board of Directors in December 2008. He served as our Chief Operating Officer from January 2006 to March 2008 and as Vice President, Chief Financial Officer of ViroPharma from November 1997 to March 2008. Mr. Milano has also previously served as our Vice President, Finance & Administration, as Treasurer, and as Executive Director, Finance & Administration. Prior to joining ViroPharma, Mr. Milano was with KPMG LLP, independent certified public accountants, where he was a Senior Manager. Mr. Milano received his Bachelor of Science degree in Accounting from Rider College.

Charles A. Rowland, Jr. has served as our Vice President, Chief Financial Officer since he joined the company in October 2008. Prior to joining ViroPharma, Mr. Rowland served as Executive Vice President, Chief Financial Officer of Endo Pharmaceuticals from December 2006 to September 2008. Mr. Rowland was Senior Vice President and CFO of Biovail Pharmaceuticals, Inc. prior to joining Endo Pharmaceuticals. From 2001 to 2004, he was Chief Operating and Financial Officer for Breakaway Technologies, a management consulting company. His pharmaceutical industry career includes positions of increasing scope and responsibility at Pharmacia Corp., where he had global responsibility for Finance and Information Technology for the Pharmaceutical Business and financial responsibility for the Global Supply organization as Vice President, Finance Global Supply and VP Finance & IT-Global Pharma Ops; Novartis Pharmaceuticals Corp., where he was Vice President, Planning and Decision Support, and Bristol-Myers Squibb, where he served as Director of Finance. Mr. Rowland received his Bachelor of Science degree in Accounting from St. Joseph’s University and a MBA from Rutgers University.

Colin Broom, M.D. has served as Vice President, Chief Scientific Officer of ViroPharma since May 2004. From 2000 until 2003, Dr. Broom served as Vice President of Clinical Development and Medical Affairs, Europe, for Amgen. 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 was with Glaxo and then SmithKline Beecham, where he 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 is Vice President, Strategic Initiatives as of January 2008. Mr. Doyle previously served as Vice President, General Counsel of ViroPharma from November 1997 to January 2008, as Secretary from February 1997 to January 2008 and as Executive Director, Counsel since joining ViroPharma in November 1996 to February 1997. 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 Bachelor of Science degree in Accounting from Mt. St. Mary's College.

Daniel B. Soland has served as Vice President, Chief Commercial Officer of ViroPharma since November 2006. Effective March 31, 2008, Mr. Soland will also serve as our Chief Operating Officer. From February 2005 until June 2006, Mr. Soland served as President of Chiron Vaccines. From March 2003 until February 2005, Mr. Soland was President and Chief Executive Officer at Epigenesis Pharmaceuticals, a privately held biopharmaceutical company. Prior to that, Mr. Soland spent nine years with GlaxoSmithKline as the Vice President and Director of Worldwide Marketing Operations, and five years as GSK's Vice President and Director of the U.S. Vaccines Business Unit. Mr. Soland holds a Bachelor of Science degree in Pharmacy from the University of Iowa, in Iowa City, IA.

Robert G. Pietrusko, Phrm.D., has served as Vice President, Global Regulatory Affairs and Quality since joining ViroPharma in 2007. Prior to joining ViroPharma, Dr. Pietrusko served as Senior Vice President of Worldwide Regulatory Affairs for Millennium Pharmaceuticals, Inc. from 2001 through May 2007. Dr. Pietrusko spent 19 years at GlaxoSmithKline, culminating in his tenure as Vice President and Director, Anti-infective and Antiviral Therapeutic Areas, U.S. Regulatory Affairs Dr. Pietrusko holds a Bachelor of Science degree in Biology and a Bachelors of Pharmacy degree from Rutgers University, and a Doctor of Pharmacy degree from the Philadelphia College of Pharmacy and Science.

J. Peter Wolf has served as Vice President, General Counsel, and Secretary since January 1, 2008. Mr. Wolf previously served as Associate General Counsel of ViroPharma since 2004. From 2000 to 2004 Mr. Wolf was a corporate attorney with the law firm of Pepper Hamilton LLP. Mr. Wolf received his J.D. from the George Washington University National Law Center and his Bachelor of Arts from the University of Delaware.

Richard S. Morris, CPA has served as Chief Accounting Officer of ViroPharma since April 2008. From December 2001 until April 2008, Mr. Morris has served in increasing levels of responsibility at ViroPharma, most recently as Controller from January of 2005 through April 2008. Prior to joining ViroPharma, Mr. Morris worked for KPMG LLP in their Healthcare Assurance practice. Mr. Morris holds a bachelor's degree in Accounting from Saint Joseph's University and has been a CPA since 1999.

**Available Information**

Our Internet website is www.viropharma.com and you may find our SEC filings on the "Investors" tab of that website. We provide access to all of our filings with the 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 or any other filings we make with the SEC.

## ITEM 1A. RISK FACTORS

*You should carefully consider the risk factors described below and all other information contained or incorporated by reference in this Annual Report on Form 10-K before you make an investment decision. If any of the following risk factors, as well as other risks and uncertainties that are not currently known to us or that we currently believe are not material, actually occur, our business, financial condition, results of operations and liquidity could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose part or all of your investment.*

**We have historically depended heavily on the continued sales of Vancocin.**

If revenue from Vancocin materially declines, our financial condition and results of operations will be materially harmed because, other than potential royalties and milestone payments, sales of Vancocin currently are our only material source of revenue. In addition, to the extent that revenue from Vancocin materially declines prior to Cinryze achieving significant commercial success, our financial condition and results of operations may be further harmed because sales of Cinryze may be our only other material source of revenue for at least the next several years.

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

- the development and approval of competitive generic versions of oral Vancocin, approval of products which are currently marketed for other indications by other companies or new pharmaceuticals and technological advances to treat the conditions addressed by Vancocin;
- manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Vancocin to meet demand for the product;
- changes in the prescribing or procedural practices of physicians in the areas of infectious disease, gastroenterology and internal medicine, including off-label prescribing of other products;
- decreases in the rate of infections for which Vancocin is prescribed;
- the level and effectiveness of our sales and marketing efforts;
- decrease in the sensitivity of the relevant bacterium to Vancocin;
- changes in terms required by wholesalers, including “fee-for-service” contracts;
- marketing or pricing actions by one or more of our competitors;
- our ability to maintain 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 U.S. from other countries;
- regulatory action by the FDA and other government regulatory agencies;
- changes in the reimbursement or substitution policies of third-party payors or retail pharmacies; and
- product liability claims.

Revenues from the sale of Vancocin may not remain at or above current levels or achieve the level of net product sales that we expect. We believe the rate of infections for which Vancocin is prescribed decreased during the second half of 2007 and remained flat during 2008 and that the rates of infection may remain flat or decline during 2009. During the third quarter of 2007, we made the decision to, for the first time, to create a small sales organization targeting teaching institutions to promote Vancocin. Our sales organization commenced operations during the first quarter of 2008. In the event our sales and marketing efforts are not effective and the rate of infections for which Vancocin is prescribed continues to decline, we could experience a decrease in sales of Vancocin. A decrease in sales of Vancocin, combined with increased expenses from the development of maribavir and the commercial launch of Cinryze could result in our inability to maintain profitability and could have a material adverse effect on our business, financial condition, results of operations and liquidity.

**If we are unable to successfully commercialize Cinryze, or are significantly delayed or limited in doing so, our business will be materially harmed.**

The FDA approved Cinryze for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema on October 10, 2008. Cinryze became commercially available for routine prophylaxis against HAE in December 2008. The commercial success of Cinryze will depend on several factors, including the following:

- the number of patients with HAE that may be treated with Cinryze;
- acceptance by physicians and patients of Cinryze as a safe and effective treatment;
- our ability to effectively market and distribute Cinryze in the United States;
- cost effectiveness of HAE treatment using Cinryze;
- relative convenience and ease of administration of Cinryze;
- potential advantages of Cinryze over alternative treatments;
- the timing of the approval of competitive products including another C1 esterase inhibitor for the acute treatment of HAE;
- patients’ ability to obtain sufficient coverage or reimbursement by third-party payors;

- sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze; and
- manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product.

If we are not successful in commercializing Cinryze in the U.S., or are significantly delayed or limited in doing so, we could fail to maintain profitability and our financial condition, results of operations and liquidity will be materially adversely impacted.

**Our long-term success depends upon our ability to develop, receive regulatory approval for and commercialize drug product candidates and, if we are not successful, our ability to generate revenues from the commercialization and sale of products resulting from our product candidates will be limited.**

All of our drug candidates will require governmental approvals prior to commercialization. Our failure to develop, receive regulatory approvals for and commercialize our development stage product candidates successfully will prevent us from generating revenues from the sale of products resulting from our product candidates. Our product candidates are in the development stage and may not be shown to be safe or effective.

*Cinryze*

In December 2008, we submitted a supplemental Biologics Application (sBLA) for Cinryze as a treatment for acute attacks of HAE based on a re-analysis and resubmission of data from a pivotal Phase 3 acute treatment study of Cinryze and interim data from an ongoing open label acute study of the drug. In February 2009, the sBLA was granted priority review with a Prescription Drug User Fee Act (PDUFA) date of June 3, 2009.

*Maribavir*

We initiated a phase 3 study in stem cell transplant patients for maribavir in September 2006 and a second phase 3 study in liver transplant patients in July 2007. On February 9, 2009 we announced that such phase 3 study did not achieve its primary endpoint or key secondary endpoints. We are evaluating our maribavir program in light of these results. In the event we are unable to develop a path forward, we will not generate any future revenue from maribavir.

*HCV-796*

We initiated our phase 2 program with Wyeth for HCV-796 in October 2006. In August 2007, we and Wyeth decided to discontinue dosing with HCV-796 in combination with pegylated interferon and ribavirin in our phase 2 study as 8% of patients showed elevated liver enzyme levels after 8 weeks or more of therapy with HCV-796 with pegylated interferon and ribavirin. In April 2008, we and Wyeth jointly determined to discontinue the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. We do not expect to continue to collaborate on future development of hepatitis C treatment candidates with Wyeth, however a decision to terminate the First Amended and Restated Collaboration and License Agreement dated June 26, 2003 has not been reached.

*Non-toxigenic difficile*

In February 2006, we entered into a licensing agreement for the rights to develop non-toxigenic strains of C. *difficile*, or *NTCD,* for the treatment and prevention of CDI. We plan to initially focus our efforts on the opportunity to prevent recurrence of CDI following treatment with antibiotics such as Vancocin. NTCD is in the preclinical phase which we expect will move into humans for the first time during 2009. These results of the clinical trials may not support further clinical development.

We cannot be certain that our efforts and the efforts of our partners regarding our product candidates will lead to commercially viable products. Negative, inconclusive or inconsistent clinical trial results, such as the results relating to our Phase 3 study of maribavir in stem cell transplant patients 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 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, we will not have a source of revenue other than Vancocin and Cinryze. Moreover, the failure of one or more of our product candidates in clinical development could harm our ability to raise additional capital. Furthermore, results from our clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval of a drug candidate. For example, our phase 3 trial evaluating maribavir in stem cell transplant patients did not achieve its primary endpoint and failed to meet its key secondary endpoints.

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 or other regulatory authorities forbid we 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, safer, or more cost-effective product.

Even if we believe that the clinical data sufficiently 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. 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 the rights to 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.

**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 a product candidate for the prevention and treatment of CMV in clinical development and a product candidate, NTCD, in pre-clinical development for the treatment and prevention of CDI. Schering-Plough is conducting the clinical development of pleconaril. We must complete significant laboratory, animal and clinical testing on these product candidates before submitting marketing applications in the U.S. and abroad.

The rate of completion of clinical trials depends upon many factors, including the rates of initiation of clinical sites and enrollment of patients. For example, our enrollment of patients in our phase 2 clinical trial for maribavir was impacted by our ability to identify and successfully recruit a sufficient number of patients who have undergone allogeneic hematopoietic stem cell/bone marrow transplantation. Our phase 3 studies for maribavir required substantially more clinical sites and patients than were required for the phase 2 study, and many of these clinical sites and patients are located in Europe. We do not have extensive experience in executing clinical trials in Europe. We also initiated a second phase 3 study of maribavir in liver transplant patients. We have never conducted clinical studies in this population and it has experienced enrollment at a rate which is lower than anticipated at the initiation of the study. If we are unable to initiate a sufficient number of clinical sites and accrue sufficient clinical patients who are eligible to participate in the trials during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. In addition, the FDA, Independent Safety Monitoring Boards 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. In addition, we may be unable to submit a NDA to the FDA or marketing petitions to other regulatory authorities such as the EMEA for our product candidates within the time frame we currently expect, or at all. Once an NDA or other form of petition for marketing authority is submitted, it must be approved by the FDA or other marketing authority 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 number, order and timing of clinical indications pursued;
- the number of patients required for enrollment;
- the length of time required to enroll these patients;
- the costs and difficulty of obtaining clinical supplies of the product candidate; and
- the difficulty in obtaining sufficient patient populations and clinicians.

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 product candidate for the desired indications could delay the commercialization of the product.

In 2003, Congress enacted the Pediatric Research Equity Act requiring the development and submission of pediatric use data for new drug products. In Europe, a Pediatric Investigational Plan must be agreed before a MAA can be submitted. our failure to obtain these data, or to obtain a deferral of, or exemption from, these requirements could adversely affect our chances of receiving regulatory approval, or could result in regulatory or legal enforcement actions.

**Because the target patient population for Cinryze is small and has not been definitively determined, we must be able to successfully identify HAE patients and achieve a significant market share in order to maintain profitability.**

The prevalence of HAE patients has not been definitively determined but has been estimated at approximately 4,600 to 6,000 total patients in the U.S. There can be no guarantee that any of our programs will be effective at identifying HAE patients and the number of HAE patients in the U.S. may turn out to be lower than expected or such patients may not be amenable to treatment with Cinryze. Accordingly, our product sales of Cinryze and overall business could be adversely affected if we are unable to identify sufficient numbers of HAE patients to maintain profitability.

**Our core patent protection for Vancocin has expired, which could result in significant competition from generic products and lead to a significant reduction in sales of Vancocin.**

The last core patent protecting Vancocin expired in 1996. As a result, there is a potential for significant competition from generic products that treat the same conditions addressed by Vancocin. Such competition could result in a significant reduction in sales of Vancocin. We believe that regulatory hurdles (notwithstanding the recent actions taken by the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research (OGD), which are described in more detail below and which we are vigorously opposing), as well as product manufacturing trade secrets, know-how and related non-patent intellectual property, may present barriers to market entry of generic competition. However, these barriers may not actually delay or prevent generic competition. The effectiveness of these non-patent-related barriers to competition will depend primarily upon:

- the current or future regulatory approval requirements for any generic applicant;
- the complexities of the manufacturing process for a competitive product;
- the nature of the market which Vancocin serves and the position of Vancocin in the market from time to time;
- the growth of the market which Vancocin serves; and
- our ability to protect Vancocin know-how as a trade secret.

Generic competitors may take advantage of the absence of patent protection for Vancocin to attempt to develop a competing product. We have become aware of information suggesting that other potential competitors are attempting to develop a competing generic product. For example, multiple generic manufacturers have publicly stated that they have filed to receive product approval and commence a marketing launch of a generic version of oral Vancocin. We are not able to predict the time period in which a generic drug may enter the market, as this timing will be affected by a number of factors, including:

- whether an in-vitro method of demonstrating bioequivalence is available to an applicant to gain marketing approval by the FDA in lieu of performing clinical studies;
- the nature of any clinical trials which are required, if any;
- the timing of filing an Abbreviated New Drug Application, or an ANDA, the amount of time required by the FDA to review the ANDA and whether a generic drug application is afforded an accelerated review by the FDA;
- the specific formulation of drug for which approval is being sought; and
- the time required to develop appropriate manufacturing procedures.

On March 17, 2006, we learned that the OGD changed its approach regarding the conditions that must be met in order for a generic drug applicant to request a waiver of in-vivo bioequivalence testing for vancomycin hydrochloride capsules. Specifically, we were informed that a generic applicant may be able to request such a waiver provided that dissolution testing demonstrates that the test product is rapidly dissolving at certain specified conditions. This deviated from our understanding of OGD's historical practices which would require, for a poorly-absorbed, locally acting gastrointestinal drug (such as Vancocin) a demonstration of bioequivalence through clinical studies or a demonstration of bioequivalence using an appropriately validated in-vitro methodology.

On March 17, 2006, we filed a Petition for Stay of Action with the FDA regarding the requirements for waivers of in-vivo bioequivalence testing for Vancocin, and we have amended that petition several times through additional filings in support of our opposition to any approach that does not require rigorous scientific methods to demonstrate a rate and extent of drug release to the site of action consistent with good medicine and science.

In December 2008, the FDA changed OGD's 2006 bioequivalence recommendation by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin, or Q1 and Q2 the same, to demonstrate bioequivalence through comparative dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. The comment period for this proposed change is scheduled to expire on March 19, 2009. We are opposing both the substance of the FDA's bioequivalence method and the manner in which it was developed**.**

In the event the OGD's revised approach regarding the conditions that must be met in order for a generic drug applicant to request a waiver of in-vivo bioequivalence testing for Vancocin remains in effect, the time period in which a generic competitor may enter the market would be reduced. There can be no assurance that the FDA will agree with the positions stated in our Vancocin related submissions or that our efforts to oppose the OGD's March 2006 and December 2008 recommendation to determine bioequivalence to Vancocin through in-vitro dissolution testing will be successful. We cannot predict the timeframe in which the FDA will make a decision regarding either our citizen petition for Vancocin or the approval of generic versions of Vancocin. If we are unable to change the recommendation set forth by the OGD in March 2006 as revised in December 2008, the threat of generic competition will be high.

Multiple generic manufacturers have publicly stated that they have filed to receive product approval and commence a marketing launch of a generic version of oral Vancocin. If a generic competitor or multiple generic competitors were to formulate a competing product that was approved by the FDA and that gained market acceptance, it would have a material adverse effect on our operating results, cash flows and possibly asset valuations, on our business and our guidance.

**A competitor has submitted a biologics license application with the FDA for a product candidate for the acute treatment of HAE. If we are not first to receive FDA approval of Cinryze for the acute treatment of HAE, the Orphan Drug Act may provide a competitor C1 Inhibitor product with up to seven years of market exclusivity in the acute indication.**

The Orphan Drug Act was created to encourage companies to develop therapies for rare diseases by providing incentives for drug development and commercialization. One of the incentives provided by the act is seven years of market exclusivity for the first product in a class licensed for the treatment of a rare disease. HAE is considered to be a rare disease under the Orphan Drug Act, and companies may obtain orphan drug status for therapies that are developed for this indication. The approval of Cinryze for the routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE would not prevent another company from gaining licensure related to the acute treatment of HAE. We believe CSL Behring and Pharming NV are currently developing products that the FDA may determine to be in the same class as our C1 INH product candidate for the acute treatment of HAE.

Based on discussions with the FDA, in October 2008 we withdrew the portion of the BLA referring to data for the acute treatment of HAE attacks. We resubmitted data as a supplemental BLA, along with additional data from ongoing open label acute studies of Cinryze, in December 2008. While we do not believe that an additional study will be required, it is possible that the FDA may require additional studies. In March 2008, CSL Behring submitted a biologics license application with the FDA for a product candidate for the acute treatment of HAE. We cannot assure that our supplemental BLA regarding acute treatment will be reviewed by the FDA prior to CSL Behring's application. In the event that another company is first to obtain FDA licensure for their product for acute treatment of HAE, we could be prevented from obtaining licensure and marketing our C1 INH product candidate for the acute treatment of HAE which could reduce our potential future revenues from sales of Cinryze.

**We do not know whether Vancocin will continue to be competitive in the markets which it serves, nor do we know if Cinryze will be, or will remain competitive in the markets which it is intended to serve.**

We currently generate revenues from sales of Vancocin in the U.S. for the treatment of antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* infection, or CDI or C. difficile, and enterocolitis caused by *S. aureus* , including methicillin-resistant strains. Vancocin sales for treatment of antibiotic-associated pseudomembranous colitis caused by C. difficile have increased over the past 12 months; however, Vancocin's share of the U.S. market for this indication may decrease due to competitive forces and market dynamics, including an increase in the oral use of intravenous vancomycin. Metronidazole, a generic product, is regularly prescribed to treat CDI at costs which are substantially lower than for Vancocin. In addition, products which are currently marketed for other indications by other companies may also be prescribed to treat this indication. Other drugs that are in development by our competitors, including Salix Pharmaceuticals, Optimer Pharmaceuticals and Genzyme Corporation, could be found to have competitive advantages over Vancocin. Approval of new products, or expanded use of currently available products, to treat CDI, and particularly severe disease caused by CDI, could materially and adversely affect our sales of Vancocin.

The FDA approved Cinryze for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema on October 10, 2008 and Cinryze became commercially available for prophylaxis against HAE in December 2009. While we are not aware of other companies which are developing a product for the prophylaxis of HAE, we believe CSL Behring, Dyax, Pharming NV and Jerini/Shire are currently developing products for the acute treatment of HAE. In addition, steroid based products are currently used for prophylaxis of HAE. Approval of new products, or expanded use of currently available products, to prophylax or treat HAE, could materially and adversely affect our sales of Cinryze.

**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.**

We currently have a limited marketing staff in the U.S. and Europe. During the third quarter of 2007, we made the decision to, for the first time, create a small sales organization targeting teaching institutions to promote Vancocin. Our sales organization commenced operations during the first quarter of 2008. As a result of our acquisition of Vancocin, we established a small group of regional medical scientists and commenced medical education programs. In connection with our acquisition of Cinryze, we established a modest national sales organization targeting allergists and we increased the number of marketing personnel.

The development of a marketing and sales capability for our marketed products, product candidates in clinical development, or for products that we may acquire if we are successful in our business development efforts, in the U.S. and Europe 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. If we are unable to successfully establish a sales and marketing capability in the U.S. and Europe in a timely manner, our business and results of operations will be harmed. Even if we are able to develop a sales force, it may not successfully penetrate the markets for any of our proposed products.

Under our agreement with GSK, we have the exclusive right to market and sell maribavir throughout the world, other than Japan. Schering-Plough is solely responsible for the marketing, promotion and sale of intranasal pleconaril in the event pleconaril receives marketing approval.

**The distribution of our commercial products is dependent upon a limited number of third party service providers and disruptions in these relationships could result in our failure to achieve the sales of our products that we expected.**

We rely on a single third party to provide all necessary distribution and logistics services with respect to our sales of Vancocin and Cinryze, including warehousing of finished product, accounts receivable management, billing, collection and recordkeeping. The third party logistics service provider stores and distributes our products from two warehouses located in the central U.S. and western U.S. A disaster occurring at or near either facility could materially and adversely impact our ability to supply Vancocin and Cinryze to our distribution partners, which would result in a reduction in revenues from sales.

Approximately 94% of our Vancocin sales are to the three largest pharmaceutical wholesalers. If any of these wholesalers ceases to purchase our product for any reason, then unless and until the remaining wholesalers increase their purchases of Vancocin or alternative distribution channels are established:

- our commercial operations could be significantly disrupted;
- the availability of Vancocin to patients could be disrupted; and
- we may not achieve the sales of Vancocin that we expected, which could decrease our revenues and potentially affect our ability to maintain profitability.

Additionally, we do not require collateral from our wholesalers but rather maintain credit limits and as a result we have an exposure to credit risk in our accounts receivable. The highest account receivable during 2008 we experienced from any one wholesaler was approximately $16.1 million and we anticipate that this amount could increase if Vancocin sales continue to increase. While we have experienced prompt payment by wholesalers and have not had any defaults on payments owed, a default by a large wholesaler could have a material adverse effect on our earnings and cash position.

We have entered into agreements with two specialty distributors / specialty pharmacies that distribute Cinryze to physicians, hospitals, pharmacies, home health providers and patients. We also entered into an agreement with a single service provider who will provide patient support services including benefit coverage investigations, assistance with prior authorizations, appeals assistance, and broad based reimbursement assistance.

If our third party service providers cease to be able to provide us with these services, or do not provide these services in a timely or professional manner, it could significantly disrupt our commercial operations, and may result in our not achieving the sales of Vancocin and Cinryze that we expected. Additionally, any interruption to these services could cause a delay in delivering product to our customers, which could have a material adverse effect on our business.

**We currently depend, and will in the future continue to depend, on third parties to manufacture raw, intermediate and finished goods for Vancocin, Cinryze and our product candidates. If these manufacturers fail to meet our requirements and the requirements of regulatory authorities, our future revenues may be materially adversely affected.**

We do not have the internal capability to manufacture quantities of pharmaceutical products to supply our clinical or commercial needs under the FDA's current Good Manufacturing Practice regulations, or cGMPs. In order to continue to develop products, apply for regulatory approvals and commercialize our products, we will need to contract with third parties that have, or otherwise develop, the necessary manufacturing capabilities.

There are a limited number of manufacturers that operate under cGMPs that are 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 for our development stage product candidates, there may be additional costs and delays in the development and commercialization of these 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 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 FDA inspection, the approval and eventual commercialization of our products and product candidates may be delayed.

All of our contract manufacturers must comply with the applicable cGMPs, 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 cGMPs and other FDA regulatory requirements, we may be subject to product liability claims, the availability of marketed products for sale could be reduced, our product commercialization could be delayed or subject to restrictions, we may be unable to meet demand for our products and may lose potential revenue 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.

We rely on a single source of vancomycin, the active pharmaceutical ingredient (API) of Vancocin and also rely on a single manufacturer of Vancocin capsules. Our third party API supplier and finished product supplier are the only manufacturers qualified by the FDA to manufacture API and Vancocin capsule finished product for distribution and sale in the U.S. We are therefore dependent upon these suppliers. We attempt to maintain Vancocin inventory levels to meet our current projections, plus a reasonable stock in excess of those projections.

We rely on a single manufacturer of Cinryze. Pursuant to our distribution agreement, Sanquin Blood Supply Foundation will supply us with certain annual minimum and maximum amounts of C1 INH. In the event demand for C-1NH is greater than the amount supplied by Sanquin, we would have to find alternative suppliers of C1 INH. Pursuant to an agreement with Sanquin we are required to finance a portion of the costs of the project to increase the manufacturing capacity of its facilities. Assuming the completion of construction, Sanquin would need to obtain the requisite regulatory approvals for the facility on a timely basis in order to manufacture Cinryze for us. If they cannot obtain necessary approvals for these contemplated expansions, or complete the planned construction in a timely manner, we may need to locate an alternative supplier. Currently, to our knowledge there is only one other commercial supplier of C1 esterase inhibitor and that supplier is also developing a product competitive with our lead product candidate. Accordingly, we cannot be certain that we would be able to locate another willing supplier for our product on the terms we require. While our current production schedule is sufficient to supply currently anticipated demand in the near term, unexpected increases in demand or supply interruptions could significantly impact our ability to meet demand while retaining an adequate level of reserve inventory.

Numerous factors could cause interruptions in the supply of our products, including manufacturing capacity limitations, 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. In addition, 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. Any interruption in the supply of finished products could hinder our ability to timely distribute our products and satisfy customer demand. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose those orders, our customers may cancel other orders, and they may choose instead to stock and purchase 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.

**If supplies of U.S. human plasma are interrupted or if we are unable to acquire adequate supplies of U.S. human plasma to meet demand for Cinryze, our ability to maintain inventory levels could suffer and future revenues may be delayed or reduced.**

We have relied exclusively and are dependent on certain third party source suppliers to supply U.S. human plasma for Cinryze. In connection with our commercial launch of Cinryze and our ongoing open label trials and future phase 4 clinical trial, we will need increased supplies of plasma. The plasma market has been constrained in recent years.

On July 19, 2007, we entered into an agreement for the purchase and sale of plasma with DCI Management Group, LLC, pursuant to which we purchase quantities of U.S. source plasma. Under this agreement, DCI agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices.

If we are unable to obtain or maintain this level of plasma supply, we will need to obtain our supply from other parties in order to satisfy our expected needs. Establishing additional or replacement suppliers for plasma may take a substantial amount of time. In addition, we may have difficulty obtaining similar supplies from other suppliers that are acceptable to the FDA. If we have to switch to a replacement supplier, we may face additional regulatory delays and the manufacture and delivery of Cinryze could be interrupted for an extended period of time, which may decrease sales of Cinryze or result in increased costs.

**Cinryze is derived from human plasma, and is therefore subject to the risk of biological contamination inherent in plasma-derived products. This risk could adversely affect our ability to obtain raw materials and market our products.**

Cinryze is derived from donated human plasma. Many disease-causing viruses, bacteria and other pathogens are present in the plasma of infected individuals. If infected individuals donate plasma, the plasma would likely contain those pathogens. As a result, the sourcing of plasma, and the production of products derived from plasma, is regulated extensively by the FDA and other medical product and health care regulatory agencies. We rely on our suppliers to maintain compliance with the regulations promulgated by such agencies. The failure to comply with these regulations or the accidental contamination of plasma could adversely affect our ability to source plasma at commercially reasonable prices. Moreover, public perception about the safety of plasma-derived products could adversely affect the market for our products. Concern over the safety of plasma-derived products, driven in part by past screening failures in the industry and the appearance of infectious agents like HIV, has resulted in the adoption of rigorous screening procedures by regulatory authorities, and screening procedures are likely to become stricter and more complex over time. As screening procedures have become more rigorous, potential donors have been disqualified and other potential donors have been discouraged from donating due to their reluctance to undergo the required screening procedures. Increasingly stringent measures could adversely affect plasma supplies, with a corresponding adverse effect on our ability to obtain raw materials at a commercially acceptable price, or at all. The safety concerns associated with plasma-derived products also affect our ability to market our products. Medical events or studies that raise or substantiate concerns about the safety of our or other similar products would negatively impact public perception of all plasma-derived products and of the plasma donation process. Further, any failure in screening, whether by us or by other manufacturers of these products, could adversely affect our reputation, the support we receive from the medical community and overall demand for our products.

**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 and Cinryze. 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, liquidity 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.

**In order to continue to expand our business and sustain our revenue growth, we will need to acquire additional marketed products or product candidates in clinical development through in-licensing or the acquisitions of businesses that we believe are a strategic fit with us. We may not be able to in-license or acquire suitable products at an acceptable price or at all. In addition, engaging in any in-licensing or acquisitions will incur a variety of costs, and we may never realize the anticipated benefits of any such in-license or acquisition.**

As part of our long-term strategy and in order to sustain our revenue growth, we intend to seek to acquire or in-license additional marketed products or product candidates in clinical development to treat the patient population targeted by Vancocin, Cinryze and our current product candidates, or products / product candidates in clinical development to treat serious medical conditions which require modest sales and marketing infrastructure, or to complement the markets that we hope our CMV and NTCD programs will serve or in which Vancocin and Cinryze are prescribed. Even if we are able to locate products, product candidates in clinical development or businesses that fit within our strategic focus, we cannot assure you that we will be able to negotiate agreements to acquire or in-license such additional products or product candidates in clinical development on acceptable terms or at all. Further, if we acquire a product, product candidates in clinical development or business, the process of integrating the acquired product, product candidates in clinical development or business may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits for a variety of reasons, such as an acquired product candidate proving to not be safe or effective in later clinical trials. We may fund any future acquisition by issuing equity or debt securities, which could dilute the ownership percentages of our existing stockholders. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. We cannot assure you that an acquired product, product candidates in clinical development or business will have the intended effect of helping us to sustain our revenue growth. If we are unable to do so, our business could be materially adversely affected.

**There are many potential competitors with respect to our product candidates under development, who may develop products and technologies that make our products and/or technologies 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 our products under development.

There are products already marketed by F. Hoffman La-Roche, AstraZeneca and Gilead Sciences Inc. for the prevention and treatment of CMV. Developments by these or other entities may render our product candidates non-competitive or obsolete. Furthermore, many of our competitors have greater resources available to them to assist with 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 for product candidates. Competitors may succeed in developing products that are more effective and less costly than any that we develops 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.

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

Even if our product candidates are approved by the FDA and other regulatory authorities, they may not achieve market acceptance by patients, prescribers and 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 from payors such as government health programs 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.

If our product candidates do not achieve market acceptance by a sufficient number of patients, prescribers and third-party payors, our business will be materially adversely affected.

**The current credit and financial market conditions may exacerbate certain risks affecting our business.**

Sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers and third party distributors. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

Due to the recent tightening of global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including our product manufacturing, supply chain management, conduct of clinical trials, and raw materials. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected. Finally, if the banking system or the financial markets continue to deteriorate or remain volatile, our investment portfolio may be impacted and the values and liquidity of our investments could be adversely affected.

**Funding, especially on terms acceptable to us, may not be available to meet our future capital needs because of the deterioration of the credit and capital markets.**

Global market and economic conditions have been, and continue to be, disruptive and volatile. The debt and equity capital markets have been impacted by significant write-offs in the financial services sector and the re-pricing of credit risk in the broadly syndicated market, among other things. These events have negatively affected general economic conditions.

In particular, the cost of raising money in the debt and equity capital markets has increased substantially while the availability of funds from those markets has diminished significantly. Also, as a result of concern about the stability of financial markets generally and the solvency of counterparties specifically, the cost of obtaining money from the credit markets has increased as many lenders and institutional investors have increased interest rates, enacted tighter lending standards and reduced and, in some cases, ceased to provide funding to borrowers.

If funding is not available when needed, or is available only on unfavorable terms, meeting our capital needs or otherwise taking advantage of business opportunities may become challenging, which could have a material adverse effect on our business plans, revenues and results of operations.

**Our strategic plan may not achieve the intended results.**

In January 2004, we made the strategic decision to focus on the development of later stage opportunities by expanding 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. As a result of this strategic decision, we substantially discontinued our early stage activities, including discovery research and most internal preclinical development activities. Our restructuring efforts have placed, and may continue to place, a significant strain on our managerial, operational, financial and other resources.

We may not be successful in executing our strategy. We may not be able to in-license or acquire suitable products at an acceptable price, or at all. In addition, engaging in any in-licensing or acquisition will incur a variety of costs, and we may never realize the anticipated benefits of any such in-license or acquisition. We may need additional financing in order to acquire additional new products or product candidates. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed.

We cannot assure you that an acquired product, product candidates in clinical development or business will have the intended effect of helping us sustain our revenue growth. If we are unable to do so, our business could be materially adversely affected.

**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 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. Sanofi-Aventis also has exclusive rights to market and sell pleconaril in countries other than the U.S. and Canada for which we will receive a royalty. Schering-Plough will receive a portion of any royalty payments made to us under our license agreement with Sanofi-Aventis for rights to pleconaril. If Schering-Plough or Sanofi-Aventis does not successfully market and sell products in their respective territories, we will not receive revenue from royalties on their sales of products.

Sales of Cinryze are dependent on distribution rights that we have received from Sanquin pursuant to a distribution agreement relating to the treatment of HAE. Upon commercial launch of our product candidate for the treatment of HAE and thereafter during the term of the agreement, Sanquin will supply us with our commercial requirements for C1 INH for the treatment of HAE in each country where we have received regulatory approval, subject to minimum annual purchase requirements in Euros equal to approximately $20.9 million per year, net of the agreed upon discount. If we fail to fulfill certain obligations under the distribution agreement, the distribution agreement may be terminated. In addition, Sanquin has the right to terminate the agreement if it is unable to maintain liability insurance for its U.S. obligations, under certain circumstances as described in the distribution agreement. In addition, either party may terminate the agreement upon an uncured breach.

We also entered into a license agreement with Sanquin pursuant to which they granted us an exclusive license to use certain patent, patent applications and know-how related to the use of C1 INH technology for the treatment of AMI. Under the terms of the license agreement for AMI, we are obligated to make minimum and earned royalty and other payments to Sanquin. If we fail to fulfill those obligations or other material obligations, the license agreement may be terminated by Sanquin. If Sanquin terminates the license agreement, we will have no further rights to utilize the intellectual property covered by the license agreement, we would not be able to commercialize the applicable product candidate for the treatment of AMI and we may be forced to cease our operations relating to the treatment to AMI using C1 INH. However, in light of the parties' focus on obtaining marketing approval for Cinryze™, we have agreed with Sanquin to temporarily suspend efforts to develop a commercialization plan for AMI. The parties, however, did not terminate the license agreement. The parties may agree in the future to continue their efforts at commercializing a plan for applying C1 INH for the treatment of AMI.

In August 2003, we entered into a license agreement with GSK under which we acquired exclusive worldwide rights, excluding Japan, from GSK to develop and commercialize 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 retained the exclusive right to market and sell products covered by these patents and patent applications in Japan.

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.

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 it needs to develop and commercialize its 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 interest. 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. 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 us to suspend the licenses granted to us by Lilly in the event of uncured defaults by us until such time as the default is cured or otherwise resolved.

Our license agreement with GSK imposes various obligations on us, including milestone payment requirements and royalties. If we fail to comply with these obligations, GSK has or 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 the termination of the development, manufacture and commercialization of our product candidates or to litigation.

**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 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. 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.

**If we are unable to obtain reimbursement for Cinryze from government health administration authorities, private health insurers and other organizations, Cinryze may be too costly for regular use and our ability to generate revenues would be harmed.**

Our future revenues and profitability will be adversely affected if governmental, private third-party payors and other third-party payors, including Medicare and Medicaid, do not sufficiently defray the cost of Cinryze to the consumer. If these entities do not provide coverage and reimbursement for Cinryze or determine to provide an insufficient level of coverage and reimbursement, Cinryze may be too costly for general use, and physicians may not prescribe it. Cinryze is significantly more expensive than traditional drug treatments. Many third-party payors cover only selected drugs, making drugs that are not preferred by such payor more expensive for patients, and often require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payors may be especially likely to impose these obstacles to coverage for higher-priced drugs such as Cinryze.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability and worsen our financial condition. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

Because Cinryze is too expensive for most patients to afford without sufficient health insurance coverage, if adequate coverage and reimbursement by third-party payors is not available, our ability to successfully commercialize Cinryze may be adversely impacted. Any limitation on the use of Cinryze or any decrease in the price of Cinryze will have a material adverse effect on our business.

Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford. We intend to financially support the HAE financial assistance programs established by Patient Services Incorporated (PSI), which, among other things, assists patients in acquiring drugs such as Cinryze. Organizations such as PSI assist patients who have no insurance coverage for drugs locate insurance and also provide financial assistance to patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. In addition to assistance from organizations such as PSI, we anticipate that we will provide Cinryze without charge for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our ability to maintain profitability.

In furtherance of our efforts to facilitate access to Cinryze, we have contracted with a third party to provide the Cinryze*Solutions*™ program, a treatment support service for patients with HAE and their healthcare providers. Cinryze*Solutions* personnel will provide education about HAE and Cinryze and help facilitate solutions for reimbursement, coverage and access. Although case managers will assist patients and healthcare providers in locating and accessing Cinryze, we cannot guarantee a sufficient level of coverage, reimbursement or financial assistance.

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

Historically, only a portion of the cost of Vancocin prescriptions has been 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 and, to a lesser degree, prescribing physicians. For example, metronidazole, a drug frequently prescribed for CDI, is significantly less expensive than Vancocin. If adequate reimbursement levels are not provided for Vancocin, or if reimbursement policies increasingly favor other products, our market share and net sales could be negatively affected, as could our overall business and financial condition.

**Our successful commercialization of our product candidates will depend, in part, on the availability and adequacy 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 U.S., 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 U.S., there have been, and we expects 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 U.S. 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.

In recent years, various legislative proposals have been offered in the U.S. 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.

**We rely on our employees, consultants, contractors, suppliers, manufacturers and collaborators 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, in order to protect our significant investment in these products from the risk of discovery by generic drug manufacturers and other potential competition. We require each of our employees, consultants, advisors, contractors, suppliers, manufacturers and collaborators 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 U.S. 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 three issued U.S. patents, one non-U.S. patents and have a number of pending U.S. patent applications, some of which we co-own with collaborators. We also have filed international, regional and non-U.S. 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 U.S. 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.

**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 U.S. 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.

**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, Vincent J. Milano, our Vice President, Chief Operating Officer, Daniel B. Soland, our Vice President, Chief Financial Officer, Charles Rowland, our Vice President, Chief Scientific Officer, Colin Broom, our Vice President, Global Regulatory Affairs and Quality, Robert Pietrusko and our Vice President, Strategic Initiatives, Thomas Doyle. Our ability to grow and expand into new areas and activities will require additional expertise and the addition of new qualified personnel in both the United States and Europe. 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 or employment 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.

**Even after regulatory approval is received, as with Vancocin and Cinryze, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions or withdrawal from the market.**

Vancocin and Cinryze are, and any other product for which we obtain marketing approval from the FDA or other regulatory authority 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 and Cinryze, we currently have, significant ongoing regulatory compliance obligations related to manufacturing processes, quality control, labeling, post-approval clinical data collection and promotional activities for each such product. 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;
- class restrictions or "black-box" warnings

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

As part of the approval for Cinryze, we are required to conduct a clinical study designed to evaluate safety, including thrombotic adverse events, efficacy and immunogenicity of higher than labeled doses of Cinryze for routine prophylaxis. Collection and periodic reporting of CMC data also have been requested as a post-approval commitment. In the event we are unable to comply with these requirements and commitments, we may be subject to penalties or other actions.

Over the past few years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities, including the DOJ and various U.S. Attorney's Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the FTC and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with off-label promotion of products, pricing and Medicare and/or Medicaid reimbursement. It is both costly and time-consuming for us to comply with these extensive regulations to which it is subject. Additionally, incidents of adverse drug reactions, unintended side effects or misuse relating to our products could result in additional regulatory controls or restrictions, or even lead to withdrawal of a product from the market.

Companies may not promote drugs for "off-label" uses — that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the Federal Food, Drug and Cosmetics Act and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG) and FDA both actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG and the FDA allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Although we believe that all of our communications regarding all of our products are in compliance with the relevant legal requirements, the OIG or the FDA may disagree, and we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the OIG may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Should the government choose to initiate action against us, we could face substantial penalties, which could have a material adverse effect on our business, financial condition and results of operations. In addition, management's attention could be diverted and our reputation could be damaged.

In addition, anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, or pay any remuneration in exchange for purchasing, leasing or ordering any service or items including the purchase or prescription of a particular drug for which payment may be made under a federal health care program. Because of the sweeping language of the federal anti-kickback statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the U.S. Department of Health and Human Services has published regulations – known as "safe harbors" – that identify exceptions or exemptions to the statute's prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. We seek to comply with anti-kickback statutes and to fit within one of the defined "safe harbors". However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that our practices will not be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from U.S. federal healthcare programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition and results of operations.

In recent years, several states and localities, including California, the District of Columbia, Maine, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered by the federal government and other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. If we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Any of these events could result in a material adverse effect on our revenues and financial condition.

**Our future product revenues from sales of Vancocin and Cinryze could be reduced by imports from countries where similar products are available at lower prices.**

Vancocin has been approved for sale outside of the U.S., including but not limited to Canada, Brazil and Europe, and Lilly or its licensees continue to market Vancocin outside of the U.S. There are products similar to Cinryze which are approved in the E.U. There have been cases in which pharmaceutical products were sold at steeply discounted prices in markets outside the U.S. and then 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 U.S. If this happens with Vancocin or Cinryze 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 the U.S. Congress and in some state legislatures that would authorize re-importation of pharmaceutical products into the U.S. from other countries including Canada. We cannot predict the outcome of such initiatives, which if adopted, could result in increased competition for our products and lower prices.

**Risks associated with our international business relationships could materially adversely affect our business.**

We are engaged in clinical trials and have employees located in Europe, are establishing manufacturing relationships, and are seeking approval for our drug candidate maribavir in Europe. We may also establish our own commercial sales and marketing personnel in Europe. In the future, we may enter into distribution arrangements with third parties to market our products and product candidates in countries outside of the United States and Europe. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals in foreign countries;
- changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating a subsidiary in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

**If we are not successful in integrating Lev into our business, then the benefits of the acquisition will not be fully realized and the market price of our common stock may be negatively affected.**

We may not achieve successful integration of the Lev assets in a timely manner, or at all, and we may not realize the benefits acquisition to the extent, or in the timeframe, anticipated. The successful integration of Lev will require, among other things, integration of Lev's assets into our operations. It is possible that the integration process could result in the loss of key employees, diversion of our management's attention, the disruption or interruption of, or the loss of momentum in our ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition, or could reduce our earnings or otherwise adversely affect our business and financial results as a result, adversely affect the market price of we common stock.

**Charges to earnings resulting from the application of accounting methods may adversely affect the market value of our common stock as a result of the acquisition of Lev.**

In accordance with Statement of Financial Accounting Standard No. 141, Business Combinations, the total initial purchase price is allocated to Lev's net tangible assets or identifiable intangible assets based on their fair values as of the date of completion of the merger. We will incur additional amortization expense based on the identifiable amortizable intangible assets acquired pursuant to the merger agreement and their relative useful lives. These amortization charges will have a material impact on our results of operations, and therefore could have an adverse impact on the market value of our common stock.

**If Lev stockholders sell the ViroPharma common stock received as consideration in connection with the merger, such sales could cause a decline in the market price of our common stock.**

We issued approximately 7,359,667 shares of our common stock, or approximately 10.5% of the number of outstanding shares of our common stock currently in the public market, to Lev stockholders in connection with the merger. The issuance of the common stock may result in fluctuations in the price of our common stock, including a stock price decline. The common stock issued by us in connection with the merger was registered with the SEC. As a result, such registered shares are immediately available for resale in the public market. If this occurs, or if other holders of our common stock sell significant amounts of our common stock immediately after the merger is completed, the market price of our common stock may decline.

**Our indebtedness and other financial obligations may harm our financial condition and results of operations.**

Our total consolidated long-term debt as of December 31, 2008 is $250.0 million. Our level of indebtedness could have important consequences to you, because:

- a portion of our cash flows from operations will have to be dedicated to interest and may not be available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;
- it may impair our ability to obtain additional financing in the future;
- it may limit our flexibility in planning for, or reacting to, changes in our business and industry; and
- it may make us more vulnerable to downturns in our business, our industry or the economy in general.

Our operations may not generate sufficient cash to enable us to service our debt. If we fail to make a payment on the senior convertible notes, we could be in default on the senior convertible notes, and this default could cause us to be in default on our other outstanding indebtedness. Conversely, a default on our other outstanding indebtedness may cause a default under the senior convertible notes.

We have two future liabilities in the form of contingent value payments to the former stockholders of Lev upon the achievement of regulatory and commercial targets. The first CVR payment of $0.50 per share (or $87.5 million) would become payable when either (i) Cinryze is approved by the FDA for acute treatment of HAE and the FDA grants orphan exclusivity for Cinryze encompassing the acute treatment of HAE to the exclusion of all other human C1 inhibitor products or, (ii) orphan exclusivity for the acute treatment of HAE has not become effective for any third party's human C1 inhibitor product by October 21, 2010. The second CVR payment of $0.50 per share ($87.5 million) would become payable when Cinryze reaches at least $600 million in cumulative net product sales within 10 years of closing of the acquisition. We cannot predict if or when these payments may be payable or if they could materially adversely affect our business at the time of payment.

**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 twelve months ended December 31, 2008, the market price for our common stock fluctuated between $15.09 and $8.18 per share and has fluctuated between $14.15 and $4.15 through February 27, 2009, following the announcement of the results of our clinical trial results relating to maribavir. 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;
- approvals of generic products that compete with Vancocin;
- our ability to successfully commercialize Cinryze;
- results of clinical trials with respect to our product candidates in development or those of our competitors, such as the February 2009 clinical trial results relating to maribavir;
- developments with our collaborators;
- 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 our or its competitors (including related litigation);
- any other future announcements concerning we or its competitors;
- any announcement regarding our acquisition of product candidates or entities;
- future announcements concerning our industry;
- governmental regulation;
- changes in federal, state and foreign tax laws and related regulations;
- 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, including changes in accounting estimates;
- our cash and cash equivalents balances;
- changes in our capital structure;
- changes in estimates of our performance by securities analysts;
- market conditions applicable to our business sector; and
- general market conditions.

**As of February 25, 2009 our market capitalization is less than our book value. As a result, we may be required to take a significant non-cash goodwill impairment charge and may be required to write off goodwill or other intangible assets in the future. If we are required to write off goodwill or other intangible assets, our financial position and results of operations could be adversely affected.**

Goodwill represents cost in excess of the fair value of net tangible and identifiable net intangible assets acquired in business combinations. Based on the guidance of the Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), we will perform a test for impairment of goodwill and indefinite-lived assets if impairment indicators or other triggering events arise during the year. As such, in accordance with SFAS 142, as of March 31, 2009, we may have to perform a goodwill impairment test based on a triggering event resulting from the significant decrease in the price of our outstanding common stock during the first quarter 2009. As our market capitalization currently is less than the book value of our assets, depending upon the trading price of our common stock on March 31, 2009, such goodwill impairment test may cause us to take a non-cash goodwill impairment charge and we may be required to write off goodwill or other intangible assets in the future. The carrying value of our goodwill may not be recoverable due to factors such as a decline in stock price and market capitalization, reduced estimates of future cash flows and slower growth rates in our industry. Estimates of future cash flows are based on an updated long-term financial outlook of our operations. However, actual performance in the near-term or long-term could be materially different from these forecasts, which could impact future estimates.

**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 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 its 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 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. 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.

**The convertible note hedge and warrant transactions may affect the value of the senior convertible notes and our common stock.**

In connection with the issuance of the senior convertible senior notes, we have entered into privately-negotiated transactions with two counterparties, or the counterparties, comprised of purchased call options and warrants sold. These transactions are expected to generally reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes.

In connection with establishing their initial hedge of these transactions, the counterparties may have entered into various derivative transactions with respect to our common stock concurrently with, or shortly after, the pricing of the senior convertible notes. These activities could have the effect of increasing or preventing a decline in the price of our common stock concurrently with or following the pricing of the senior convertible notes. In addition, the counterparties (and/or their affiliates) may modify their hedge positions following the pricing of the senior convertible notes from time to time by entering into or unwinding various derivative transactions with respect to our common stock or by purchasing or selling our common stock in secondary market transactions, which could adversely affect the value of our common stock or could have the effect of increasing or preventing a decline in the value of our common stock. Additionally, these transactions expose us to counterparty credit risk for nonperformance. We manage our exposure to counterparty credit risk through specific minimum credit standards, and diversification of counterparties.

The potential effect, if any, of any of these transactions and activities on the market price of our common stock will depend in part on market conditions and cannot be ascertained at this time. Any of these activities could adversely affect the value of our common stock.

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the senior convertible notes or the shares of our common stock. In addition, we do not make any representation that the counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

**The fundamental change purchase feature of the senior convertible notes may delay or prevent an otherwise beneficial attempt to take over our company.**

The terms of the senior convertible notes require us to purchase the senior convertible notes for cash in the event of a fundamental change. A takeover of our company would trigger the requirement that we purchase the senior convertible notes. Alternatively, if certain transactions that constitute a fundamental change occur, under certain circumstances, we will increase the conversion rate by a number of additional shares of our common stock to compensate holders for the lost option time value of the senior convertible notes as a result of such transaction. This increased conversion rate will apply only to holders who convert their senior convertible notes in connection with any such transaction. The number of the additional shares of our common stock will be determined based on the date on which the transaction becomes effective and the price paid per share of our common stock. This may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

In March 2008, we entered into a lease, comprising 78,264 square feet of office and related space, for the Company’s new headquarters located in Exton, Pennsylvania. The lease expires seven years and six months from the point in which we begin to occupy the space, which occurred in October 2008. In connection with the new lease, we also received a leasehold improvement allowance of $2.3 million.

In May 2008, we entered into a lease in Maidenhead, United Kingdom, comprising 8,000 square feet of office space, for our European operations. The lease expires in May 2018.

On January 30, 2007, we purchased a 33,000 square feet facility located in Exton, PA. This space was originally purchased for our corporate and development activities for $7.65 million, which was funded from available cash. We vacated this space in October 2008 when we moved into our new headquarters. This facility is currently for sale or lease.

## ITEM 3. LEGAL PROCEEDINGS

From time to time we are a party to litigation in the ordinary course of our business. We do not believe these matters, even if adversely adjudicated or settled, would have a material adverse effect on our financial condition, results of operations or cash flows.

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

None.

## PART II

## ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Market Information

Our common stock is traded on the Global 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 2007 and 2008 and through February 22, 2008.

| | High | Low |
|---|---|---|
| Year ended December 31, 2007 | | |
| First Quarter | $ 18.39 | $ 13.75 |
| Second Quarter | $ 16.62 | $ 13.09 |
| Third Quarter | $ 15.00 | $ 7.51 |
| Fourth Quarter | $ 9.99 | $ 7.11 |
| Year ended December 31, 2008 | | |
| First Quarter | $ 9.96 | $ 8.18 |
| Second Quarter | $ 11.28 | $ 8.73 |
| Third Quarter | $ 15.09 | $ 9.41 |
| Fourth Quarter | $ 13.46 | $ 9.49 |
| First Quarter 2009 (through February 27, 2009) | $ 14.15 | $ 4.15 |

### Holders and Dividends

There were approximately 686 record holders of our common stock as of February 20, 2009. 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 February 25, 2009, 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. We anticipate for the foreseeable future, we will retain our earnings in order to finance investments in our business.

## ITEM 6. SELECTED FINANCIAL DATA

The selected financial data presented below under the caption "Consolidated Statement of Operations Data" for the years ended December 31, 2008, 2007, 2006, 2005 and 2004 and under the caption "Consolidated Balance Sheet Data" as of December 31, 2008, 2007, 2006, 2005 and 2004 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.

In November 2004, we acquired all rights in the U.S. and its territories to manufacture market and sell Vancocin, as well as rights to certain related vancomycin products, from Eli Lilly and Company (Lilly). See Note 10 of the Consolidated Financial Statements. In October 2008, we acquired Lev Pharmaceuticals, Inc. See Note 3 of the Consolidated Financial Statements.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| (in thousands, except per share amounts) | 2008 | 2007 | 2006 | 2005 | 2004 |
| **Consolidated Statement of Operations Data:** | | | | | |
| Net product sales | $ 232,307 | $ 203,770 | $ 166,617 | $ 125,853 | $ 8,348 |
| Total revenues | 232,307 | 203,770 | 167,181 | 132,417 | 22,389 |
| Operating expenses: | | | | | |
| Cost of sales (excluding amortization of product rights) | 8,874 | 8,934 | 18,984 | 18,029 | 1,717 |
| Research and development | 66,280 | 35,869 | 19,162 | 10,610 | 16,388 |
| Selling, general and administrative | 65,424 | 37,051 | 24,560 | 10,475 | 15,643 |
| Intangible amortization and acquisition of technology rights | 10,809 | 6,120 | 5,669 | 5,158 | 650 |
| Impairment loss on assets held for sale | 2,265 | — | — | — | — |
| Total operating expenses | 153,652 | 87,974 | 68,375 | 44,272 | 34,398 |
| Operating income (loss) | 78,655 | 115,796 | 98,806 | 88,145 | (12,009) |
| Interest income | 14,296 | 24,265 | 9,853 | 2,008 | 1,080 |
| Interest expense | (5,852) | (4,395) | (686) | (11,304) | (10,320) |
| Other income (expense) | — | — | 555 | (2,949) | 1,715 |
| Income tax expense (benefit) | 19,482 | 40,313 | 41,862 | (37,805) | — |
| Net income (loss) from continuing operations | $ 67,617 | $ 95,353 | $ 66,666 | $ 113,705 | $ (19,534) |
| Net income (loss) per share from continuing operations: | | | | | |
| Basic | $ 0.95 | $ 1.37 | $ 0.97 | $ 2.56 | $ (0.73) |
| Diluted | $ 0.83 | $ 1.21 | $ 0.95 | $ 2.02 | $ (0.73) |
| Shares used in computing net income (loss) from continuing operations per share: | | | | | |
| Basic | 71,391 | 69,827 | 68,990 | 44,334 | 26,578 |
| Diluted | 85,712 | 80,891 | 70,338 | 57,610 | 26,578 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | 2007 | 2006 | 2005 | 2004 |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and short-term investments (1) | $ 275,839 | $ 584,328 | $ 255,409 | $ 233,413 | $ 44,210 |
| Working capital | 317,413 | 594,403 | 266,443 | 166,666 | 42,918 |
| Total assets | 1,053,684 | 776,066 | 429,694 | 435,525 | 178,360 |
| Long-term debt (2) | 250,000 | 250,000 | — | — | 190,400 |
| Total stockholders' equity (deficit) | 661,024 | 496,563 | 411,899 | 326,977 | (26,138) |

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

(2) Of the $190.4 million of long-term debt that were outstanding at December 31, 2004, $78.9 million was outstanding as of December 31, 2005. The subordinated convertible notes are reported as a current obligation, a component of working capital, since, as of December 31, 2005, it was the Company's intent to redeem these notes the first quarter of 2006.

We have never paid dividends on our common stock.

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

### Background

ViroPharma is an international biopharmaceutical company dedicated to the development and commercialization of products that address serious diseases, with a focus on products used by physician specialists or in hospital settings. We intend to grow through sales of our marketed products, Vancocin® and Cinryze™, through continued development of our product pipeline and through potential acquisition or licensing of products or acquisition of companies. We have two marketed products, and three development programs.

We market and sell Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is a potent antibiotic approved by the U.S. Food and Drug Administration, or the FDA, to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* infection (CDI), or *C. difficile*, and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On October 21, 2008, we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev), a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. As a result of the merger, we obtained Cinryze, a C1 inhibitor, which has been approved by the FDA for routine prophylaxis of hereditary angioedema (HAE) also known as C1 inhibitor deficiency, a rare, severely debilitating, potentially life-threatening genetic disorder. In December 2008, we submitted a supplemental Biologics Application (sBLA) for Cinryze as a treatment for acute attacks of HAE based on a re-analysis and resubmission of data from a pivotal Phase 3 acute treatment study of Cinryze and interim data from an ongoing open label acute study of the drug. In February 2009, the sBLA was granted priority review with a Prescription Drug User Fee Act (PDUFA) date of June 3, 2009.

ViroPharma is developing two new product candidates, maribavir for the prevention and treatment of cytomegalovirus, or CMV disease; and non-toxigenic strains of C. *difficile* (NTCD) for the treatment and prevention of CDI. On February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant (SCT) patients did not achieve its primary endpoint. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. Additionally, on February 13, 2009, we announced that enrollment in our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to current standard of care.

We have licensed the U.S. and Canadian rights for a third product development candidate, an intranasal formulation of pleconaril, to Schering-Plough for the treatment of picornavirus infections.

We intend to continue to evaluate in-licensing or other opportunities to acquire products in development, or those that are currently on the market. We plan to seek products that treat serious medical conditions which require modest sales and marketing infrastructure, or to complement the markets that we hope our CMV and NTCD programs will serve or in which Vancocin and Cinryze are prescribed.

### Executive Summary

Since January 1, 2008, we experienced the following:

*Development Activities*

CMV:

- Announced on February 9, 2009 that maribavir did not achieve its primary endpoint and also failed to meet its key secondary endpoint in Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell or bone marrow transplant patients; and
- Discontinued dosing in Phase 3 trial of maribavir in solid organ (liver) transplant patients;

HAE:

- Initiated commercial launch of Cinryze for routine prophylaxis of hereditary angioedema;
- Filed supplemental biologics license application (sBLA) for Cinryze for treatment of acute attacks of HAE;
- Developed and successfully launched Cinryze patient access program, CinryzeSolutions™;
- Launched new sales team for Cinryze.

*C. difficile* infection (CDI):

- Continued work to optimize manufacturing and scale up of non-toxigenic *C. difficile* spores.

*Business Development*

- Acquisition of Lev Pharmaceuticals, Inc. completed for upfront consideration of $453.1 million, or $2.75 per Lev share, comprised of $2.25 per share in cash and $0.50 per share in ViroPharma common stock;
- Contingent consideration of up to $1.00 per share or $174.6 million may be paid on achievement of certain regulatory and commercial milestones;
- FDA approved Cinryze for prophylaxis of hereditary angioedema in adolescents and adults and granted seven years exclusivity in indication; and

HCV (with our partner Wyeth):

- Announced in April that we have discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C;

*Financial Results*

- Decreased working capital by $277.0 million to $317.4 million, primarily driven by the acquisition of Lev;
- Net sales increased 14.0% as compared to 2007 and were impacted by fluctuations in:
  - prescriptions, which increased 6.7% in 2008 as compared to 2007; and
  - pricing, which was higher during 2008 as compared to 2007; and
- Increased development costs by $30.4 million in 2008 over 2007 to $66.3 million.

*Liquidity*

- Generated net cash from operating activities of $91.4 million; and
- Decreased cash and cash equivalents and short-term investments by $308.5 million to $275.8 million.

During 2009 and going forward, we expect to face a number of challenges, which include the following:

The commercial sale of approved pharmaceutical products is 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, for reasons that include, but are not limited to, generic and non-generic competition for Vancocin and/or changes in prescribing habits or disease incidence. Additionally, period over period fluctuations in net product sales are expected to occur as a result of wholesaler buying decisions.

We cannot assure you that generic competitors will not take advantage of the absence of patent protection for Vancocin to attempt to market a competing product. We are not able to predict the time period in which a generic drug may enter the market. On March 17, 2006, we learned that the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research ("OGD") permitted a generic drug applicant to request a waiver of in-vivo bioequivalence testing for copies of Vancocin if the generic applicant could show that its product was rapidly dissolving. In December 2008, FDA changed OGD's 2006 bioequivalence recommendation by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin ("Q1 and Q2 the same") to demonstrate bioequivalence through comparative dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin. The comment period for this proposed change is scheduled to expire on March 19, 2009. We are opposing both the substance of the FDA's bioequivalence method and the manner in which it was developed. However, if FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor may enter the market would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly asset valuations. There can be no assurance that the FDA will agree with the positions stated in our Vancocin related submissions or that our efforts to oppose the OGD's March 2006 and December 2008 recommendations to determine bioequivalence to Vancocin through in vitro dissolution testing will be successful. We cannot predict the timeframe in which the FDA will make a decision regarding either our citizen petition for Vancocin or the approval of generic versions of Vancocin. If we are unable to change the recommendation set forth by the OGD in March 2006 or December 2008, the threat of generic competition will be high.

The FDA approved Cinryze for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema on October 10, 2008. Cinryze became commercially available for routine prophylaxis against HAE in December 2008 and the commercial success of Cinryze will depend on several factors, including: the number of patients with HAE that may be treated with Cinryze; acceptance by physicians and patients of Cinryze as a safe and effective treatment; our ability to effectively market and distribute Cinryze in the United States; cost effectiveness of HAE treatment using Cinryze; relative convenience and ease of administration of Cinryze; potential advantages of Cinryze over alternative treatments; the timing of the approval of competitive

products including another C1 esterase inhibitor for the acute treatment of HAE; patients' ability to obtain sufficient coverage or reimbursement by third-party payors; sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze; and manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product. We are also seeking FDA approval of Cinryze for the acute treatment of HAE and our inability to receive such an approval could have a material impact on future revenues from Cinryze.

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.

The outcome of our clinical development programs is subject to considerable uncertainties. We cannot be certain that we will be successful in developing and ultimately commercializing any of our product candidates, that the FDA or other regulatory authorities will not require additional or unanticipated studies or clinical trial outcomes before granting regulatory approval, or that we will be successful in gaining regulatory approval of any of our product candidates in the timeframes that we expect, or at all. For example, on February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone, marrow, transplant patients did not achieve its primary endpoints. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. In addition, the study failed to meet its key secondary endpoints. Maribavir was generally well tolerated in this clinical study. Additionally, in August 2007, we and Wyeth decided to discontinue dosing with HCV-796 in a phase 2 study as a result of potential safety concerns. There can be no assurance that we will conduct additional HCV studies in the future as the FDA or other regulatory authorities may either prohibit any future studies with HCV-796 or alternatively may require additional or unanticipated studies or clinical trial outcomes before granting regulatory approval.

We cannot assure you that our current cash, cash equivalents and short-term investments or cash flows from Vancocin and Cinryze sales will be sufficient to fund all of our ongoing development and operational costs, as well as the interest payable on the senior convertible notes, 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. Moreover, the results of our business development efforts could require considerable investments.

Our actual results could differ materially from those results expressed in, or implied by, our expectations and assumption described in this Annual Report on Form 10-K. The risks described in this report, our Form 10-K for the year ended December 31, 2008 are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Please also see our discussion of the "Risk Factors" in Item 1A, which describe other important matters relating our business.

**Results of Operations**

***Years ended December 31, 2008 and 2007***

| | For the year ended December 31, | |
|---|---|---|
| **(in thousands), except per share data** | **2008** | **2007** |
| Net product sales | $ 232,307 | $ 203,770 |
| Cost of sales (excluding amortization of product rights) | $ 8,874 | $ 8,934 |
| Operating income | $ 78,655 | $ 115,796 |
| Net income | $ 67,617 | $ 95,353 |
| Net income per share: | | |
| Basic | $ 0.95 | $ 1.37 |
| Diluted | $ 0.83 | $ 1.21 |

The decrease in net income for 2008 resulted primarily from a $65.7 million increase in operating expenses and a $10.0 million decrease in interest income, offset by the $28.5 million increase in sales. The $37.1 million decrease in operating income resulted from the increased costs to support our CMV and NTCD development programs and increase intangible amortization expense related to our acquisition of Cinryze product rights. Additionally, we incurred costs related to the product launch of Cinryze and the continuation of the Cinryze open label trial. The year ended December 31, 2008 includes $8.9 million share-based compensation expense and $4.0 million of costs associated with our opposition to the OGD's change in approach.

*Revenues*

Revenues consisted of the following:

| (in thousands) | For the year end December 31, 2008 | 2007 |
|---|---|---|
| Net product sales | $ 232,307 | $ 203,770 |

*Revenue*

Our net product sales are related to Vancocin and Cinryze. We sell Vancocin only to wholesalers who then distribute the product to pharmacies, hospitals and long-term care facilities, among others. Our sales of Vancocin are influenced by wholesaler forecasts of prescription demand, wholesaler buying decisions related to their desired inventory levels, and, ultimately, end user prescriptions, all of which could be at different levels from period to period.

We sell Cinryze to specialty pharmacy/ specialty distributors (SP/SD's) who then distribute to physicians, hospitals and patients, among others. We have recognized revenue related to shipments of Cinryze from the SP/SD's to patients who have had Cinryze approved by the healthcare providers. Shipments as of December 31, 2008 to SP/SD's (less shipments to patients) are classified as deferred revenue on our consolidated financial statements.

During the year ended December 31, 2008, net sales of Vancocin increased 14.0% compared to the same period in 2007 primarily due to an increase of units sold and the impact of a price increase during 2008.

Approximately 94% of our sales are to three wholesalers. Vancocin product sales are influenced by prescriptions and wholesaler forecasts of prescription demand, which could be at different levels from period to period. We receive inventory data from our three largest wholesalers through our fee for service agreements. We do not independently verify this data. Based on this inventory data and our estimates, we believe that as of December 31, 2008, the wholesalers did not have excess channel inventory.

*Cost of sales*

Vancocin cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights and were consistent between years. Cinryze cost of sales includes the cost of materials, manufacturing and distribution costs and excludes amortization of product rights. Cinryze cost of sales in 2009 may include approximately $5.0 million to $8.0 million of patient assistance program expenses while we continue to work with patients to achieve final reimbursement.

Since units are shipped based upon earliest expiration date, our cost of sales will be impacted by the cost associated with the specific units that are sold. Additionally, we may experience fluctuations in quarterly manufacturing yields and if this occurs, we would expect the cost of product sales of Vancocin to fluctuate from quarter to quarter.

*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, stock compensation and other overhead costs.

Research and development expenses were divided between our research and development programs in the following manner:

| (in thousands) | For the years ended December 31, 2008 | 2007 |
|---|---|---|
| ***Direct—Core programs*** | | |
| CMV | $ 35,332 | $ 21,676 |
| HCV | 762 | 909 |
| Cinryze | 5,305 | — |
| NTCD | 4,703 | 982 |
| Vancocin | 1,078 | 473 |
| ***Indirect*** | | |
| Development | 19,100 | 11,829 |
| Total | $ 66,280 | $ 35,869 |

Direct Expenses—Core Development Programs

Our direct expenses related to our CMV program increased significantly during 2008 as we advanced through our two Phase 3 clinical studies. Specifically, we continued and in May 2008 completed recruitment into the phase 3 study of maribavir in patients undergoing allogeneic stem cell transplant at transplant centers in the U.S., Canada and several European countries. Data collection for the six month assessments continued through the end of November 2008. We also continued enrollment in our Phase 3 clinical study of maribavir in patients receiving liver transplantation in the U.S. and Europe. In February 2009, based upon preliminary analysis of the data, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone, marrow, transplant patients did not achieve its primary endpoints. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. In addition, the study failed to meet its key secondary endpoints. We are continuing to analyze the study results. Additionally, we announced that our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to current standard of care. This decision was made based on the results of the Phase 3 study of maribavir in stem cell transplant patients, and the recommendation from our independent Data Monitoring Committee who considered the rate of viremia in both arms of the study. During 2007 we continued recruitment into an Phase 3 study of maribavir in patients undergoing allogeneic stem cell transplant, began recruiting patients into a second Phase 3 study of maribavir in liver transplant patients, and began executing on our pre-launch plans for our clinical, regulatory and commercial activities for the maribavir program in Europe.

Related to our HCV program, costs in the 2008 primarily represent those paid to Wyeth in connection with our cost-sharing arrangement related to discovery efforts to identify potential back-ups/follow-on compounds to HCV-796. During 2007, costs included continued recruitment in the 500 mg BID arms of a phase 2 study of HCV-796 when dosed in combination with pegylated interferon and ribavirin and ongoing follow-up of patients in that study. In April 2008, we announced that ViroPharma and Wyeth, have jointly discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. We also announced that ViroPharma and Wyeth do not expect to continue to collaborate on future development of hepatitis C treatment candidates.

In October 2008, we acquired Cinryze, a C1 inhibitor, which has been approved by the FDA for routine prophylaxis of hereditary angioedema (HAE) also known as C1 inhibitor deficiency, a rare, severely debilitating, life-threatening genetic disorder. During 2008, we incurred costs related to the open label trial for additional product and patient follow-up.

The increase in costs of NTCD in 2008 over 2007 relate to increased research and development activities and the costs associated with manufacturing NTCD spores.

Related to our Vancocin program, costs in 2008 and 2007 related to additional research activities.

Anticipated fluctuations in future direct expenses are discussed under "**Liquidity** – ***Development Programs***."

Direct Expenses—Non-core Development Programs

We incurred minimal direct costs related to our common cold program licensed to Schering-Plough.

Indirect Expenses

These costs primarily relate to the compensation of and overhead attributable to our development team. The increase in 2008 as compared to 2007 is primarily due to increased personnel costs of $6.1 million resulting from additional hiring in the US and EU to support our clinical studies of maribavir and prepare for a regulatory submission and commercial expenses to support a potential future product launch.

*Selling, general and administrative expenses*

Selling, general and administrative (SG&A) expenses increased $28.3 million in 2008 to $65.4 million from $37.1 million in 2007. For 2008, the largest contributors to these increases were compensation costs, including share based compensation, as a result of increased headcount from the addition of our European operations and the Vancocin sales force ($12.6 million), medical education activities ($8.1 million) and marketing efforts ($4.5 million).

Included in SG&A are legal and consulting costs incurred related to our opposition to the attempt by the OGD regarding the conditions that must be met in order for a generic drug application to request a waiver of in-vivo bioequivalence testing for copies of Vancocin, which were $4.0 million in the year 2008 as compared to $3.3 million the same period in 2007. We anticipate that these additional legal and consulting costs will continue at higher levels in future periods.

*Intangible amortization and acquisition of technology rights*

Intangible amortization is the result of the Vancocin product rights acquisition in the fourth quarter of 2004, as well as the acquisition of Lev in October 2008. Additionally, as described in our agreement with Lilly, to the extent that we incur an obligation to Lilly for additional payments on Vancocin sales, we have contingent consideration. We record the obligation as an adjustment to the carrying amount of the related intangible asset and a cumulative adjustment to the intangible amortization upon achievement of the related sales milestones. Contingent consideration and Lilly related additional payments are more fully described in Note 7 of the Consolidated Financial Statements.

Intangible amortization for the years ended December 31, 2008 and 2007 were $10.8 million and $6.1 million respectively. The comparatives are impacted by cumulative adjustments for contingent consideration paid to Lilly, which were $1.0 million in 2008 and $0.6 million in 2007, and the amortization of Cinryze product rights from the date of the Lev acquisition to December 31, 2008.

On an ongoing periodic basis, we evaluate the useful life of these intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives. This evaluation did not result in a change in the life of the intangible assets during the year ended December 31, 2008. We will continue to monitor the actions of the OGD and consider the effects of our opposition efforts and the announcements by generic competitors or other adverse events for additional impairment indicators and we will reevaluate the expected cash flows and fair value of our Vancocin-related assets, as well as estimated useful lives, at such time.

*Other Income (Expense)*

Impairment loss

During 2008, we incurred a $2.3 million impairment related to our previous Corporate Headquarters that is classified as held for sale at December 31, 2008.

During the first quarter of 2009, the market capitalization of ViroPharma fell below the carrying value of ViroPharma's net assets due to the announcements surrounding our maribavir development program. In accordance with SFAS 142, "Goodwill and Other Intangible Assets", this situation would require us to test for impairment of our goodwill and other intangible assets if the situation continues at March 31, 2009. This analysis will be conducted at March 31, 2009 and depending on our stock price and fair market value of our assets, this could lead to an impairment charge at that time.

Interest Income

Interest income for the years ended December 31, 2008 and 2007 was $14.3 million and $24.3 million, respectively. Interest income decreased primarily due to lower interest rates in 2008 as well as decreased short-term investments during 2008.

Interest Expense

Interest expense and amortization of finance costs in 2008 and 2007 relates entirely to the senior convertible notes issued on March 26, 2007, as described in Note 9 to the Consolidated Financial Statements.

*Income Tax Expense*

Our effective income tax rate was 22.4% and 29.7% for the years ended December 31, 2008 and 2007, respectively. Income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences. The decrease in the 2008 rate as compared to 2007 is primarily due to the impact of the orphan drug credit for maribavir. Additionally, in connection with our acquisition of Lev, we reduced our valuation allowance by $63.1 million to recognize deferred tax assets due to recognition of deferred tax liabilities in connection with our acquisition of Lev.

***Years ended December 31, 2007 and 2006***

| | For the year ended December 31, | |
|---|---|---|
| **(in thousands), except per share data** | **2007** | **2006** |
| Net product sales | $ 203,770 | $ 166,617 |
| Total revenues | $ 203,770 | $ 167,181 |
| Cost of sales (excluding amortization of product rights) | $ 8,934 | $ 18,984 |
| Operating income | $ 115,796 | $ 98,806 |
| Net income | $ 95,353 | $ 66,666 |
| Net income per share: | | |
| Basic | $ 1.37 | $ 0.97 |
| Diluted | $ 1.21 | $ 0.95 |

The increase in net income for 2007 resulted primarily from the $37.2 million increase in sales, along with a $10.1 million reduction in the cost of sales. The $17.0 million increase in operating income resulted from factors described above, offset by the increased costs to support our CMV and HCV development programs. The year ended December 31, 2007 includes $7.6 million share-based compensation expense and $3.3 million of costs associated with our opposition to the OGD's change in approach.

*Revenues*

Revenues consisted of the following:

| (in thousands) | For the year end December 31, 2007 | 2006 |
|---|---|---|
| Net product sales | $ 203,770 | $ 166,617 |
| License fees and milestones revenues | — | 564 |
| Total revenues | $ 203,770 | $ 167,181 |

Revenue—Vancocin product sales

Our net product sales are solely related to Vancocin. We sell Vancocin only to wholesalers who then distribute the product to pharmacies, hospitals and long-term care facilities, among others. Our sales of Vancocin are influenced by wholesaler forecasts of prescription demand, wholesaler buying decisions related to their desired inventory levels, and, ultimately, end user prescriptions, all of which could be at different levels from period to period.

During the year ended December 31, 2007, net sales of Vancocin increased 22.3% compared to the same period in 2006 primarily due to an increase of units sold, the impact of a price increase during 2007 and wholesaler inventory levels which were stable in 2007 compared to decreased levels in 2006. We believe, based upon data reported by IMS Health Incorporated, that prescriptions during the year ended December 31, 2007 exceeded prescriptions in the 2006 period by 4%.

Approximately 93% of our sales are to three wholesalers. Vancocin product sales are influenced by prescriptions and wholesaler forecasts of prescription demand, which could be at different levels from period to period. We receive inventory data from one of our three largest wholesalers through our fee for service agreement. We do not independently verify this data. Based on this inventory data and our estimates, we believe that as of December 31, 2007, the wholesalers did not have excess channel inventory.

*Cost of sales*

Vancocin cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights. The decrease of $10.1 million over the prior year primarily results from the sale of units manufactured by NPI Pharmaceuticals (formerly OSG Norwich), which carry a lower inventory cost.

During 2007 and the second half of 2006, all of the finished product we purchased was produced by NPI Pharmaceuticals. As of June 30, 2006, Lilly no longer manufactured finished product for us because our third-party manufacturing supply chain was approved in the second quarter of 2006 and in July 2006, we began receiving regular shipments of product produced by NPI Pharmaceuticals. Our finished product that was sold in the second half of 2006 included product produced by both Lilly and NPI Pharmaceuticals. As such, our cost of sales began to steadily decrease in the second half of 2006 and remained consistent during 2007.

Since units are shipped based upon earliest expiration date, our cost of sales will be impacted by the cost associated with the specific units that are sold. Additionally, we may experience fluctuations in quarterly manufacturing yields and if this occurs, we would expect the cost of product sales of Vancocin to fluctuate from quarter to quarter.

*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, stock compensation and other overhead costs. Due to recent advancements in our clinical development programs, we expect future costs to exceed current costs.

Research and development expenses were divided between our research and development programs in the following manner:

| | For the years ended December 31, | |
|---|---|---|
| **(in thousands)** | **2007** | **2006** |
| ***Direct—Core programs*** | | |
| CMV | $ 21,676 | $ 10,496 |
| HCV | 909 | 753 |
| Vancocin | 473 | 794 |
| NTCD | 982 | — |
| ***Direct—Non-core programs*** | | |
| Common cold | — | 28 |
| ***Indirect*** | | |
| Development | 11,829 | 7,091 |
| Total | $ 35,869 | $ 19,162 |

Direct Expenses—Core Development Programs

Our direct expenses related to our CMV program increased significantly in 2007 as we advanced the program into larger Phase 3 clinical studies. Specifically, during the year 2007 we continued recruitment into an ongoing phase 3 study of maribavir in patents undergoing allogeneic stem cell transplant and began recruiting patients into a second phase 3 study in patients undergoing liver transplantation during the second quarter of 2007. We began executing on our pre-launch plans for our clinical, regulatory and commercial activities for the maribavir program in Europe. During the year 2006 we concluded analysis of data from our phase 2 clinical trial with maribavir, which demonstrated that maribavir significantly reduces CMV reactivation in patients who had undergone allogeneic stem cell transplantation. We initiated dosing in a phase 3 study of maribavir in the prevention of CMV disease in allogeneic stem cell transplantation and continued conducting and analyzing data from various phase 1 clinical trials. We also prepared for a second phase 3 study of maribavir in solid organ transplant patients. Included in the CMV expenses during 2006 was $3.0 million related to a milestone payment due to GlaxoSmithKline associated with the initiation of the phase 3 study of maribavir, which was paid in February 2007.

Related to our HCV program, costs in 2007 primarily represent those paid to Wyeth in connection with our cost-sharing arrangement related to discovery efforts to identify potential back-ups/follow-on compounds to HCV-796. Development activity for our HCV product candidate, HCV-796, during the year 2007 included completion of enrollment in the 500 mg BID arms of a phase 2 study of HCV-796 when dosed in combination with pegylated interferon and ribavirin and ongoing follow-up of patients in that study. In August 2007, we announced that elevated liver enzyme levels in a subset of patients in this study indicated a potential safety issue. Consequently, all dosing with HCV-796 was discontinued, although patients in the phase 2 study had the option of continuing to receive pegylated interferon and ribavirin as per standard of care. Therefore, monitoring and follow-up of patients in the phase 2 study will continue. During the year 2006, we conducted a phase 1b clinical trial which demonstrated the antiviral activity of HCV-796 in combination with pegylated interferon and began dosing in a phase 2 study of HCV-796. Wyeth pays a substantial portion of the collaboration's predevelopment and development expenses.

Related to our Vancocin/*C. difficile* program, costs in 2007 and 2006 related to research and development activities, including costs related to non-toxigenic strains of *C. difficile*.

Anticipated fluctuations in future direct expenses are discussed under "**Liquidity** – ***Development Programs***."

Direct Expenses—Non-core Development Programs

We incurred minimal direct costs related to our common cold program licensed to Schering-Plough.

Indirect Expenses

These costs primarily relate to the compensation of and overhead attributable to our development team, primarily due to increased personnel costs of $2.1 million.

*Selling, general and administrative expenses*

Selling, general and administrative (MG&A) expenses increased $12.5 million in 2007 to $37.1 million from $24.6 million in 2006. The largest contributors to this increase were medical education costs ($3.1 million), legal and consulting costs ($1.7 million), and compensation ($1.6 million) and share-based compensation expense ($1.5 million) due to increased personnel, Other contributors included corporate franchise taxes and commercial related expenses, which collectively increased by $2.3 million.

Included in the increased legal and consulting costs are expenses incurred related to our opposition to the attempt by the OGD regarding the conditions that must be met in order for a generic drug application to request a waiver of in-vivo bioequivalence testing for copies of Vancocin, which were $3.3 million in the year 2007 as compared to $2.3 million the same period in 2006. We anticipate that these additional legal and consulting costs will continue at higher levels in future periods.

*Intangible amortization and acquisition of technology rights*

Intangible amortization is the result of the Vancocin product rights acquisition in the fourth quarter of 2004. Additionally, as described in our agreement with Lilly, to the extent that we incur an obligation to Lilly for additional payments on Vancocin sales, we have contingent consideration. We record the obligation as an adjustment to the carrying amount of the related intangible asset and a cumulative adjustment to the intangible amortization upon achievement of the related sales milestones. Contingent consideration and Lilly related additional payments are more fully described in Note 7 of the Consolidated Financial Statements.

Intangible amortization for the years ended December 31, 2007 and 2006 were comparable at $6.1 million and $5.7 million respectively. The comparatives are impacted by cumulative adjustments, which were $0.6 million in 2007 and $0.4 million in 2006.

In March 2006, as a result of OGD's change in approach relating to generic bioequivalence determinations, we reviewed the value of the intangible asset and concluded that there was no impairment of the carrying value of the intangible assets or change to the useful lives as estimated at the acquisition date. Additionally, on an ongoing periodic basis, we evaluate the useful life of these intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives. This evaluation did not result in a change in the life of the intangible assets during the year ended December 31, 2007. We will continue to monitor the actions of the OGD and consider the effects of our opposition efforts and the announcements by generic competitors or other adverse events for additional impairment indicators and we will reevaluate the expected cash flows and fair value of our Vancocin-related assets, as well as estimated useful lives, at such time.

*Other Income (Expense)*

Gain on sale of short term investments

During 2006, we sold our marketable securities investment in SIGA Technologies, Inc. for a gain of $1.7 million.

Net (loss) gain on bond redemption

On March 1, 2006, we redeemed the then remaining $78.9 million principal amount of our subordinated convertible notes for $79.6 million. This eliminated our long-term debt that was outstanding at December 31, 2005. The charge of $1.1 million related to this payment in the first quarter of 2006, represents a premium of $0.7 million and the write-off of deferred finance costs of $0.4 million at March 1, 2006.

Interest Income

Interest income for the years ended December 31, 2007 and 2006 was $24.3 million and $9.9 million, respectively. Interest income increased primarily due to increased short-term investments during 2007 and to a lesser extent, an increased rate of return.

Interest Expense

Interest expense and amortization of finance costs in 2007 relates entirely to the senior convertible notes issued on March 26, 2007, as described in Note 9 to the Consolidated Financial Statements.

Interest expense in 2006 relates entirely to the subordinated convertible notes, which were redeemed on March 1, 2006. In the third quarter of 2006, we recorded a credit to interest expense related to the beneficial conversion feature because we released the remaining liability associated with the auto-conversion provisions as the likelihood of payment was remote.

*Income Tax Expense*

Our effective income tax rate was 29.7% and 38.6% for the years ended December 31, 2007 and 2006, respectively. Income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences. The decrease in the 2007 rate as compared to 2006 is primarily due to our current estimate of the impact of orphan drug credit for maribavir as well as a $4.0 million benefit for the valuation allowance adjustment primarily related to additionally deferred tax assets that management believes is more likely than not to be utilized.

**Liquidity**

We expect that our near term sources of revenue will arise from Vancocin and Cinryze product sales. However, we cannot predict what the actual sales of Vancocin will be in the future, and the outcome of our effort to oppose the OGD's approach to bioequivalence determinations for generic copies of Vancocin is uncertain. In addition, there are no assurances that demand for Vancocin will continue at historical or current levels. Finally, we cannot predict the actual sales of Cinryze as the product has not just recently been launched commercially and has no history of revenue.

Our ability to generate positive cash flow is also impacted by the timing of anticipated events in our CMV and NTCD programs, including the scope of the clinical trials required by regulatory authorities, results from clinical trials, the results of our product development efforts, and variations from our estimate of future direct and indirect expenses.

While we anticipate that cash flows from Vancocin and Cinryze, as well as our current cash, cash equivalents and short-term investments, should allow us to fund substantially all of our ongoing development and other operating costs for the foreseeable future, as well as the interest payable on the senior convertible notes, we may need additional financing in order to expand our product portfolio. At December 31, 2008, we had cash, cash equivalents and short-term investments of $275.8 million.

***Overall Cash Flows***

During the year ended December 31, 2008, we generated $91.4 million of net cash from operating activities, primarily from net income of $67.6 million, the impact of noncash expenses and a decreased interest receivable. Partially offsetting net income was the impact of higher inventory related to Cinryze and increased other assets. We also provided $15.4 million of cash for investing activities as a result of our maturing and selling of our short term investments, largely offset from our purchase of Lev. Our net cash used in financing activities for the year ended December 31, 2008 was $10.1 million.

***Operating Cash Inflows***

We began to receive cash inflows from the sale of Vancocin in January 2005. 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 collaboration 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. The most significant of our near-term operating development cash inflows are as described under "***Development Programs***".

***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, servicing our debt, and income tax payments. 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. However, due to advancements in our trials, our initiative to develop non-toxigenic strains of C. *difficile* and our expansion into Europe, we expect future costs to exceed current costs. The most significant of our near-term operating development cash outflows are as described under "***Development Programs***".

***Development Programs***

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. Additionally, for some of our development programs, we have cash inflows and outflows upon achieving certain milestones.

*Core Development Programs*

CMV program—From the date we in-licensed maribavir through December 31, 2008, we paid $79.1 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 in September 2003.

During 2009, we will continue to analyze the study results for the Phase 3 trial evaluating maribavir used as prophylaxis stem cell transplant patients that did not achieve its primary endpoint. In 2009, we will continue to incur costs related to analyzing of our Phase 3 results, patient monitoring and study wind down costs. 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, 2008, we paid $4.5 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.

In April 2008 we, along with Wyeth, discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. Additionally, we announced that ViroPharma and Wyeth do not expect to continue to collaborate on future development of hepatitis C treatment candidates.

Cinryze—We acquired Cinryze in October 2008 and have spent approximately $5.3 million in direct research and development costs related to Cinryze since acquisition. During 2009, we continue to expect research and development costs related to Cinryze as we complete our Phase 4 commitment. We are solely responsible for the costs of Cinryze development.

Vancocin—We acquired Vancocin in November 2004 and have spent approximately $1.9 million in direct research and development costs related to Vancocin since acquisition.

NTCD—We acquired NTCD in February 2006 and through December 31, 2008 have spent approximately $5.7 million in direct research and development costs. During 2009, we expect our research and development activities on NTCD to increase significantly, therefore, we expect direct costs to increase materially above 2008 levels.

*Direct Expenses—Non-Core Development Programs*

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 have not incurred any significant direct expenses in connection with this program since 2004, nor will we in the future, 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 $10.0 million in December 2004 and purchased our existing inventory of bulk drug substance for an additional $6.0 million in January 2005. We will also be 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.

***Business development activities***

Through December 31, 2008, we paid an acquisition price of $116.0 million, paid $30.1 million related to additional purchase price consideration tied to product sales (see Note 7 of the Consolidated Financial Statements) and incurred $2.0 million of fees and expenses in connection with the Vancocin acquisition.

On October 21, 2008, we completed our acquisition under which ViroPharma acquired Lev Pharmaceuticals, Inc. (Lev). Lev is a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration of $453.1 million, or $2.75 per Lev share, comprised of $2.25 per share in cash and $0.50 per share in ViroPharma common stock, and contingent consideration of up to $1.00 per share which may be paid on achievement of certain regulatory and commercial milestones. The Company used approximately $381 million of existing cash and cash equivalents to fund the acquisition, including deal related expenses, and issued approximately 7,359,667 shares in conjunction with the merger.

In addition, we intend to seek to acquire additional products or product candidates. The costs associated with evaluating or 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 evaluating or acquiring business development candidates, it is not feasible to predict what our actual evaluation or acquisition costs would be, if any, however, the costs could be substantial.

***Debt service requirements***

*Senior Convertible Notes*

On March 26, 2007, we issued $250.0 million of 2% senior convertible notes due March 2017 (the "senior convertible notes") in a public offering. The $250.0 million includes an issuance pursuant to the underwriters' exercise of an overallotment in the amount of $25.0 million that was closed concurrently on March 26, 2007. Net proceeds from the issuance of the senior convertible notes were $241.8 million. The senior convertible notes are unsecured unsubordinated obligations and rank equally with any other unsecured and unsubordinated indebtedness. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007. As of December 31, 2008, we have accrued $1.4 million in interest payable to holders of the senior convertible notes. Debt issuance costs of $8.2 million have been capitalized and are being amortized over the term of the senior convertible notes, with the balance to be amortized as of December 31, 2008 being $6.6 million.

The senior convertible notes are convertible into shares of our common stock at an initial conversion price of $18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the "measurement period") in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to ViroPharma's option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of December 31, 2008, the fair value of the $250.0 million convertible senior notes outstanding was approximately $194.4 million, based on the level 2 valuation hierarchy under SFAS No. 157, *Fair Value Measurements* (SFAS 157).

Concurrent with the issuance of the senior convertible notes, we entered into privately-negotiated transactions, comprised of purchased call options and warrants sold, to reduce the potential dilution of our common stock upon conversion of the senior convertible notes. The transactions, taken together, have the effect of increasing the initial conversion price to $24.92 per share. The net cost of the transactions was $23.3 million.

The call options allow ViroPharma to receive up to approximately 13.25 million shares of its common stock at $18.87 from the call option holders, equal to the number of shares of common stock that ViroPharma would issue to the holders of the senior convertible notes upon conversion. These call options will terminate upon the earlier of the maturity dates of the related senior convertible notes or the first day all of the related senior convertible notes are no longer outstanding due to conversion or otherwise. Concurrently, we sold warrants to the warrant holders to receive shares of its common stock at an exercise price of $24.92 per share. These warrants expire ratably over a 60-day trading period beginning on June 13, 2017 and will be net-share settled.

The purchased call options are expected to reduce the potential dilution upon conversion of the senior convertible notes in the event that the market value per share of ViroPharma common stock at the time of exercise is greater than $18.87, which corresponds to the initial conversion price of the senior convertible notes, but less than $24.92 (the warrant exercise price). The warrant exercise price is 75.0% higher than the price per share of $14.24 of the Company's stock on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options ($18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants ($24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants.

The purchased call options and sold warrants are separate transactions entered into by us with the counterparties, are not part of the terms of the senior convertible notes, and will not affect the holders' rights under the senior convertible notes. Holders of the senior convertible notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options and sold warrants meet the definition of derivatives under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133). These instruments have been determined to be indexed to the Company's own stock (in accordance with the guidance of the Emerging Issues Task Force (EITF) Issue No. 01-6, *The Meaning of Indexed to a Company's Own Stock* and have been recorded in stockholders' equity in our Consolidated Balance Sheet (as determined under EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*). As long as the instruments are classified in stockholders' equity they are not subject to the mark to market provisions of SFAS 133.

We used the net proceeds from the offering to apply to working capital and general corporate purposes. We may also use a portion of the net proceeds to acquire, license or invest in complementary businesses, technologies or products.

***Contractual Obligations***

Future contractual obligations and commercial commitments at December 31, 2008 are as follows:

| (in thousands) Contractual Obligations [1][2][6] | Total | 1 year or less | 2-3 years | 4-5 years | More than 5 years |
|---|---|---|---|---|---|
| Operating leases (3) | $ 14,826 | $ 1,313 | $ 3,408 | $ 3,648 | $ 6,457 |
| Senior convertible notes (4) | 292,500 | 5,000 | 10,000 | 10,000 | 267,500 |
| Purchase obligations (5) | 89,647 | 27,801 | 61,846 | — | — |
| Total | $ 396,973 | $ 34,114 | $ 75,254 | $ 13,648 | $ 273,957 |

(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, it does not include any additional payments due to Lilly in connection with the Vancocin acquisition, as the amount and timing of future additional payments are not determinable. Under the terms of the agreement with Lilly, Lilly is entitled to additional payments of 35% of annual net sales between $45 and $65 million of Vancocin during 2009 through 2011.

No additional payments are due to Lilly on net sales of Vancocin below or above the net sales levels reflected above. We account for purchase price consideration as contingent consideration and will record an adjustment to the carrying amount of the related intangible asset and a cumulative adjustment to the intangible amortization upon achievement of the related sales milestones. Assuming the maximum threshold is met at the end of each year, the cumulative amortization adjustment would be $1.3 million, $1.5 million and $1.8 million in the years ended December 31, 2009, 2010 and 2011, respectively.

In the event we develop any product line extensions, revive discontinued vancomycin product lines (injectable or oral solution), 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.

Finally, the table does not include additional payments to Lev CVR holders. The merger agreement with Lev states that the first CVR payment of $0.50 per share would become payable when either (i) Cinryze is approved by the FDA for acute treatment of HAE and the FDA grants orphan exclusivity for Cinryze encompassing the acute treatment of HAE to the exclusion of all other human C1 inhibitor products for which we submitted a sBLA in December 2008 and have a PDUFA date of June 3, 2009 or, (ii) orphan exclusivity for the acute treatment of HAE has not become effective for any third party's human C1 inhibitor product for two years from the later of the date of closing and the date that orphan exclusivity for Cinryze for the prophylaxis of HAE becomes effective. The second CVR payment of $0.50 per share would become payable when Cinryze reaches at least $600 million in cumulative net product sales within 10 years of closing of the acquisition. Each CVR payment would be approximately $87 million.

(2) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture product candidates, and for consulting and other contracted services due to the cancelable nature of the services. We accrue the costs of these agreements based on estimates of work completed to date. We estimate that approximately $38.8 million will be payable in future periods under arrangements in place at December 31, 2008. Of this amount, approximately $8.5 million has been accrued for work estimated to have been completed as of December 31, 2008 and approximately $30.3 million relates to future performance under these arrangements.

(3) Operating leases represent building and equipment leases.

(4) These payments represent interest and principal related to our 2% senior convertible notes due March 2017.

(5) In conjunction with our acquisition of Lev, we acquired purchase obligations related to the supply and manufacturing of Cinryze. We have committed to purchase 75,000 liters of plasma per year through 2011 from our supplier and also have committed to purchase plasma collected from the Plasma Centers of America collection centers until our purchase of these centers. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer.

(6) This table does not include $1.1 million of a non-current income tax payable which represents uncertain tax positions due to the uncertainty of the amount and period of payment.

***Capital Resources***

While we anticipate that revenues from Vancocin and Cinryze will continue to generate positive cash flow and should allow us to fund substantially all of our ongoing development and other operating costs, we may need additional financing in order to expand our product portfolio. Should we need financing, we would seek to access the public or private equity or debt markets, enter into additional arrangements with corporate collaborators to whom we may issue equity or debt securities or enter into other alternative financing arrangements that may become available to us.

*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.

If we raise additional capital by accessing debt markets, the terms and pricing for these financings may be much more favorable to the new lenders than the terms obtained from our prior lenders. These financings also may require liens on certain of our assets that may limit our flexibility.

Additional equity or debt financing, however, may not be available on acceptable terms from any source as a result of, among other factors, our operating results, 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.

**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. Actual results could differ from such estimates. 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 the 2008 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:

- Product Sales—Our net sales consist of revenue from sales of our products, Vancocin and Cinryze, less estimates for chargebacks, rebates, distribution service fees, returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, distribution service fees, returns and losses are reasonably determinable, and when collectability is reasonably assured. Revenue from the launch of a new or significantly unique product may be deferred until estimates can be made for chargebacks, rebates and losses and all of the above conditions are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch. Once we can estimate our gross to net adjustments for Cinryze, we will record net sales at the time of delivery to specialty distributors and specialty pharmacies.

- At the end of each reporting period, as part of an analysis of returns, utilizing our revenue recognition policy (derived from the criteria of SEC Staff Accounting Bulletin No. 104, including SFAS No. 48, *Revenue Recognition When Right of Return Exists*) we analyze our estimated channel inventory and we defer recognition of revenue on product that has been delivered if we believe that channel inventory at a period end is in excess of ordinary business needs and if we believe the value of potential returns is materially different than our returns accrual. Further, in connection with our analysis of returns, if we believe channel inventory levels are increasing without a reasonably correlating increase in prescription demand, we proactively delay the processing of wholesaler orders until these levels are reduced.

  We establish accruals for chargebacks and rebates, sales discounts and product returns. These accruals are primarily based upon the history of Vancocin, including both Lilly and our ownership periods. For Cinryze, our analysis is based on our evaluation of payee's known to us through information obtain from our wholesalers and CinryzeSolutions. We also consider the volume and price of our products in the channel, trends in wholesaler inventory, conditions that might impact patient demand for our product (such as incidence of disease and the threat of generics) and other factors.

  In addition to internal information, such as unit sales, we use information from external resources, which we do not verify, to estimate the Vancocin channel inventory. Our external resources include prescription data reported by IMS Health Incorporated and written and verbal information obtained from our three largest wholesaler customers with respect to their inventory levels. Based upon this information, we believe that inventory held at these warehouses are within normal levels.

  Chargebacks and rebates are the most subjective sales related accruals. While we currently have no contracts with private third party payors, such as HMO's, we do have contractual arrangements with governmental agencies, including Medicaid. We establish accruals for chargebacks and rebates related to these contracts in the period in which we record the sale as revenue. These accruals are based upon historical experience of government agencies' market share, governmental contractual prices, our current pricing and then-current laws, regulations and interpretations. We analyze the accrual at least quarterly and adjust the balance as needed. We believe that if our estimates of the rate of chargebacks and rebates as a percentage of annual gross sales were incorrect by 10%, our operating income and accruals would be impacted by approximately $1.5 million in the period of correction, which we believe is immaterial.

  Annually, as part of our process, we performed an analysis on the share of Vancocin and Cinryze sales that ultimately go to Medicaid recipients and result in a Medicaid rebate. As part of that analysis, we considered our actual Medicaid historical rebates processed, total units sold and fluctuations in channel inventory. We also consider our payee mix for Cinryze based on information obtained at the time of prescription.

  Product returns are minimal. Product return accruals are estimated based on Vancocin's history of damage and product expiration returns and are recorded in the period in which we record the sale of revenue. Cinryze has a no returns policy. At each reporting period, we also compare our returns accrual balance to the estimated channel inventory to ensure the accrual balance is reasonable and within an acceptable range. For example, if the estimated channel inventory is at a high level, we could be required to adjust our accrual upward.

  Discounts are related to payment terms and are fully accrued in the period in which we record the sale of revenue. Since our customers consistently take the payment discount, we do not believe that future periods will be materially impacted by a change in a previous discount accrual.

- Impairment of Long-lived Assets—We review our fixed and intangible assets, as well as goodwill, for possible impairment annually and whenever events occur or circumstances indicate that the carrying amount of an asset may not be recoverable in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144). 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, for example, projections of future cash flows and the timing and number of generic/competitive entries into the market, in determining the undiscounted cash flows, and if necessary, the fair value of the asset and whether an impairment exists. These assumptions are subjective and could result in a material impact on operating results in the period of impairment. While we reviewed our intangible assets in March 2006 and December 2008 in light of the actions taken by the OGD, we did not recognize any impairment charges. See Note 7 of the Consolidated Financial Statements for further information. We will continue to monitor the actions of the OGD and consider the effects of our opposition actions and the announcements by generic competitors or other adverse events for additional impairment indicators and we will reevaluate the expected cash flows and fair value of our Vancocin-related assets at such time.

  On an ongoing periodic basis, we evaluate the useful life of intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives. While we reviewed the useful life of our intangible assets in March 2006 and December 2008 in light of the actions taken by the OGD, we did not change the useful life of our intangible assets during the year ended December 31, 2008. See Note 7 of the Consolidated Financial Statements for further information.

- Short-term Investments—We review our short-term investments on a periodic basis for other-than-temporary impairments. This review considers credit worthiness and our intent and ability to hold debt securities until maturity and is subjective as it requires management to evaluate whether an event or change in circumstances has occurred in that period that may have a significant adverse effect on the fair value of the investment.
- Share-Based Employee Compensation—We adopted SFAS No. 123R, *Share-based Payment* (SFAS 123R), effective January 1, 2006. The calculation of this expense includes judgment related to the period of time used in calculating the volatility of our common stock, the amount of forfeitures and an estimate of the exercising habits of our employees, which is also influenced by our Insider Trading Policy. Changes in the volatility of our common stock or the habits of our employees could result in variability in the fair value of awards granted.
- Income Taxes—Our annual effective tax rate is based on expected pre-tax earnings, existing statutory tax rates, limitations on the use of tax credits and net operating loss carryforwards, evaluation of qualified expenses related to the orphan drug credit and tax planning opportunities available in the jurisdictions in which we operate. Significant judgment is required in determining our annual effective tax rate and in evaluating our tax position.

  On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax audits. We recognize the benefit of tax positions that we have taken or expect to take on the income tax returns we file if such tax position is more likely than not of being sustained. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution.

  In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences becomes deductible or the NOLs and credit carryforwards can be utilized. When considering the reversal of the valuation allowance, we consider the level of past and future taxable income, the reversal of deferred tax liabilities, the utilization of the carryforwards and other factors. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.
- Acquisition Accounting —Businesses acquired before December 31, 2008 are accounted for in accordance with SFAS No. 141, *Business Combinations* and the total purchase price will be allocated to Lev's net tangible assets or identifiable intangible assets based on their fair values as of the date of the acquisition. The application of the purchase accounting requires certain estimates and assumptions especially concerning the determination of the fair values of the acquired intangible assets and property, plant and equipment as well as the liabilities assumed at the date of the acquisition. Moreover, the useful lives of the acquired intangible assets, property, plant and equipment have to be determined.

  Measurement of fair value and useful lives are based to a large extent on anticipated cash flows. If actual cash flows vary from those used in calculating fair values, this may significantly affect the Company's future results of operations. In particular, the estimation of discounted cash flows of intangible assets of newly developed products is subject to assumptions closely related to the nature of the acquired products. Factors that may affect the assumptions regarding future cash flows:

  - long-term sales forecasts,
  - anticipation of selling price erosion after the end of orphan exclusivity due to follow-on biologic competition in the market,
  - behavior of competitors (launch of competing products, marketing initiatives etc.).

  For significant acquisitions, the purchase price allocation is carried out with assistance from independent third-party valuation specialists. The valuations are based on information available at the acquisition date.

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 December 2007, the Accounting Standards Board (FASB) issued SFAS No. 141R, *Business Combinations* (SFAS 141R), which will significantly change the accounting for business combinations. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company will apply the guidance of the Statement to business combinations completed on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – An Amendment of ARB No. 51* (SFAS 160), which establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 is effective for the Company beginning January 1, 2009. We do not anticipate a material impact on operating results or financial position.

In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). The FSP requires the issuer of convertible debt instruments with cash settlement features to separately account for the liability and equity components of the instrument. The debt is recognized at the present value of its cash flows discounted using the issuer's nonconvertible debt borrowing rate. The equity component is recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The FSP will be effective for financial statements for years beginning after December 15, 2008 and interim periods within those years. The Company expects that adoption of the proposal will reduce long-term debt, increase stockholders' equity, and reduce net income and earnings per share. In 2009, the adoption of the FSP will require the Company to record approximately $7.0 million of additional non-cash interest expense related to the outstanding senior convertible debt instruments. Adoption will cause us to recast our 2008 and 2007 financial statements and will require the Company to record approximately $6.5 million and $4.9 million of additional non-cash interest expense, respectively. Adoption of the proposal would not affect the Company's cash flows.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities — an amendment of FASB Statement No. 133* (SFAS 161), which changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. Companies are required to adopt SFAS 161 for fiscal years beginning after November 15, 2008. The Company is currently evaluating the impact of this standard and expects it will require additional disclosures.

In November 2007, the FASB issued EITF 07-1 *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1) which is focused on how the parties to a collaborative agreement should disclose costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. EITF 07-1 is effective for fiscal years ended after December 15, 2008. Upon adoption, we do not anticipate a material impact on operating results or financial position.

In June 2008, the FASB issued FSP EITF No. 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities*. Under the FSP, unvested share-based payment awards that contain rights to receive nonforfeitable dividends (whether paid or unpaid) are participating securities, and should be included in the two-class method of computing EPS. This FSP is effective for fiscal years beginning after December 15, 2008. The Company does not have share-based payment awards that contain rights to nonforfeitable dividends, thus this FSP is not anticipated to have an impact on the Company's consolidated financial statements.

In April 2008, FSP No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP No. FAS 142-3) was issued which provides for additional considerations to be used in determining useful lives and requires additional disclosure regarding renewals. FSP No. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. Early adoption is not permitted. The FSP must be applied prospectively to intangible assets acquired after the effective date. The Company will apply the guidance of the FSP to intangible assets acquired after January 1, 2009.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies on the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. We do not expect any impact on operating results or financial position.

In November 2008, the Emerging Issues Task Force issued EITF No. 08—7, *Accounting for Defensive Intangible Assets* (EITF 08 -7) that clarifies accounting for defensive intangible assets subsequent to initial measurement. EITF 08—7 applies to acquired intangible assets which an entity has no intention of actively using, or intends to discontinue use of, the intangible asset but holds it (locks up) to prevent others from obtaining access to it (i.e., a defensive intangible asset). Under EITF 08—7, the Task Force reached a consensus that an acquired defensive asset should be accounted for as a separate unit of accounting (i.e., an asset separate from other assets of the acquirer); and the useful life assigned to an acquired defensive asset should be based on the period during which the asset would diminish in value. ETIF 08—7 is effective for defensive intangible assets acquired in fiscal years beginning on or after December 15, 2008. The Company does not believe EITF 08—7 will have a significant impact on the Company's consolidated financial statements

**Off-Balance Sheet Arrangements**

In conjunction with our acquisition of Lev, we acquired purchase obligations related to the supply and manufacturing of Cinryze. We have committed to purchase 75,000 liters of plasma per year through 2011 from our supplier and also have committed to purchase plasma collected from the Plasma Centers of America collection centers until our purchase of these centers. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer. The total minimum purchase commitments for these arrangements as of December 31, 2008 are approximately $89.6 million. Additionally we have a CVR of $87.5 million due upon approval of Cinryze for acute treatment of HAE. We submitted a sBLA in December 2008 and have a PDUFA date of June 3, 2009.

**Forward-Looking Statements**

Certain statements made in this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Additionally, words such as "seek," "intend," "believe," "plan," "estimate," "expect," "anticipate" and other similar expressions are forward-looking statements within the meaning of this act. Some or all of the results anticipated by these forward-looking statements may not occur due to a number of risks and uncertainties, including, but not limited to, our historical dependence on sales of Vancocin; our successful and timely commercialization of Cinryze; our ability to develop and receive regulatory approval for and commercialize drug product candidates and our ability to generate revenues from the commercialization and sale of products resulting from our product candidates; the time and expense associated with the regulatory process and commercialization of our product candidates; our ability to successfully identify HAE patients and achieve a significant market share in order to maintain profitability; the potential for significant competition from generic products due to the fact that our core patent protection for Vancocin has expired; the potential that the Orphan Drug Act may provide a competitor with up to seven years of market exclusivity for the acute treatment of HAE; our ability to remain competitive in the markets in which Vancocin or Cinryze serves; our limited sales and marketing infrastructure and ability to develop our own sales and marketing capability; our dependence upon the limited number of third party service providers who distribute our commercial products; our current and future dependence on third parties to manufacture raw, intermediate and finished goods for Vancocin, Cinryze and our product candidates; our dependence on supplies of U.S. human plasma; the risk of biological contamination inherent in plasma-derived products; the potential for us to become subject to product liability claims; the potential for competitors to develop products and technologies that make our products and/or technologies non-competitive or obsolete; the potential that any of our future products may not be accepted by the market; the potential that the current credit and financial market may exacerbate certain risks affecting our business; the potential that our strategic plan may not achieve the intended results; our dependence on collaborations with third parties; our failure to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties; the potential that other entities may seek to establish collaborative arrangements for product research and development, or otherwise acquire products, in competition with us; the potential that we are unable to obtain reimbursement for Cinryze from government health administration authorities, private health insurers and other organizations; the potential that there may be limitations on the amount of payment and reimbursement available to patients from third party payors related to Vancocin; the dependence of the successful commercialization of our product candidates on the availability and adequacy of third party reimbursement; our reliance on and the ability of our employees, consultants, contractors, suppliers, manufacturers and collaborators to keep our trade secrets confidential; our dependence on patents and proprietary rights for our products which are in clinical development; the ability of our licensors to protect our rights under our license agreements and to maintain the effectiveness of the license agreements; our dependence on and ability to retain key personnel; our compliance with regulatory requirements and unanticipated problems with our approved products; the effect of imports on revenues generated by our sales of Vancocin and Cinryze; the successful integration of, and our ability to realize the benefits associated with, our acquisition of Lev; risks associated with our international business relationships; the potential affect of charges to earnings resulting from the application of accounting methods on our common stock as a result of the acquisition of Lev; the potential that our indebtedness and other financial obligations may harm our financial condition and results of operations; the potential effect of the rights that have been, and may in the future be, granted to holders of our common or preferred stock on the rights other stockholders and any potential takeover; the potential that Lev stockholders may sell the ViroPharma common stock received as consideration in connection with the merger, on the market price of our common stock; that our stock price could continue to be volatile; the potential that the convertible note hedge and warrant transactions may affect the value of the senior convertible notes and our common stock; and the effect of the fundamental change purchase feature of the senior convertible notes on a potential takeover of our company.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our holdings of financial instruments are primarily 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 annualized weighted average nominal interest rate of our investment portfolio at during the year ended December 31, 2008, was approximately 0.6%. A one percent change in the interest rate would have resulted in a $0.6 million impact to interest income for the year ended December 31, 2008.

At February 25, 2009, we had outstanding $250 million of our senior convertible notes. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007. The senior convertible notes are convertible into shares of the Company's common stock at an initial conversion price of $18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the "measurement period") in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to ViroPharma's option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of December 31, 2008, the fair value of the $250.0 million convertible senior notes outstanding was approximately $194.4 million, based on the level 2 valuation hierarchy under SFAS 157.

In connection with the issuance of the senior convertible senior notes, we have entered into privately-negotiated transactions with two counterparties (the "counterparties"), comprised of purchased call options and warrants sold. These transactions are expected to generally reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes. These transactions expose the Company to counterparty credit risk for nonperformance. The Company manages its exposure to counterparty credit risk through specific minimum credit standards, and diversification of counterparties.

Beginning in 2006, we also have been exposed to movements in foreign currency exchange rates, specifically the Euro, for certain immaterial expenses. We have used foreign currency forward exchange contracts based on forecasted transactions to reduce this exposure to the risk that the eventual net cash outflows, resulting from purchases from foreign testing sites, will be adversely affected by changes in exchange rates. The nominal amount of these forwards as of December 31, 2008 was $0.3 million and the associated fair value was approximately $24,000, which is credited to research and development expenses.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements required by this item are attached to this Report beginning on page 68.

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

Not Applicable.

## ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO, and our 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, 2008. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2008 our disclosure controls and procedures were 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 within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company's management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

### Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2008, 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. We have not evaluated the effectiveness of internal control over financial reporting at Lev, which was acquired on October 21, 2008 and, as such, management's assessment of internal control over financial reporting does not extend to these controls.

### Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to the company's management and board of directors regarding the preparation and fair presentation of published consolidated financial statements. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues within a company are detected. The inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Management has not evaluated the effectiveness of internal control over financial reporting at Lev Pharmaceuticals, Inc. (Lev) which was acquired on October 21, 2008 and, as such, does not extend its conclusion regarding the effectiveness of internal control over financial reporting to the controls of that entity. Lev total assets were $102.8 million and total net sales were $23,000 as of and for the year ended December 31, 2008. See Note 3 of the notes to the consolidated financial statements for additional information on the Lev acquisition. Accordingly, management's assessment as of December 31, 2008 does not include the internal control over financial reporting of Lev.

Our management assessed the effectiveness of its internal control over financial reporting as of December 31, 2008. In making this assessment, it used the criteria based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control — Integrated Framework" (COSO). Based on our assessments we believe that, as of December 31, 2008, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm, KPMG LLP, has issued a report on the effectiveness of the Company's internal control over financial reporting appears on the next page.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ViroPharma Incorporated:

We have audited ViroPharma Incorporated's (the Company's) internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control — Integrated Framework issued by COSO.

The Company acquired Lev Pharmaceuticals, Inc. on October 21, 2008, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2008, Lev Pharmaceuticals, Inc.'s internal control over financial reporting associated with total assets of $102.8 million and total revenues of $23,000 included in the consolidated financial statements of the Company as of and for the year ended December 31, 2008. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of Lev Pharmaceuticals, Inc.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2008 and 2007, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2008, and our report dated February 27, 2009 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Short Hills, New Jersey
February 27, 2009

**ITEM 9B. OTHER INFORMATION**

Not Applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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 Annual Report in Part I entitled "Executive Officers of the Registrant".

Our Board of Directors has adopted a code of business conduct and ethics that applies to our principal executive officers, principal financial officer, and controller, as well as all other employees. A copy of this code of business conduct and ethics has been posted on our Internet website at www.viropharma.com under the investing – corporate governance section. In addition, hard copies can be obtained free of charge through our investor relations department. Any amendments to, or waivers from, a provision of our code of ethics that applies to our principal executive officer, principal financial officer, controller, or persons performing similar functions and that relate to any element of the code of ethics enumerated in paragraph (b) of Item 406 of Regulation S-K shall be disclosed by posting such information on our website.

The information concerning our corporate governance 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 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 AND RELATED STOCKHOLDER MATTERS

**Equity Compensation Plans**

We maintain the 2005 Equity Incentive Plan (the "2005 Plan"), the 1995 Stock Option and Restricted Share Plan (the "1995 Plan"), the 2001 Equity Incentive Plan (the "2001 Plan") and the 2000 Employee Stock Purchase Plan (the "ESPP"), pursuant to which we may grant equity awards to eligible persons. The 1995 Plan expired in September 2005, although there remain options outstanding that were previously granted under that plan. The 2001 Plan is described more fully below.

The following table gives information about equity awards under our 1995 Plan, 2001 Plan , 2005 Plan and ESPP as of December 31, 2008:

| Plan Category | (a) Number of securities to be issued upon exercise of outstanding options, warrants and rights | (b) Weighted-average exercise price of outstanding options, warrants and rights | (c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| Equity compensation plans approved by securities holders (the 1995 Plan, 2005 Plan and the ESPP) | 6,007,238(1) | $ 11.09(1) | 4,554,619 |
| Equity compensation plans not approved by security holders (the 2001 Plan) | 294,476 | $ 8.16 | 28,209 |
| Total | 6,301,714 | $ 10.95 | 4,582,828 |

(1) Does not include rights granted under the ESPP for which rights were granted in connection with the 6-month offering period that commenced in January 2009. The next scheduled purchase date under the Employee Stock Purchase Plan is June 30, 2009.

**2001 Equity Incentive Plan**

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

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

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

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

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

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

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

The additional 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, AND DIRECTOR INDEPENDENCE

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. PRINCIPAL ACCOUNTING 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 AND FINANCIAL STATEMENT SCHEDULES

| Exhibit No. | Description |
|---|---|
| 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. (1) (Exhibit 3.1) |
| 3.2 | Amended and Restated By-Laws of the Company. (2) (Exhibit 3.3) |
| 4.1 | Form of Indenture dated March 19, 2007 between the Company and Wilmington Trust Company, as Trustee. (26) (Exhibit 4.1) |
| 4.2 | First Supplemental Indenture, dated as of March 26, 2007, by and between the Company and Wilmington Trust Company, as Trustee. (26) (Exhibit 4.2) |
| 10.1†† | Form of Employment Agreement. (19) (Exhibit 10.1) |
| 10.2 | Form of Indemnification Agreement. (19) (Exhibit 10.2) |
| 10.3 | Investment Agreement among ViroPharma Incorporated and Perseus-Soros Biopharmaceutical Fund, L.P. dated May 5, 1999. (5) (Exhibit 10.20) |
| 10.4† | Stock Purchase Agreement dated December 9, 1999 between American Home Products Corporation and ViroPharma Incorporated. (7) (Exhibit 10.26) |
| 10.5† | First Amended and Restated Agreement dated February 27, 2001 between Sanofi-Synthelabo and ViroPharma Incorporated. (9) (Exhibit 10.32) |
| 10.6†† | 2001 Equity Incentive Plan. (10) (Exhibit 10.33) |
| 10.7 | Letter Agreement between ViroPharma Incorporated and Wyeth dated May 29, 2002. (11) (Exhibit 10.35) |
| 10.8†† | Amended and Restated ViroPharma Incorporated Employee Stock Purchase Plan. (12) |
| 10.9††* | Form of Change of Control Agreement between ViroPharma and certain of its employees. |
| 10.10† | First Amended and Restated Collaboration and License Agreement dated June 26, 2003 between ViroPharma Incorporated and Wyeth. (13) (Exhibit 10.33) |
| 10.11† | Amendment to Stock Purchase Agreement dated June 26, 2003 between ViroPharma Incorporated and Wyeth. (13) (Exhibit 10.34) |
| 10.12† | License Agreement dated August 8, 2003 by and between GlaxoSmithKline and ViroPharma Incorporated. (4) (Exhibit 10.35) |
| 10.13† | Letter Agreement dated November 24, 2003 between Sanofi-Synthelabo and the Company. (14) (Exhibit 10.34) |
| 10.14† | Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004.(15) (Exhibit 2.1) |
| 10.15† | Amendment No. 1 to the Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated November 8, 2004.(15) (Exhibit 2.2) |
| 10.16† | License Agreement between ViroPharma Incorporated and Schering Corporation dated November 3, 2004. (16) (Exhibit 2.1) |
| 10.17†† | ViroPharma Severance Plan. (19) (Exhibit 10.37) |
| 10.18†† | ViroPharma Cash Bonus Plan. (28) (Exhibit 10.2) |
| 10.19††* | ViroPharma Board Compensation Policy. |
| 10.20†† | Amended and Restated 1995 ViroPharma Stock Option and Restricted Share Plan. (18) |
| 10.21†† | 2005 Equity Incentive Plan. (24) |
| 10.22†† | Form Of Non-Qualified Stock Option Agreement For Member Of The Board Of Director. (20) (Exhibit 10.2) |
| 10.23†† | Form Of Non-Qualified Stock Option Agreement. (20) (Exhibit 10.3) |

| Exhibit No. | Description |
|---|---|
| 10.24†† | Form of Incentive Stock Option Agreement. (20) (Exhibit 10.4) |
| 10.25† | Master Agreement by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated effective as of December 1, 2005. (21) (Exhibit 10.41) |
| 10.26† | Project Agreement No. 1 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated. (21) (Exhibit 10.42) |
| 10.27† | Bulk Supply Agreement between ViroPharma and Alpharma Inc. dated April 13, 2006. (22) (Exhibit 10.1) |
| 10.28† | Project Agreement No. 2 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated dated May 15, 2006. (22) (Exhibit 10.2) |
| 10.29 | Real Estate Purchase Agreement between LV Associates, L.P. and the Company dated December 22, 2006. (28) (Exhibit 10.33) |
| 10.30 | Confirmation of Convertible Bond Hedge Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Credit Suisse International and Credit Suisse, New York Branch, as agent for Credit Suisse International. (26) (Exhibit 10.1) |
| 10.31 | Confirmation of Convertible Bond Hedge Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association. (26) (Exhibit 10.2) |
| 10.32 | Confirmation of Issuer Warrant Transaction dated as of March 20, 2007, by and between ViroPharma Incorporated and Credit Suisse International and Credit Suisse, New York Branch, as agent for Credit Suisse International. (26) (Exhibit 10.3)) |
| 10.33 | Confirmation of Issuer Warrant Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association.(26) (Exhibit 10.4) |
| 10.34 | Amendment to Confirmation of Issuer Warrant Transaction dated as of March 22, 2007, by and between ViroPharma Incorporated and Credit Suisse International and Credit Suisse, New York Branch, as agent for Credit Suisse International. (26) (Exhibit 10.4)) |
| 10.35 | Amendment to Confirmation of Issuer Warrant Transaction, dated as of March 22, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association. (26) (Exhibit 10.5) |
| 10.36† | Amended and Restated Bulk Supply Agreement between ViroPharma and Alpharma Inc. dated October 26, 2007.(23) (Exhibit 10.38) |
| 10.37 | Agreement and Plan of Merger, dated as of July 15, 2008, by and among ViroPharma Incorporated, HAE Acquisition Corp., and Lev Pharmaceuticals, Inc. (3) (Exhibit 2.1) |
| 10.38 | Form of Contingent Value Rights Agreement, by and among ViroPharma Incorporated, Lev Pharmaceuticals, Inc. and StockTrans, Inc. (3) (Exhibit 2.1) |
| 10.39†† | Separation Agreement, dated July 15, 2008, by and between Lev Pharmaceuticals, Inc., ViroPharma Incorporated and Joshua Schein. (6) (Exhibit 10.5) |
| 10.40†† | Separation Agreement, dated July 15, 2008, by and between Lev Pharmaceuticals, Inc., ViroPharma Incorporated and Judson Cooper. (6) (Exhibit 10.6) |
| 10.41† | Distribution and Manufacturing Services Agreement between Lev Pharmaceuticals, Inc. and Sanquin Blood Supply Foundation dated as of January 16, 2004 (8) (Exhibit 10.3) |
| 10.42 | First Amendment to the Distribution and Manufacturing Services Agreement between Lev Development Corp. and Sanquin Blood Supply Foundation dated as of January 30, 2006 (27)(Exhibit 10.3.1) . |
| 10.43† | Amendment No. 2 to Distribution and Manufacturing Services Agreement between Lev Development Corp. and Sanquin Blood Supply Foundation dated as of January 31, 2006 (27)(Exhibit 10.3.2) |
| 10.44 | Exclusive License Agreement between Lev Pharmaceuticals, Inc. and Sanquin Blood Supply Foundation dated as of January 27, 2004 (29) (Exhibit 10.4) |
| 10.45† | Plasma Supply Agreement dated April 12, 2007 (30) (Exhibit 10.4) |
| 10.46† | Agreement for the Purchase and Sale of Blood Plasma dated July 12, 2007 (31)(Exhibit 10.1) |

| Exhibit No. | Description |
|---|---|
| 10.47† | Amendment to Distribution and Manufacturing Services Agreement with Sanquin Blood Supply Foundation, dated as of September 24, 2007 (32) (Exhibit 10.2) |
| 10.48 | Strategic Supply Agreement, dated as of April 3, 2008, between the Company and Plasma Centers of America, LLC (33) ( Exhibit 10.2) |
| 10.49 | Intermediate Supply Agreement, dated as of April 9, 2008, between the Company and Biotest, AG (34) (Exhibit 10.2) |
| 10.50 | Lease Agreement with 730 Stockton Drive Associates, L.P. dated March 14, 2008. (35) (Exhibit 10.1) |
| 10.51†† | Letter Agreement with Michel de Rosen dated March 30, 2008 (36) (Exhibit 10.1) |
| 10.52†† | Letter Agreement between the Company and Robert Pietrusko dated January 9, 2009 (28) (Exhibit 10.1) |
| 14 | Code of Conduct and Ethics. (14)(Exhibit 14) |
| 21* | List of Subsidiaries. |
| 23* | Consent of KPMG LLP, Independent Registered Public Accounting Firm. |
| 24* | Power of Attorney (included on signature page). |
| 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 24b-2 under the Securities Exchange Act of 1934, as amended.

†† Compensation plans and arrangements for executives and others.

(1) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2000.
(2) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 14, 2008.
(3) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on July 18, 2008.
(4) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2003.
(5) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 1999.
(6) Filed as an Exhibit to the Current Report on Form 8-K filed with the Commission on July 18, 2008 by Lev Pharmaceuticals, Inc.
(7) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 1999.
(8) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2005.
(9) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2001.
(10) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2001.
(11) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2002.
(12) Filed as an Annex to Registrant's Proxy Statement filed with the Commission on March 27, 2003.
(13) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2003.
(14) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on April 11, 2008.
(15) Filed as an Exhibit to the Company's Current Report on Form 8-K/A filed with the Commission on November 24, 2004.
(16) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 29, 2004.
(17) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 15, 2005.
(18) Filed as an Annex to Registrant's Proxy Statement filed with the Commission on April 8, 2002.
(19) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2004.
(20) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2005.
(21) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2005.
(22) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2006.
(23) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2008.
(24) Field as Annex to Registrant's Proxy Statement filed with the Commission on April 11, 2008.
(25) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (333-141411) filed with the Commission on March 19, 2007.

(26) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 26, 2007.
(27) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006.
(28) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on January 8, 2009.
(29) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2005.
(30) Filed as an Exhibit to Form 10-QSB/A filed by Lev Pharmaceuticals, Inc. on August 27, 2007.
(31) Filed as an Exhibit to Form 8-K filed by Lev Pharmaceuticals, Inc. on July 25, 2007.
(32) Filed as an Exhibit to Form 10-QSB filed by Lev Pharmaceuticals, Inc. on November 14, 2007.
(33) Filed as an Exhibit to Form 10-Q filed by Lev Pharmaceuticals, Inc. on April 30, 2008.
(34) Filed as an Exhibit to Form 10-Q filed by Lev Pharmaceuticals, Inc. on August 8, 2008.
(35) Filed as an Exhibit Registrant's Form 10-Q for the quarter ended March 31, 2008.
(36) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on April 3, 2008.
(37) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006
(38) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006

**Copies of the exhibits are available to stockholders from Peter Wolf, Vice President, General Counsel and Secretary, ViroPharma Incorporated, 730 Stockton Drive, 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/ Vincent J. Milano

Vincent J. Milano
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 Vincent J. Milano and Charles A. Rowland, Jr. 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:**

| Name | Capacity | Date |
|---|---|---|
| /s/ VINCENT J. MILANO<br>**Vincent J. Milano** | President, Chief Executive Officer<br>(Principal Executive Officer) | February 27, 2009 |
| /s/ Charles A. Rowland, Jr.<br>**Charles A. Rowland, Jr.** | Chief Financial Officer<br>(Principal Financial Officer) | February 27, 2009 |
| /s/ Richard S. Morris<br>**Richard S. Morris** | Chief Accounting Officer and Controller<br>(Principal Accounting Officer) | February 27, 2009 |
| /s/ VINCENT J. MILANO<br>**Vincent J. Milano** | Chairman of the Board | February 27, 2009 |
| /s/ PAUL A. BROOKE<br>**Paul A. Brooke** | Director | February 27, 2009 |
| /s/ WILLIAM CLAYPOOL, M.D.<br>**William Claypool, M.D.** | Director | February 27, 2009 |
| /s/ MICHAEL R. DOUGHERTY<br>**Michael R. Dougherty** | Director | February 27, 2009 |
| /s/ ROBERT J. GLASER<br>**Robert J. Glaser** | Director | February 27, 2009 |
| /s/ JOHN R. LEONE<br>**John R. Leone** | Director | February 27, 2009 |
| /s/ Howard H. Pien<br>**Howard H. Pien** | Director | February 27, 2009 |

**ViroPharma Incorporated**

**Index to Consolidated Financial Statements**

## 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 as of December 31, 2008 and 2007, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2008. 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 as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S generally accepted accounting principles.

As discussed in Notes 2, 12, 13 and 15 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, on January 1, 2008, Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of Financial Accounting Standards No. 109, *Accounting for Income Taxes* on January 1, 2007, and Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, on January 1, 2006.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of ViroPharma Incorporated's internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2009 expressed an unqualified opinion on the effective operation of internal control over financial reporting.

/s/ KPMG LLP

Short Hills, New Jersey
February 27, 2009

**ViroPharma Incorporated**
Consolidated Balance Sheets

| (in thousands, except share and per share data) | December 31, 2008 | December 31, 2007 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 275,839 | $ 179,691 |
| Short-term investments | — | 404,637 |
| Accounts receivable, net | 15,058 | 17,684 |
| Inventory | 27,168 | 4,703 |
| Interest receivable | 5 | 5,095 |
| Prepaid expenses and other | 5,115 | 2,138 |
| Income taxes receivable | 6,867 | 842 |
| Property and building held for sale | 6,734 | — |
| Deferred income taxes | 24,094 | 7,983 |
| Total current assets | 360,880 | 622,773 |
| Intangible assets, net | 639,693 | 122,502 |
| Property, equipment and building improvements, net | 6,853 | 10,890 |
| Goodwill | 29,936 | — |
| Deferred income taxes | — | 12,312 |
| Debt issue costs, net | 6,610 | 7,550 |
| Other assets | 9,712 | 39 |
| Total assets | $ 1,053,684 | $ 776,066 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,719 | $ 2,017 |
| Due to partners | 1,278 | 1,008 |
| Accrued expenses and other current liabilities | 35,650 | 24,466 |
| Income taxes payable | 820 | 879 |
| Total current liabilities | 43,467 | 28,370 |
| Non-current income tax payable and other non-current liabilities | 4,072 | 1,133 |
| Deferred tax liabilities | 95,121 | — |
| Long-term debt | 250,000 | 250,000 |
| Total liabilities | 392,660 | 279,503 |
| Commitments and Contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, par value $0.001 per share. 5,000,000 shares authorized; Series A convertible participating preferred stock; no shares issued and outstanding | — | — |
| Series A junior participating preferred stock, par value $0.001 per share. 200,000 shares designated; no shares issued and outstanding | — | — |
| Common stock, par value $0.002 per share. 175,000,000 shares authorized; issued and outstanding 77,397,621 shares and 69,904,659 shares at December 31, 2008 and 2007 | 156 | 140 |
| Additional paid-in capital | 595,287 | 498,350 |
| Accumulated other comprehensive loss | (655) | (546) |
| Retained earnings (accumulated deficit) | 66,236 | (1,381) |
| Total stockholders' equity | 661,024 | 496,563 |
| Total liabilities and stockholders' equity | $ 1,053,684 | $ 776,066 |

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**
Consolidated Statements of Operations

| (in thousands, except per share data) | Year ended December 31, 2008 | 2007 | 2006 |
|---|---|---|---|
| **Revenues:** | | | |
| Net product sales | $ 232,307 | $ 203,770 | $ 166,617 |
| License fee and milestone revenue | — | — | 564 |
| Total revenues | 232,307 | 203,770 | 167,181 |
| **Costs and Expenses:** | | | |
| Cost of sales (excluding amortization of product rights) | 8,874 | 8,934 | 18,984 |
| Research and development | 66,280 | 35,869 | 19,162 |
| Selling, general and administrative | 65,424 | 37,051 | 24,560 |
| Intangible amortization | 10,809 | 6,120 | 5,669 |
| Impairment loss on fixed asset held for sale | 2,265 | — | — |
| Total costs and expenses | 153,652 | 87,974 | 68,375 |
| Operating income | 78,655 | 115,796 | 98,806 |
| **Other Income (Expense):** | | | |
| Interest income | 14,296 | 24,265 | 9,853 |
| Interest expense | (5,852) | (4,395) | (686) |
| Other income | — | — | 555 |
| Income before income tax expense | 87,099 | 135,666 | 108,528 |
| Income tax expense | 19,482 | 40,313 | 41,862 |
| Net income | $ 67,617 | $ 95,353 | $ 66,666 |
| **Net income per share:** | | | |
| Basic | $ 0.95 | $ 1.37 | $ 0.97 |
| Diluted | $ 0.83 | $ 1.21 | $ 0.95 |
| Shares used in computing net income per share: | | | |
| Basic | 71,391 | 69,827 | 68,990 |
| Diluted | 85,712 | 80,891 | 70,338 |

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**
Consolidated Statements of Comprehensive Income

| (in thousands) | Year ended December 31, 2008 | 2007 | 2006 |
|---|---|---|---|
| Net income | $ 67,617 | $ 95,353 | $ 66,666 |
| Other comprehensive income: | | | |
| Unrealized holding gains (losses) arising during period, net of income taxes of $300 in 2008, $(326) in 2007 and $160 in 2006 | 550 | (608) | 407 |
| Foreign currency translation adjustment | (659) | 5 | — |
| Comprehensive income | $ 67,508 | $ 94,750 | $ 67,073 |

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**
Consolidated Statements of Stockholders' Equity

| (in thousands) | Preferred stock Number of shares | Preferred stock Amount | Common stock Number of shares | Common stock Amount | Additional paid-in capital | Accumulated other comprehensive income (loss) | Accumulated deficit | Total stockholders' equity |
|---|---|---|---|---|---|---|---|---|
| Balance, December 31, 2005 | — | $ — | 68,564 | $ 137 | $ 490,590 | $ (350) | $ (163,400) | $ 326,977 |
| Issuance of common stock, net of issuance costs | — | — | 982 | 2 | 9,935 | — | — | 9,937 |
| Exercise of common stock options | — | — | 208 | 1 | 811 | — | — | 812 |
| Employee stock purchase plan | — | — | 16 | — | 106 | — | — | 106 |
| Unrealized gains on available-for-sale securities | — | — | — | — | — | 407 | — | 407 |
| Share-based compensation | — | — | — | — | 5,055 | — | — | 5,055 |
| Record liability classified share-based obligations | — | — | — | — | (113) | — | — | (113) |
| Stock option tax benefits | — | — | — | — | 703 | — | — | 703 |
| Excess tax benefits due to debt conversions | — | — | — | — | 1,349 | — | — | 1,349 |
| Net income | — | — | — | — | — | — | 66,666 | 66,666 |
| Balance, December 31, 2006 | — | $ — | 69,770 | 140 | 508,436 | 57 | (96,734) | 411,899 |
| Issuance of common stock | — | — | 22 | — | 187 | — | — | 187 |
| Exercise of common stock options | — | — | 113 | — | 525 | — | — | 525 |
| Cost of call spread options, net | — | — | — | — | (23,250) | — | — | (23,250) |
| Unrealized gains on available-for-sale securities | — | — | — | — | — | (608) | — | (608) |
| Share-based compensation | — | — | — | — | 7,641 | — | — | 7,641 |
| Tax benefit on convertible note hedge | — | — | — | — | 4,507 | — | — | 4,507 |
| Stock option tax benefits | — | — | — | — | 304 | — | — | 304 |
| Cumulative translation adjustment | — | — | — | — | — | 5 | — | 5 |
| Net income | — | — | — | — | — | — | 95,353 | 95,353 |
| Balance, December 31, 2007 | — | $ — | 69,905 | $ 140 | $ 498,350 | $ (546) | $ (1,381) | $ 496,563 |
| Issuance of common stock | — | — | 21 | — | 180 | — | — | 180 |
| Exercise of common stock options | — | — | 112 | 1 | 359 | — | — | 360 |
| Unrealized gains on available-for-sale securities | — | — | — | — | — | 550 | — | 550 |
| Share-based compensation | — | — | — | — | 8,932 | — | — | 8,932 |
| Tax benefit on convertible note hedge | — | — | — | — | 1,262 | — | — | 1,262 |
| Stock option tax benefits | — | — | — | — | 184 | — | — | 184 |
| Cumulative translation adjustment | — | — | — | — | — | (659) | — | (659) |
| Acquisition of Lev | — | — | 7,360 | 15 | 86,020 | — | — | 86,035 |
| Net income | — | — | — | — | — | — | 67,617 | 67,617 |
| Balance, December 31, 2008 | — | $ — | 77,398 | $ 156 | $ 595,287 | $ (655) | $ 66,236 | $ 661,024 |

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**
Consolidated Statements of Cash Flows

| (in thousands) | Year ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| Cash flows from operating activities: | | | |
| Net income | $ 67,617 | $ 95,353 | $ 66,666 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Non-cash share-based compensation expense | 8,938 | 7,600 | 4,998 |
| Non-cash building impairment | 2,265 | — | — |
| Non-cash interest expense | 789 | 625 | 75 |
| Deferred tax provision | 13,831 | 11,464 | 19,387 |
| Depreciation and amortization expense | 11,989 | 6,924 | 6,166 |
| Other | — | — | (555) |
| Changes in assets and liabilities, excluding the effect of acquisition: | | | |
| Accounts receivable | 2,991 | (8,237) | 5,440 |
| Inventory | (3,129) | 57 | 6,236 |
| Interest receivable | 5,095 | (1,805) | (3,278) |
| Prepaid expenses and other current assets | (118) | (111) | (127) |
| Income taxes payable/receivable | (6,084) | (23) | 2,037 |
| Other assets | (8,279) | 10 | — |
| Accounts payable | 1,573 | (726) | (6,513) |
| Due to partners | 270 | 225 | 762 |
| Accrued expenses and other current liabilities | (6,387) | 10,378 | (5,893) |
| Non-current income tax payable and other | 76 | 1,133 | — |
| Other liabilities | — | — | (385) |
| Net cash provided by operating activities | 91,437 | 122,867 | 95,016 |
| Cash flows from investing activities: | | | |
| Purchase of Lev Pharmaceuticals, Inc., net of cash acquired | (380,218) | — | — |
| Purchase of Vancocin assets | (7,000) | (5,950) | (6,650) |
| Purchase of equipment and leasehold improvements | (2,529) | (8,866) | (1,771) |
| Purchases of short-term investments | — | (789,707) | (1,256,862) |
| Maturities and sales of short-term investments | 405,187 | 588,347 | 1,056,285 |
| Net cash provided by (used in) investing activities | 15,440 | (216,176) | (208,998) |
| Cash flows from financing activities: | | | |
| Repayment of acquired debt | (12,056) | — | — |
| Net proceeds from the issuance of senior convertible notes | — | 241,825 | — |
| Net purchase of call spread options | — | (23,250) | — |
| Tax benefit from call spread transactions | 1,262 | 1,880 | — |
| Net proceeds from issuance of common stock | 540 | 712 | 10,855 |
| Excess tax benefits from share-based payment arrangements | 184 | 304 | 703 |
| Excess tax benefits due to debt conversions | — | — | 1,349 |
| Redemption of subordinated convertible notes | — | — | (79,596) |
| Net cash provided by (used in) financing activities | (10,070) | 221,471 | (66,689) |
| Effect of exchange rate changes on cash | (659) | 5 | — |
| Net increase (decrease) in cash and cash equivalents | 96,148 | 128,167 | (180,671) |
| Cash and cash equivalents at beginning of year | 179,691 | 51,524 | 232,195 |
| Cash and cash equivalents at end of year | $ 275,839 | $ 179,691 | $ 51,524 |

See accompanying notes to consolidated financial statements.

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

## Note 1. Organization and Business Activities

ViroPharma Incorporated and subsidiaries ("ViroPharma" or the "Company") is a global biopharmaceutical company dedicated to the development and commercialization of products that address serious diseases, with a focus on products used by physician specialists or in hospital settings. The Company intends to grow through sales of its marketed products, Vancocin and Cinryze™, through continued development of its product pipeline and through potential acquisition or licensing of products or acquisition of companies. ViroPharma has two marketed products, and three development programs.

The Company markets and sells Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. 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* infection (CDI), or *C. difficile*, and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On October 21, 2008, we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev), a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. As a result of the merger, we obtained Cinryze, which has been approved by the FDA for the prophylactic treatment of hereditary angioedema (HAE) and was launched commercially in 2008. Post the acquisition, we resubmitted the portion of the Cinryze BLA referring to the data for the acute treatment of HAE attacks along with additional data from the ongoing open label acute studies of Cinryze. Cinryze is a C1 inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor deficiency, a rare, severely debilitating, life-threatening genetic disorder.

ViroPharma is developing two new product candidates, maribavir for the prevention and treatment of cytomegalovirus, or CMV disease; and non-toxigenic strains of C. *difficile* (NTCD) for the treatment and prevention of CDI. On February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant (SCT) patients did not achieve its primary endpoint. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. Additionally, on February 13, 2009, we announced that enrollment in our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to current standard of care.

## Note 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 subsidiaries. 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.

*Short-term investments*

During 2008 and 2007, short-term investments have consisted 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 and are intended to meet the ongoing liquidity needs of the Company. Net unrealized holding gains and losses are included in accumulated other comprehensive income (loss). For purposes of determining gross realized gains and losses, the cost of short-term investments sold is based upon specific identification. Discounts and premiums are amortized over the term of the security and reported in interest income. The investments are reviewed on a periodic basis for other-than-temporary impairments (See Note 4).

*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 to reduce the Company's credit risk.

The Company has an exposure to credit risk in its trade accounts receivable from sales of Vancocin. Vancocin is distributed through wholesalers that sell the product to pharmacies and hospitals. Three wholesalers represent approximately 88% of our trade accounts receivable at December 31, 2008 and approximately 94% of our 2008 net product sales.

The Company, in connection with the issuance of the senior convertible senior notes, have entered into privately-negotiated transactions with two counterparties (the "counterparties"), comprised of purchased call options and warrants sold. These transactions will reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes. These transactions expose the Company to counterparty credit risk for nonperformance. The Company manages its exposure to counterparty credit risk through specific minimum credit standards, and diversification of counterparties.

*Single source supplier*

The company currently outsources all of our toll manufacturing agreements to single source manufactures for Vancocin and Cinryze. A change in suppliers for Vancocin or Cinryze could cause a delay in manufacturing and a possible loss of sales, which would affect operating results adversely.

*Accounts receivable*

Accounts receivable are recorded at the invoiced amount, net of related cash discounts and do not bear interest. The allowance for doubtful accounts is based on a specific review of the Company's accounts receivable. At December 31, 2008 and 2007, there was no allowance for doubtful accounts. The Company does not have any off-balance sheet exposure related to its customers.

*Inventories*

Inventories are stated at the lower of cost, using the first-in, first-out method, or market. At December 31, 2008 and 2007, inventory consists of finished goods. work-in-process (WIP) and certain starting materials required to produce inventory of Vancocin and Cinryze. At December 31, 2007, inventory consists of finished goods and certain starting materials required to produce inventory of Vancocin.

*Property, equipment and building improvements*

Property, equipment and building 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, which ever is shorter, ranging from three to thirty years.

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

*Goodwill and Intangible Assets*

Goodwill is not amortized, but is evaluated annually for impairment or when indicators of a potential impairment are present. Our impairment testing of goodwill is performed separately from our impairment testing of individual indefinite-lived intangibles. The annual evaluation for impairment of goodwill is based on valuation models that incorporate assumptions and internal projections of expected future cash flows and operating plans. We believe such assumptions are also comparable to those that would be used by other marketplace participants.

Intangible assets, net of accumulated amortization, includes the allocation of the cost to acquire the rights to the oral formulation of Vancocin, the rights to certain vancomycin related Vancocin products (Note 7), from Eli Lilly and Company (Lilly) and Cinryze product rights (Note 3) from Lev in conjunction with our acquisition of Lev in October 2008. The Company based its intangible assets' valuation and related estimated useful life on third party evaluations of the assets. Intangible assets acquired as part of the Vancocin and Lev acquisitions are being amortized on a straight-line basis over their estimated useful lives of 25 years. 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 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, as necessary in accordance with Statement of Financial Accounting Standards (SFAS) SFAS No. 144, *Accounting for the impairment or disposal of long-lived assets* (SFAS 144). 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 impairment is indicated, a charge is recognized for the difference between the asset's carrying value and fair value. In 2008 we recorded an impairment of $2.3 million related to our previous Company headquarters that is no longer being utilized. The building was classified as held for sale in the fourth quarter of 2008 and the impairment represents the difference between the carrying value and the estimated sales price less costs to dispose.

During the first quarter of 2009, the market capitalization of ViroPharma fell below the carrying value of ViroPharma's net assets due to the announcements surrounding our maribavir development program. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), this situation would require us to test for impairment of our goodwill and other intangible assets if the situation continues at March 31, 2009. This analysis will be conducted at March 31, 2009 and depending on our stock price and fair market value of our assets, this could lead to an impairment charge at that time

*Revenue recognition*

Revenue is recognized when all four of the following criteria are met (1) the Company has persuasive evidence an arrangement exists, (2) the price is fixed and determinable, (3) title has passed, and (4) collection is reasonably assured. 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.

Product revenue for Vancocin is recorded upon delivery to the wholesaler, when title has passed. 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 periodically estimates and evaluates the wholesalers' inventory position and would defer recognition of revenue on product that has been delivered if the Company believes that channel inventory at a period end is in excess of ordinary business needs and if the Company believes the value of potential returns is materially different than the returns accrual. During 2008, 2007 and 2006, the Company did not defer any Vancocin product sales. Product revenue for Cinryze, due to its recent launch, is recognized when prescribed and deferred until the product is shipped to the end customer by the specialty pharmacy.

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.

*Sales Allowances*

The Company records appropriate sales allowances upon the recognition of product revenue. The Company's return policy for Vancocin is limited to damaged or expired product. Cinryze has a no return policy. The return allowance is determined based on analysis of the historical rate of returns associated with Vancocin, which is then applied to sales, and is analyzed considering estimated wholesaler inventory and prescriptions. The chargeback and rebate allowances are determined based on analysis of the historical experience of government agencies' market share and governmental contractual prices relative to current selling prices, as well as the payor mix information provided by our wholesalers and from information obtained through Cinryze Solutions.

*Customers*

The Company's net product sales are related to Vancocin and Cinryze. For Vancocin, our customers are wholesalers who then distribute the product to pharmacies, hospitals and long term care facilities, among others. In December 2008, we shipped a limited amount of Cinryze to specialty pharmacy and specialty distributors (SP/SD) who will distribute the product to physicians, hospitals and patients.

Three wholesalers represent the majority of the Company's consolidated total revenue, as approximated below:

| | Percentage of total revenues | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| Customer A | 39% | 37% | 38% |
| Customer B | 38% | 40% | 35% |
| Customer C | 17% | 16% | 19% |
| Total | 94% | 93% | 92% |

*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.

*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. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which related temporary difference becomes deductible. The benefit of tax positions taken or expected to be taken in the Company's income tax returns are recognized in the consolidated financial statements if such positions are more likely than not of being sustained.

*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.

*Share-based payments*

The Company adopted SFAS No. 123R, *Share-based Payments* (SFAS 123R) using the modified prospective approach effective January 1, 2006. While this adoption had an immaterial impact on our financial statements on the date of adoption, the consolidated financial statements for the year ended December 31, 2006 were materially impacted. Results for prior periods are not restated. The Company previously accounted for share-based compensation under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and related interpretations. Under APB 25, compensation cost for employee and director grants was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123R requires 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. 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 are estimated using the Black-Scholes option-pricing model adjusted for the unique characteristics of those instruments. See Note 12 for the disclosures related to share-based compensation.

Compensation expense for options granted to non-employees is determined in accordance with SFAS 123R, 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.

*Earnings per share*

Basic earnings per share (EPS) is calculated by dividing net income by the weighted average shares of common stock outstanding during the period. Diluted EPS reflects the potential dilution of securities that could share in the earnings, including the effect of dilution to net income of convertible securities, stock options and warrants. (See Note 14)

*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 U.S. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and does not have separately reportable segments as defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

*Comprehensive income*

SFAS No. 130, *Reporting Comprehensive Income* (SFAS 130), establishes standards for reporting and presentation of comprehensive income and its components in a full set of financial statements. Comprehensive income consists of net income and net unrealized gains (losses) on available–for-sale securities and is presented in the consolidated statements of comprehensive income. SFAS 30 requires only additional disclosures in the financial statements; it does not affect the Company's financial position or results of operations.

*Reclassification*

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

*New Accounting Standards*

In June 2007, the Emerging Issues Task Force (EITF) issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 7-03) that provides guidance for upfront payments related to goods and services of research and development costs. The Company adopted this EITF as of January 1, 2008 with no material impact on operating results or financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), which allow companies to elect fair-value measurement when an eligible financial asset or financial liability is initially recognized or when an event, such as a business combination, triggers a new basis of accounting for that financial asset or financial liability. The election must be applied to individual contracts, is irrevocable for every contract chosen to be measured at fair value, and must be applied to an entire contract, not to only specified risks, specific cash flows, or portions of that contract. Changes in the fair value of contracts elected must be measured at fair value and recognized in earnings each reporting period. The Company adopted this SFAS as of January 1, 2008 with no impact on operating results or financial position.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS 157) which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. This statement applies under other accounting pronouncements that require or permit fair value measurements. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model. Relative to SFAS 157, the FASB issued FASB Staff Positions (FSP) 157-1, FSP 157-2, and proposed FSP 157-c. FSP 157-1 amends SFAS 157 to exclude SFAS 13 and its related interpretive accounting pronouncements that address leasing transactions, while FSP 157-2 delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. FSP 157-c clarifies the principles in SFAS 157 on the fair value measurement of liabilities. Public comments on FSP 157-c were due in February 2008, and responses and recommendations were presented to the board on April 9, 2008. We adopted SFAS 157 as of January 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities. While we are currently evaluating the impact of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities on our financial statements upon adoption, we do not anticipate a material impact on our operating results or financial position. Refer to Note 15 of the Consolidated Financial Statements for additional discussion on fair value measurements.

In October 2008, the FASB issued FSP FAS No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. The FSP clarifies the application of SFAS 157 when the market for a financial asset is not active. The FSP was effective upon issuance, including reporting for prior periods for which financial statements have not been issued. The adoption of the FSP for reporting as of December 31, 2008 did not have a material impact on the Company's consolidated financial statements. See Note 15 for further information on fair value measurements.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertain Tax Positions*, (FIN 48) to clarify the criteria for recognizing tax benefits related to uncertain tax positions under SFAS No. 109, *Accounting for Income Taxes*, and to require additional financial statement disclosure. FIN 48 requires that the Company recognize in its consolidated financial statements the impact of a tax position if that position is more likely than not to be sustained upon examination, based on the technical merits of the position. Adoption of FIN 48 as of January 1, 2007 is reflected in Note 13.

**Note 3. Lev Pharmaceuticals, Inc Acquisition**

In October 2008, we acquired all the outstanding common stock of Lev Pharmaceuticals, Inc. (Lev). Lev was a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration of $453.1 million, or $2.75 per Lev share, comprised of $2.25 per share in cash and $0.50 per share in ViroPharma common stock, and contingent consideration (CVR's) of up to $1.00 per share which may be paid on achievement of certain regulatory and commercial milestones. The first CVR payment of $0.50 per share (or $87.5 million) would become payable when either (i) Cinryze is approved by the FDA for acute treatment of HAE and the FDA grants orphan exclusivity for Cinryze encompassing the acute treatment of HAE to the exclusion of all other human C1 inhibitor products or, (ii) orphan exclusivity for the acute treatment of HAE has not become effective for any third party's human C1 inhibitor product by October 21, 2010. The second CVR payment of $0.50 per share ($87.5 million) would become payable when Cinryze reaches at least $600 million in cumulative net product sales within 10 years of closing of the acquisition.

The purchase price was as follows:

| | (in thousands) |
|---|---|
| Amount of cash paid to holders of Lev common stock, stock options and warrants | $ 367,079 |
| Fair value of shares of ViroPharma common stock | 86,035 |
| Original cost of ViroPharma's investment in Lev common stock | 20,000 |
| Transaction fees, including separation payments of $13.3 million made to Lev senior management at closing | 20,983 |
| Total purchase price | $ 494,097 |

The total cost of the acquisition was allocated to Lev's assets acquired and liabilities as follows:

| | (in thousands) |
|---|---|
| Cash | $ 27,844 |
| Accounts receivable | 365 |
| Inventory | 19,336 |
| Property and equipment | 177 |
| Deferred income taxes | 115,685 |
| Loan receivable | 3,111 |
| Other assets | 1,147 |
| Intangible product rights | 521,000 |
| Goodwill | 29,936 |
| **Total assets** | $ 718,601 |
| **Liabilities assumed:** | |
| Accounts payable | $ 2,129 |
| Accrued expenses | 17,142 |
| Long-term debt | 12,056 |
| Deferred tax liabilities | 193,177 |
| **Total liabilities** | $ 224,504 |
| **Total purchase price** | $ 494,097 |

The value of the CVR's has not been included in the total cost of the acquisition, as the payment of these amounts is not reasonably assured at this time. Should any of the contingently issued payments be made, that value would be added to the purchase price. Additionally, as part of the purchase price allocation, we released the valuation allowance for ViroPharma's existing deferred tax assets that management believes are more likely than not to be realized as a result of the acquisition. This allocation of purchase price to Lev's assets acquired and liabilities assumed is preliminary and may change when final purchase price allocation is completed within one year.

As a result of the acquisition, we obtained Cinryze, a C1 inhibitor, which has been approved by the FDA for routine prophylaxis of hereditary angioedema (HAE) also known as C1 inhibitor deficiency, a rare, severely debilitating, life-threatening genetic disorder. We determined that Cinryze product rights have a fair value of $521.0 million. The estimated fair value of the identifiable product rights for Cinryze was determined based upon a discounted cash flows model using a discount rate of 19%. Additionally, we have determined that the estimated useful life for the Cinryze product rights is 25 years. The amortization expense recognized in 2008 is $4.0 million.

The results of Lev's operations have been included in the consolidated financial statements beginning October 21, 2008. The following unaudited pro forma consolidated financial information reflects the Company's consolidated results of operations for the years ended December 31, 2008 and December 31, 2007 as if the acquisition had occurred as of January 1, 2008 and January 1, 2007. These pro forma results have been prepared for information purposes only and are not indicative of the results of operations that would have been achieved if the acquisition had taken place on January 1, 2008 and January 1, 2007 respectively or results that may occur in the future.

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| | (Unaudited) | |
| Revenue | $ 232,307 | $ 203,770 |
| Net income | $ 18,905 | $ 40,166 |
| Diluted earnings per share | $ 0.25 | $ 0.49 |

**Note 4. Short-Term Investments**

Short-term investments consist of fixed income securities with remaining maturities of greater than three months at the date of purchase, debt securities and equity securities. At December 31, 2008, we did not have any short term investments. At December 31, 2007, all of the fixed income and debt securities were classified as available for sale investments and measured as Level 1 instruments under SFAS 157.

The following summarizes the available-for-sale investments at December 31, 2007:

| (in thousands) | Cost | Gross unrealized gains | Gross unrealized losses | Fair value |
|---|---|---|---|---|
| **December 31, 2007** | | | | |
| Debt securities: | | | | |
| Corporate | $ 405,487 | $ 262 | $ 1,112 | $ 404,637 |
| | $ 405,487 | $ 262 | $ 1,112 | $ 404,637 |
| Maturities of investments were as follows: | | | | |
| Less than one year | $ 405,487 | $ 262 | $ 1,112 | $ 404,637 |

**Note 5. Inventory**

Inventory is related to Vancocin and is stated at the lower of cost, using the first-in first-out method, or market. The following represents the components of the inventory at December 31, 2008 and 2007:

| (in thousands) | 2008 | 2007 |
|---|---|---|
| Raw Materials | $ 11,861 | $ 3,355 |
| Work In Process | 10,802 | — |
| Finished Goods | 4,505 | 1,348 |
| Total | $ 27,168 | $ 4,703 |

**Note 6. Property, Equipment and Building Improvements**

Property, equipment and building improvements consists of the following at December 31, 2008 and 2007:

| (in thousands) | 2008 | 2007 |
|---|---|---|
| Land | $ — | $ 380 |
| Building | — | 7,221 |
| Computers and equipment | 6,219 | 3,576 |
| Leasehold improvements | 3,388 | 2,189 |
| | 9,607 | 13,366 |
| Less: accumulated depreciation and amortization | 2,754 | 2,476 |
| Equipment and leasehold improvements, net | $ 6,853 | $ 10,890 |

Additionally, at December 31, 2008, we had $6.7 million of Property and Building classified as “held for sale” in accordance with SFAS 144. These assets are those from our previous Company headquarters which we purchased in 2007 and vacated in October 2008.

The useful life for the major categories of property and equipment are 30 years for the building, 3 to 5 years for computers and equipment and 15 years for building improvements.

**Note 7. Intangible Assets**

The following represents the balance of the intangible assets at December 31, 2008:

| (in thousands) | Gross Intangible Assets | Accumulated Amortization | Net Intangible Assets |
|---|---|---|---|
| Product rights | $ 521,000 | $ 4,034 | $ 516,966 |
| Trademarks | 13,166 | 2,181 | 10,985 |
| Know-how | 92,160 | 15,270 | 76,890 |
| Customer relationship | 41,773 | 6,921 | 34,852 |
| Total | $ 668,099 | $ 28,406 | $ 639,693 |

The following represents the balance of the intangible assets at December 31, 2007:

| (in thousands) | Gross Intangible Assets | Accumulated Amortization | Net Intangible Assets |
|---|---|---|---|
| Trademarks | $ 12,539 | $ 1,575 | $ 10,964 |
| Know-how | 87,774 | 11,025 | 76,749 |
| Customer relationship | 39,786 | 4,997 | 34,789 |
| Total | $ 140,099 | $ 17,597 | $ 122,502 |

The estimated fair value of the identifiable product rights for Cinryze was determined based upon a discounted cash flows model using an appropriate discount rate. The asset will be amortized over its related useful life of 25 years.

In March 2006, the Company learned that the FDA's Office of Generic Drugs (OGD) had changed its approach regarding the conditions that must be met in order for a generic drug applicant to request a waiver of in-vivo bioequivalence testing for copies of Vancocin. Since this change in approach is, in accordance with SFAS 144, a triggering event and potentially impacts the recoverability or useful life of the Vancocin-related intangible assets, the Company assessed the Vancocin-related intangible assets for potential impairment or change in useful life. While the Company is opposing this attempt by the OGD, the outcome can not be reasonably determined and the impact of this change on market share and net sales is uncertain. However, the Company determined that no impairment charge was appropriate at that time as management believes the undiscounted cash flows, which consider some level of generic impact, will be sufficient to recover the carrying value of the asset and there has been no change to fair value.

In the event the OGD's revised approach for Vancocin remains in effect, the time period in which a generic competitor may enter the market would be reduced. This could result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market.

A reduction in the useful life, as well as the timing and number of generics, will impact our cash flow assumptions and estimate of fair value, perhaps to a level that could result in an impairment charge. The Company will continue to monitor the actions of the OGD and consider the effects of our opposition actions and the announcements by generic competitors or other adverse events for additional impairment indicators and will reevaluate the expected cash flows and fair value of our Vancocin-related assets at such time.

The Company is obligated to pay Eli Lilly and Company (Lilly) additional purchase price consideration based on net sales of Vancocin within a calendar year. The additional purchase price consideration is determined by the annual net sales of Vancocin, is paid quarterly and is due each year through 2011. The Company accounts for these additional payments as additional purchase price in accordance with SFAS No. 141, *Business Combinations*, which requires that the additional purchase price consideration is recorded as an increase to the intangible assets of Vancocin, is allocated over the asset classifications described above and is amortized over the remaining estimated useful life of the intangible assets. In addition, at the time of recording the additional intangible assets, a cumulative adjustment is recorded to accumulated intangible amortization, in addition to ordinary amortization expense, in order to reflect amortization as if the additional purchase price had been paid in November 2004.

As of December 31, 2008, we have paid an aggregate of $30.1 million to Lilly in additional purchase price consideration, as our net sales of Vancocin surpassed the maximum obligation level of $65 million in 2008 and 2007. The $30.1 million paid was based upon 35% of $20 million in 2008, 35% of $17 million in 2007, 35% of $19 million in 2006 and 50% of $21 million in 2005. The Company is obligated to pay Lilly additional amounts based on 35% of annual net sales between $45 and $65 million of Vancocin during 2009 through 2011.

No additional payments are due to Lilly on net sales of Vancocin below or above the net sales levels reflected above.

In the second quarter of 2008, the net sales of Vancocin exceeded the contracted range for which we are obligated to additional purchase price consideration for 2008. The additional purchase price consideration was $7.0 million and $6.0 million, for 2008 and 2007, respectively, which was recorded as an increase to the intangible assets of Vancocin, was allocated over the asset classifications described above and amortized over the remaining estimated useful life of the intangible assets, which is estimated to be 21 years as of December 31, 2008. In addition, at the time of recording the additional intangible assets, the Company recorded a cumulative adjustment in 2008 and 2007 of approximately $1.0 million and $0.6 million, respectively, to accumulated intangible amortization, in addition to ordinary amortization expense, in order to reflect amortization as if the additional purchase price had been paid in November 2004.

Amortization expense for the years ended December 31, 2008, 2007 and 2006 was $10.8 million, $6.1 million and $5.7 million, respectively. The estimated aggregated amortization expense for each of the next five years will be approximately $26.7 million, excluding any future increases related to additional purchase price consideration that may be payable to Lilly.

**Note 8. Accrued expenses and other current liabilities**

Accrued expenses and other current liabilities consist of the following at December 31, 2008 and 2007:

| (in thousands) | 2008 | 2007 |
|---|---|---|
| Rebates and returns | $ 7,243 | $ 7,089 |
| Payroll, bonus and employee benefits liabilities | 4,647 | 3,206 |
| Clinical development and research liabilities | 9,841 | 6,969 |
| Interest payable | 1,403 | 1,423 |
| Other current liabilities | 9,714 | 5,779 |
| | $ 35,650 | $ 24,466 |

**Note 9. Long-Term Debt**

Long-Term debt as of December 31, 2008 and 2007 is summarized in the following table:

| (in thousands) | 2008 | 2007 |
|---|---|---|
| Senior convertible notes | $ 250,000 | $ 250,000 |
| less: current portion | — | — |
| Total debt principal | $ 250,000 | $ 250,000 |

On March 26, 2007, the Company issued $250.0 million of 2% senior convertible notes due March 2017 (the “senior convertible notes”) in a public offering. The $250.0 million includes an issuance pursuant to the underwriters’ exercise of an overallotment in the amount of $25.0 million that was closed concurrently on March 26, 2007. Net proceeds from the issuance of the senior convertible notes were $241.8 million. The senior convertible notes are unsecured unsubordinated obligations and rank equally with any other unsecured and unsubordinated indebtedness. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007. As of December 31, 2008, the Company has accrued $1.4 million in interest payable to holders of the senior convertible notes. Debt issuance costs of $8.2 million have been capitalized and are being amortized over the term of the senior convertible notes, with the balance to be amortized as of December 31, 2008 being $6.6 million.

The senior convertible notes are convertible into shares of the Company’s common stock at an initial conversion price of $18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the “measurement period”) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to ViroPharma’s option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of December 31, 2008, the fair value of the $250.0 million convertible senior notes outstanding was approximately $194.4 million, based on the level 2 valuation hierarchy under SFAS 157.

Concurrent with the issuance of the senior convertible notes, the Company entered into privately-negotiated transactions, comprised of purchased call options and warrants sold, to reduce the potential dilution of our common stock upon conversion of the senior convertible notes. The transactions, taken together, have the effect of increasing the initial conversion price to $24.92 per share. The net cost of the transactions was $23.3 million.

The call options allow ViroPharma to receive up to approximately 13.25 million shares of its common stock at $18.87 from the call option holders, equal to the number of shares of common stock that ViroPharma would issue to the holders of the senior convertible notes upon conversion. These call options will terminate upon the earlier of the maturity dates of the related senior convertible notes or the first day all of the related senior convertible notes are no longer outstanding due to conversion or otherwise. Concurrently, the Company sold warrants to the warrant holders to receive shares of its common stock at an exercise price of $24.92 per share. These warrants expire ratably over a 60-day trading period beginning on June 13, 2017 and will be net-share settled.

The purchased call options are expected to reduce the potential dilution upon conversion of the senior convertible notes in the event that the market value per share of ViroPharma common stock at the time of exercise is greater than $18.87, which corresponds to the initial conversion price of the senior convertible notes, but less than $24.92 (the warrant exercise price). The warrant exercise price is 75.0% higher than the price per share of $14.24 of the Company's stock on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options ($18.87), the purchased call options will entitle the Company to receive from the counterparties in the aggregate the same number of shares of our common stock as the Company would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants ($24.92), the Company will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants.

The purchased call options and sold warrants are separate transactions entered into by the Company with the counterparties, are not part of the terms of the senior convertible notes, and will not affect the holders' rights under the senior convertible notes. Holders of the senior convertible notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options and sold warrants meet the definition of derivatives under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133). These instruments have been determined to be indexed to the Company's own stock (in accordance with the guidance of EITF Issue No. 01-6, *The Meaning of Indexed to a Company's Own Stock*) and have been recorded in stockholders' equity in the Company's Consolidated Balance Sheet (as determined under EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*). As long as the instruments are classified in stockholders' equity they are not subject to the mark to market provisions of SFAS 133.

*6% Subordinated Convertible Notes*

The Company made a private offering of $180.0 million of 6% subordinated convertible notes due March 2007 (the "subordinated convertible notes"), which closed on March 8, 2000. The notes were convertible into shares of the Company's common stock at a price of $109.15 per share, subject to certain adjustments. The notes bore interest at a rate of 6% per annum, payable semi-annually in arrears, and could have been redeemed by the Company, at certain premiums over the principal amount, at any time. The notes were subordinated in right of payment to all senior indebtedness of the Company. The notes were required to be repaid on the occurrence of certain fundamental changes, as defined.

In September 2004, the Company's Board authorized the Notes Repurchase Committee of the Board to approve the issuance of up to 5,000,000 shares of its common stock in exchange for the surrender of subordinated convertible notes from time to time. In 2005, the Company's Board authorized the Notes Repurchase Committee of the Board to approve the expenditure of up to $48.0 million to purchase the subordinated convertible notes from time to time, of which the Company spent $47.6 million to purchase $49.0 million of subordinated convertible notes as of December 31, 2005. The Company recorded a $1.1 million gain, net of the write off of deferred finance costs, in connection with the 2005 repurchases.

From the issuance date of the subordinated convertible notes through December 31, 2005, the Company reduced the outstanding principal amount of its subordinated convertible notes by $101.1 million, including purchasing for cash an aggregate of $99.1 million in principal amount of its subordinated convertible notes for approximately $66.2 million and entering 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 subordinated convertible notes held by such third party. The shares issued in this transaction had a market value of $1.2 million at the date of issuance.

On March 1, 2006, the Company redeemed the remaining $78.9 million principal amount of the subordinated convertible notes for $79.6 million. This eliminated the Company's long-term debt that was outstanding at December 31, 2005. The Company recognized a charge of $1.1 million related to this payment and wrote off of the remaining deferred financing costs on March 1, 2006.

**Note 10. Acquisition, License and Research Agreements**

*Vancocin Acquisition*

In November 2004, the Company acquired all rights in the U.S. and its territories to manufacture, market and sell the oral capsule formulation of Vancocin, as well as rights to certain related Vancocin products, from Lilly. Oral Vancocin is a potent antibiotic approved by the FDA to treat antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* infection and enterocolitis caused by *S. aureus* (including methicillin-resistant strains). Lilly retained its rights to vancomycin outside of the U.S. and its territories in connection with this transaction.

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 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 U.S. and its territories.

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 9). The Company spent approximately $2.0 million in fees related to this transaction. In addition, Lilly is entitled to additional payments on annual net sales of Vancocin within certain defined levels of sales occurring between 2005 and 2011 (see Note 7). In 2008, 2007 and 2006, the Company paid $7.0 million, $6.0 million and $6.6 million, respectively, of these additional payments, which was accounted for as contingent consideration, increasing the carrying amount of the related intangible assets (see Note 7).

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 7).

*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 U.S. and Canada. Under terms of the agreement, Schering-Plough paid the Company an up-front option fee of $3.0 million, which was recognized as revenue over its estimated performance period, which ended in August 2004.

In November 2004, the Company announced that Schering-Plough 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 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 was recognized in the first quarter of 2005. The Company will also be 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.

*GlaxoSmithKline Agreement*

In August 2003, the Company announced the acquisition of worldwide rights (excluding Japan) from GlaxoSmithKline (GSK) to an antiviral compound (Maribavir, 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 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 U.S. 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. In the third quarter of 2006, a milestone related to the initiation of the phase 3 study occurred and $3.0 million was charged to research and development and paid in February 2007.

*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 Company recognized $0.6 million as revenue in each 2006, 2005 and 2004. The revenue was fully amortized as of December 31, 2006, resulting in no deferred revenue on the consolidated balance sheet. In September 2006, the Company agreed to renew some limited preclinical screening activity with Wyeth. The amortization period was not extended to reflect this renewal as the economic benefit of the initial $5.0 million payment is no longer being earned and the Company's involvement with the activity is de minimus.

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 U.S. 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 U.S. 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 August 2006, Wyeth and the Company announced that data indicated that HCV-796 has achieved a "proof of concept" milestone under the companies' agreements. In connection with meeting the proof of concept milestone, Wyeth purchased 981,836 shares of ViroPharma's common stock for a purchase price of $10.0 million which represents the final stock purchase milestone outlined in the companies' agreements.

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. While, 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, in September 2006, the Company agreed to renew some limited preclinical screening activity with Wyeth. 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.

*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.

**Note 11. 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 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, which the Board has the authority to modify when deemed necessary. 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, 2008 and 2007, 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 (SEC) for the registration and potential issuance of up to $300 million of the Company's securities, of which $39 million remained at December 31, 2008. On October 19, 2001 the SEC declared the registration statement effective.

**Note 12. Equity Compensation Plans**

The Company adopted SFAS 123R as of January 1, 2006 using the modified prospective method. SFAS 123R primarily resulted in a change in the Company's method of measuring and recognizing the cost of grants under the Employee Stock Option Plans and Employee Stock Purchase Plan to a fair value method and estimating forfeitures for all unvested awards. Results for prior periods have not been restated. In connection with the adoption of SFAS 123R, the deferred compensation at December 31, 2005 of $3,000 related to previous grants of non-employee stock options was offset against additional paid-in capital. Prior to the adoption of SFAS 123R, the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows. SFAS 123R requires the cash flows resulting from tax benefits in excess of the compensation cost recognized for those options (excess tax benefits) be classified as financing cash flows.

SFAS 123R requires that the Company estimate forfeiture rates for all share-based awards. The Company monitors stock options exercises and employee termination patterns in estimating the forfeiture rate.

In accordance with Staff Accounting Bulletin No. 107 (SAB 107) issued in March 2005, share-based payment expense has been included in both research and development expense (R&D) and selling, general and administrative expense (SG&A). Share-based compensation expense consisted of the following for the year ended December 31, 2008 and 2007:

| (in thousands) | 2008 | | | 2007 | | |
|---|---|---|---|---|---|---|
| Plan | R&D | SG&A | Total | R&D | SG&A | Total |
| Employee Stock Option Plans | $ 2,948 | $ 5,899 | $ 8,847 | $ 2,271 | $ 5,306 | $ 7,577 |
| Employee Stock Purchase Plan | 57 | 28 | 85 | 35 | 29 | 64 |
| Non-employee Stock Options | 6 | — | 6 | (41) | — | (41) |
| Total | $ 3,011 | $ 5,927 | $ 8,938 | $ 2,265 | $ 5,335 | $ 7,600 |

No amounts of share-based compensation cost have been capitalized into inventory or other assets during the years ended December 31, 2008 and 2007.

*Employee Stock Option Plans*

The Company currently has three option plans in place: a 1995 Stock Option and Restricted Share Plan ("1995 Plan"), a 2001 Equity Incentive Plan ("2001 Plan") and a 2005 Stock Option and Restricted Share Plan ("2005 Plan") (collectively, the "Plans"). In September 2005, the 1995 Plan expired and no additional grants will be issued from this plan. The Plans were adopted by the Company's board of directors 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 granted under the 2005 Plan must be granted at an exercise price not less than the fair value of the Company's common stock on the date of grant. Stock options granted under the 2001 Plan can be granted at an exercise price that is less than the fair value of the Company's common stock at the time of grant. Stock options granted under the 1995 Plan were granted at an exercise price not less than the fair value of the Company's common stock on the date of grant. Stock options granted from the Plans 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. Shares issued under the Plans are new shares. The Plans provide for the delegation of certain administrative powers to a committee comprised of company officers.

Options granted during the 2008, 2007 and 2006 had weighted average fair values of $7.66, $11.30 and $11.86 per option. The fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following assumptions for the Plans:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| Expected dividend yield | — | — | — |
| Range of risk free interest rate | 1.9% - 3.7% | 3.7% - 5.1% | 4.3% - 5.1% |
| Weighted-average volatility | 87.0% | 92.7% | 103.0% |
| Range of volatility | 76.6% - 90.2% | 90.2% - 94.6% | 95.4% - 136.4% |
| Range of expected option life (in years) | 5.50 - 6.25 | 5.50 - 6.25 | 4.08 - 6.25 |

Risk free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Volatility is based on the Company's historical stock price using the expected life of the grant. Expected life is based upon the short-cut method permitted under SAB 107.

In May 2006, stockholders of the company approved an amendment to the 2005 Plan to increase the number of shares available for issuance under the plan by an additional 2,000,000 shares. As of December 31, 2008, there were 4,333,034 shares available for grant under the Plans. The following table lists the balances available by Plan at December 31, 2008:

| | 1995 Plan | 2001 Plan | 2005 Plan | Combined |
|---|---|---|---|---|
| Number of shares authorized | 4,500,000 | 500,000 | 7,850,000 | 12,850,000 |
| Number of options granted since inception | (6,997,515) | (1,255,472) | (3,854,853) | (12,107,840) |
| Number of options cancelled since inception | 2,973,908 | 783,681 | 309,678 | 4,067,267 |
| Number of shares expired | (476,393) | — | — | (476,393) |
| Number of shares available for grant | — | 28,209 | 4,304,825 | 4,333,034 |

The following table lists option grant activity for the year ended December 31, 2008:

| | Share Options | Weighted average exercise price per share |
|---|---|---|
| Balance at December 31, 2005 | 3,134,205 | $ 8.00 |
| Granted | 1,163,500 | 14.25 |
| Exercised | (209,774) | 3.87 |
| Forfeited | (85,800) | 16.35 |
| Expired | (82,709) | 6.57 |
| Balance at December 31, 2006 | 3,919,422 | 9.93 |
| Granted | 1,303,590 | 14.36 |
| Exercised | (111,677) | 4.70 |
| Forfeited | (52,520) | 13.37 |
| Expired | (84,825) | 14.01 |
| Balance at December 31, 2007 | 4,973,990 | 11.10 |
| Granted | 1,609,635 | 10.29 |
| Exercised | (112,159) | 3.20 |
| Forfeited | (115,914) | 12.81 |
| Expired | (53,838) | 17.05 |
| Balance at December 31, 2008 | 6,301,714 | $ 10.95 |

The total intrinsic value of share options exercised during the year ended December 31, 2008, 2007 and 2006 was approximately $0.7 million, $0.8 million, and $1.9 million, respectively.

The Company has 6,301,714 million option grants outstanding at December 31, 2008 with exercise prices ranging from $0.99 per share to $38.70 per share and a weighted average remaining contractual life of 6.89 years. The following table lists the outstanding and exercisable option grants as of December 31, 2008:

| | Number of options | Weighted average exercise price | Weighted average remaining contractual term (years) | Aggregate intrinsic value (in thousands) |
|---|---|---|---|---|
| Outstanding | 6,301,714 | $ 10.95 | 6.89 | $ 23,914 |
| Exercisable | 3,217,977 | $ 10.35 | 5.24 | $ 16,898 |

As of December 31, 2008, there was $20.2 million of total unrecognized compensation cost related to unvested share-based payments (including share options) granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.46 years. The total fair value of shares vested in the year ended December 31, 2008 was $9.3 million.

*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, 24,478, 18,908 and 14,395 shares were sold to employees during 2008, 2007 and 2006. As of December 31, 2008 there are approximately 249,794 shares available for issuance under this plan.

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. Since the total payroll deductions from the plan period are used to purchase shares at the end of the offering period, the number of shares ultimately purchased by the participants is variable based upon the purchase price. Shares issued under the employee stock purchase plan are new shares. There are two plan periods: January 1 through June 30 ("Plan Period One") and July 1 through December 31 ("Plan Period Two"). The plan qualifies under Section 423 of the Internal Revenue Code.

The fair value of the share-based payments was approximately $85,000. The fair value was estimated using the Type B model provided by SFAS 123R, with the following assumptions:

| | 2008 Plan Period Two | 2008 Plan Period One |
|---|---|---|
| Expected dividend yield | — | — |
| Risk free interest rate | 2.18% | 3.32% |
| Volatility | 42.3% | 62.6% |
| Expected option life (in years) | 0.50 | 0.50 |

Under Plan Period Two, 11,140 shares were sold to employees on December 31, 2008 at $7.25 per share, which represents the closing price on the offer termination date of $8.53 per share at 85%.

Under Plan Period One, 13,338 shares were sold to employees on June 30, 2008 at $9.75 per share, which represents the closing price on the offer termination date of $11.47 per share at 85%.

*Non-employee Stock Options*

In connection with the adoption of SFAS 123R on January 1, 2006, the Company reclassified approximately $116,000 from additional paid-in capital to a current liability for 9,000 shares related to outstanding stock options issued to non-employees in accordance with EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. As required by SFAS 123R, the Company remeasured the fair value of these options to approximately $56,000 as of December 31, 2006, which reduced compensation expense by approximately $60,000 in the year ended December 31, 2006. As of December 31, 2008, the Company remeasured the fair value of these options to approximately $20,800, which reduced compensation expense by approximately $6,000 for the year ended December 31, 2008. As of December 31, 2007, the Company remeasured the fair value of these options to approximately $15,000, which reduced compensation expense by approximately $41,000 for the year ended December 31, 2007. At the time of grant, the value of these options had been recorded as an expense and an increase in additional paid-in capital in accordance with APB 25.

The fair value of the non-employee share options was estimated using the Black-Scholes option-pricing model using the following range of assumptions:

| | December 31, 2008 | December 31, 2007 | December 31, 2006 |
|---|---|---|---|
| Expected dividend yield | — | — | — |
| Range of risk free interest rate | 0% - 1.0% | 2.6% - 3.5% | 4.7% - 5.1% |
| Weighted average volatility | 57.9% | 50.3% | 87.9% |
| Range of volatility | 44.0% - 66.8% | 50.3% - 69.3% | 45.4% - 97.4% |
| Contractual option life (in years) | 0.04 - 3.29 | 0.13 - 4.29 | 0.55 - 5.29 |

There were no non-employee share options vested or exercised during the year ended December 31, 2008 or 2007. Shares issued to non-employees upon exercise of stock options are new shares.

**Note 13. Income Taxes**

For the years ended December 31, 2008, 2007 and 2006, the following table summarizes the components of income before income taxes and the provision (benefit) for income taxes:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| **(in thousands)** | | | |
| Income before income taxes | $ 87,099 | $ 135,666 | $ 108,528 |
| Expense (benefit) for income taxes: | | | |
| Current: | | | |
| Federal | 145 | 22,679 | 18,602 |
| State and local | 3,763 | 4,599 | 3,873 |
| Foreign | 226 | 68 | — |
| Subtotal | 4,134 | 27,346 | 22,475 |
| Deferred: | | | |
| Federal | 14,812 | 12,137 | 18,126 |
| State and local | 177 | 873 | 1,261 |
| Foreign | 359 | (43) | — |
| Subtotal | 15,348 | 12,967 | 19,387 |
| Income tax expense (benefit) | $ 19,482 | $ 40,313 | $ 41,862 |
| Effective income tax rate | 22.4% | 29.7% | 38.6% |

Income tax expense includes federal, state and foreign income tax at statutory rates and the effects of various permanent differences. The decrease in the 2008 rate as compared to 2007 is primarily due to the impact of the orphan drug credit for maribavir and includes the benefit of an additional reduction of the valuation allowance to establish deferred tax assets in 2008. The decrease in the 2007 rate as compared to 2006 is primarily due to the Company's current estimate of the impact of the orphan drug credit for maribavir and an additional reduction of the valuation allowance to establish deferred tax assets in 2007. The 2007 income tax amounts include the benefit for the release of a portion of the valuation allowance. At December 31, 2008 and December 31, 2007, the Company had an aggregate of $2,029,000 and $78,000, respectively, of unremitted earnings of foreign subsidiaries that have been or are intended to be permanently reinvested for continued use in foreign operations and that, if distributed, would result in taxes at approximately the U.S. statutory rate.

For the year ended December 31, 2008, 2007 and 2006, the following table summarizes the principal elements of the difference between the effective income tax rate and the federal statutory income tax rate:

| | Year ended December 31, | | |
|---|---|---|---|
| **(% of pre-tax income)** | 2008 | 2007 | 2006 |
| U.S. federal statutory income tax rate | 35.0% | 35.0% | 35.0% |
| State and local income benefit, net of federal income tax effect | 3.0 | 2.6 | 3.1 |
| Share-based compensation | 1.2 | 0.8 | 0.7 |
| Orphan drug credit | (14.7) | (5.6) | — |
| Change in valuation allowance | (2.2) | (2.8) | — |
| Other | 0.1 | (0.3) | (0.2) |
| Effective income tax expense rate | 22.4% | 29.7% | 38.6% |

The following table summarizes the change in the valuation allowance:

| (in thousands) | Year ended December 31, 2008 | 2007 | 2006 |
|---|---|---|---|
| Valuation allowance at beginning of year | $ 72,703 | $ 48,278 | $ 49,060 |
| Tax expense (benefit) | (2,208) | (4,028) | (782) |
| Additional paid in capital | (8) | (120) | — |
| Additional paid in capital | (904) | 30,298 | — |
| Purchase price allocation | (63,147) | — | — |
| Reduction of deferred tax asset | — | (1,725) | — |
| Valuation allowance at end of year | $ 6,436 | $ 72,703 | $ 48,278 |

In 2008, we decreased our valuation allowance by $66.3 million to record deferred tax assets due to the exisitance of deferred tax liabilities in 2008 resulting from the Lev Acquisition. In 2007, a $30.3 million increase in the valuation allowance was recorded to offset a portion of the related deferred tax asset, also recorded in additional paid in capital, that relates to the tax basis of the convertible note. Additionally, a $4.0 million reduction in the valuation allowance was recorded which relates to additional deferred tax assets.

In 2008, 2007 and 2006, the Company also recorded $0.2 million, $0.2 million and $0.7 million related to current stock option tax benefits allocated directly to stockholders' equity, respectively. Additionally in 2008 and 2007, the Company recorded $1.3 and $4.5 million, respectively, for the tax benefit on convertible note hedge directly to stockholders' equity.

The following table summarizes the components of deferred income tax assets and liabilities:

| (in thousands) | December 31, 2008 | 2007 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 44,409 | $ 30,739 |
| Convertible note | 30,713 | 32,925 |
| Capitalized research and development costs | 17,630 | 21,248 |
| Orphan drug credit carryforward | 16,733 | — |
| Research and development credit carryforward | 6,840 | 6,690 |
| Non-deductible reserves | 1,502 | 1,679 |
| Depreciation | 891 | — |
| Intangible asset amortization | 7,839 | — |
| Equity compensation | 4,918 | 2,736 |
| Other | 2,193 | 1,374 |
| Subtotal | 133,668 | 97,391 |
| Valuation allowance | (6,436) | (72,703) |
| Deferred tax assets | 127,232 | 24,688 |
| Deferred tax liabilities: | | |
| Intangible asset amortization | 193,846 | 3,558 |
| Depreciation | 453 | 37 |
| Inventory | 2,691 | — |
| Prepaid expenses | 1,071 | 798 |
| Other | 198 | |
| Deferred tax liabilities | 198,259 | 4,393 |
| Net deferred tax assets (liability) | $ (71,027) | $ 20,295 |

At December 31, 2008 and 2007, deferred tax assets and liabilities were classified on the Company's balance sheets follows:

| (in thousands) | December 31, 2008 | 2007 |
|---|---|---|
| Current assets | $ 24,094 | $ 7,983 |
| Other assets (non-current) | — | 12,312 |
| Current liabilities | — | — |
| Other non-current liabilities | (95,121) | — |
| Net deferred tax assets (liability) | $ (71,027) | $ 20,295 |

Due to the uncertainty of the Company's ability to realize the benefit of all of the deferred tax assets, the deferred tax assets are partially offset by a valuation allowance. The Company believes that it is more likely than not that the remaining net deferred tax assets will be utilized in future periods.

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2008.

| (in thousands) | Amount | Expiration |
|---|---|---|
| Federal net operating losses | $ 92,457 | 2023 to 2028 |
| State net operating losses | 187,578 | 2018 to 2028 |
| Orphan drug credits | 16,733 | 2025 to 2028 |
| Research and development credits | 8,565 | 2010 to 2027 |

On January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies the criteria for recognizing tax benefits related to uncertain tax positions under SFAS No. 109, *Accounting for Income Taxes*, and requires additional financial statement disclosure. FIN 48 requires that the Company recognizes in its consolidated financial statements the impact of a tax position if that position is more likely than not to be sustained upon examination, based on the technical merits of the position. Adoption of FIN 48 had no net impact on the Company's consolidated results of operations and financial position.

Upon adoption, the Company identified $1.7 million of uncertain tax positions that the Company currently does not believe meet the more likely than not recognition threshold under FIN 48 to be sustained upon examination. Since these tax positions have not been utilized and have a related full valuation allowance established, the Company reduced its gross deferred tax asset and valuation allowance by $1.7 million. This amount relates to unrecognized tax benefits that would impact the effective tax rate if recognized absent the valuation allowance.

The Company does not expect any material increase or decrease in its income tax expense, in the next twelve months, related to examinations or changes in uncertain tax positions.

The following is a rollforward of our uncertain tax positions for the year ended December 31, 2008:

| | (in thousands) |
|---|---|
| Balance at January 1, 2008 | $ 1,133 |
| Additions for tax positions of prior years | 76 |
| Balance at December 31, 2008 | $ 1,209 |

The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction, in various states and foreign jurisdictions. The Company could be subject to U.S. federal or state income tax examinations by tax authorities for years ended after 2003. The Company's 2006 federal income tax return and various state returns are currently under examination. The final outcome of these reviews is not yet determinable. During the periods open to examination, the Company has utilized net operating loss and tax credit carry forwards that have attributes from closed periods. Since these NOLs and credit carry forwards were utilized in the open periods, they remain subject to examination.

The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense.

**Note 14. Earnings per share**

| (in thousands, except per share data) | For the years ended December 31, 2008 | 2007 | 2006 |
|---|---|---|---|
| **Basic Earnings Per Share** | | | |
| Net income | $ 67,617 | $ 95,353 | $ 66,666 |
| Common stock outstanding | 71,391 | 69,827 | 68,990 |
| Basic net income per share | $ 0.95 | $ 1.37 | $ 0.97 |
| **Diluted Earnings Per Share** | | | |
| Net income | $ 67,617 | $ 95,353 | $ 66,666 |
| Add interest expense on senior convertible notes | 3,561 | 2,735 | — |
| Diluted net income | 71,178 | 98,088 | 66,666 |
| Common stock outstanding | 71,391 | 69,827 | 68,990 |
| Add shares on senior convertible notes | 13,248 | 10,200 | — |
| Add "in-the-money" stock options | 1,073 | 864 | 1,348 |
| Common stock assuming conversion and stock option exercises | 85,712 | 80,891 | 70,338 |
| Diluted net income per share | $ 0.83 | $ 1.21 | $ 0.95 |

For the year ended December 31, 2008, diluted net income per share of $0.83 excludes approximately 4.4 million potentially dilutive common shares related to stock options that were not "in-the-money" as of December 31, 2008. For the year ended December 31, 2007, diluted net income per share of $1.21 excludes approximately 4.1 million potentially dilutive common shares related to stock options that were not "in-the-money" as of December 31, 2007. For the year ended December 31, 2006, diluted net income per share of $0.95 excludes approximately 2.6 million shares related to stock options that were not "in-the-money" as of December 31, 2006.

**Note 15. Fair Value Measurement**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS 157), which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. This statement applies under other accounting pronouncements that require or permit fair value measurements. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model.

Relative to SFAS 157, the FASB issued FASB Staff Positions (FSP) 157-1 and 157-2. FSP 157-1 amends SFAS 157 to exclude SFAS No. 13, *Accounting for Leases*, (SFAS 13) and its related interpretive accounting pronouncements that address leasing transactions, while FSP 157-2 delays the effective date of the application of SFAS 157 to fiscal years beginning after November 15, 2008 for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis.

In October 2008, the FASB issued FSP FAS No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. The FSP clarifies the application of SFAS 157, when the market for a financial asset is not active. The FSP was effective upon issuance, including reporting for prior periods for which financial statements have not been issued. The adoption of the FSP for reporting as of September 30, 2008 did not have a material impact on the Company's consolidated financial statements.

Valuation Hierarchy - SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2008:

| (in millions of dollars) | Total Carrying Value at December 31, 2008 | Fair Value Measurements at December 31, 2008 | | |
|---|---|---|---|---|
| | | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Cash and cash equivalents | $ 275,839 | $ 275,839 | $ — | $ — |
| Total | $ 275,839 | $ 275,839 | $ — | $ — |

Valuation Techniques - Cash and cash equivalents are measured at fair value using quoted market prices and are classified within Level 1 of the valuation hierarchy. There were no changes in valuation techniques during the year ended December 31, 2008.

**Note 16. 401(k) Employee Savings Plan**

The Company's 401(k) Employee Savings Plan (the "401(k) Plan") is available to all employees meeting certain eligibility criteria. The 401(k) Plan permits participants to contribute up to 92% of their compensation not to exceed the limits established by the Internal Revenue Code. Participants are always fully vested in their contributions. The Company matches of 25% on the first 6% of participating employee contributions. The Company contributed approximately $214,000, $114,000 and $81,000 to the 401(k) Plan in each of the years ended December 31, 2008, 2007 and 2006, 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.

**Note 17. Commitments and Contingencies**

The Company has commitments of approximately $89.6 million at December 31, 2008 in connection with several long-term supply contracts related to Cinryze.

In March 2008, the Company entered into a lease, comprising 78,264 square feet of office and related space, for the Company's new headquarters located in Exton, Pennsylvania. The lease expires seven years and six months from the point in which the Company began to occupy the space, which occurred in October 2008. In connection with the new lease, the Company also received a leasehold improvement allowance of $2.3 million, which will be amortized over the term of the lease.

In May 2008, the Company entered into a lease in Maidenhead, United Kingdom, comprising 8,000 square feet of office space, for our European operations. The lease expires in May 2018.

The Company's future minimum lease payments under the Company's other operating leases related to buildings and equipment for years subsequent to December 31, 2008 are as follows (in thousands):

| Year ending December 31, | Commitments |
|---|---|
| 2009 | $ 1,313 |
| 2010 | 1,645 |
| 2011 | 1,764 |
| 2012 | 1,802 |
| 2013 | 1,845 |
| Thereafter | 6,457 |
| Total minimum payments | $ 14,826 |

Rent expense for the years ended December 31, 2008, 2007, and 2006 aggregated $1.4 million, $53,000 and $0.7 million, respectively.

The Company has a severance plan for certain employees and change of control agreements for executive officers and certain other employees. Under its severance plan, 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.

**Note 18. Supplemental Cash Flow Information**

| (in thousands) | Year ended December 31, 2008 | 2007 |
|---|---|---|
| Supplemental disclosure of non-cash transactions: | | |
| Unrealized gains (losses) on available for sale securities | $ 550 | $ 607 |
| Liability classified share-based compensation benefit | 6 | (41) |
| Employee share based compensation expense | 8,932 | 7,641 |
| Deferred tax benefit on convertible note hedge | — | 2,627 |
| Reversal of accrued deferred finance costs | 151 | — |
| Establishment of landlord allowance | 2,063 | — |
| Non-cash lease activity | 573 | — |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | $ 5,000 | $ 2,444 |
| Cash paid for taxes | 10,348 | 24,951 |
| Cash received for stock option exercises | 360 | 525 |
| Cash received for employee stock plan purchases | 188 | 187 |

**Note 19. Subsequent Events (unaudited)**

During the first quarter of 2009, the market capitalization of ViroPharma fell below the carrying value of ViroPharma's net assets due to the announcements surrounding our maribavir development program. In accordance with SFAS 142, this situation would require us to test for impairment of our goodwill and other intangible assets. This analysis will be conducted in the first quarter of 2009 and depending on our stock price and fair market value of our assets could lead to an impairment charge at that time.

**Note 20. 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):

| | March 31, | June 30, | September 30, | December 31, (2) (3) |
|---|---|---|---|---|
| **2008 Quarter Ended** | | | | |
| Net product sales | $ 50,937 | $ 65,437 | $ 65,913 | $ 50,020 |
| Total revenues | 50,937 | 65,437 | 65,913 | $ 50,020 |
| Cost of sales (excluding amortization of product rights) | 1,918 | 2,386 | 2,460 | 2,110 |
| Operating expenses | 29,502 | 33,334 | 30,618 | 51,324 |
| Other income (expense) | 4,892 | 2,617 | 1,639 | (704) |
| Income tax expense (benefit) | 6,959 | 8,264 | 7,399 | (3,141) |
| Net income (loss) | 17,450 | 24,070 | 27,075 | (977) |
| Basic net income (loss) per share[1] | $ 0.25 | $ 0.34 | $ 0.39 | $ (0.01) |
| Diluted net income (loss) per share[1] | $ 0.22 | $ 0.30 | $ 0.33 | $ (0.01) |
| **2007 Quarter Ended** | | | | |
| Net product sales | $ 49,029 | $ 56,101 | $ 50,944 | $ 47,696 |
| Total revenues | 49,029 | 56,101 | 50,944 | $ 47,696 |
| Cost of sales (excluding amortization of product rights) | 2,230 | 2,641 | 2,029 | 2,034 |
| Operating expenses | 13,878 | 17,576 | 20,971 | 26,615 |
| Other income (expense) | 3,488 | 5,054 | 5,543 | 5,785 |
| Income tax expense | 14,351 | 9,302 | 12,199 | 4,461 |
| Net income | 22,058 | 31,636 | 21,288 | 20,371 |
| Basic net income per share[1] | $ 0.32 | $ 0.45 | $ 0.30 | $ 0.29 |
| Diluted net income per share[1] | $ 0.31 | $ 0.39 | $ 0.26 | $ 0.25 |

(1) Net 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.

(2) Fourth quarter 2008 results include expenses for Cinryze, which was acquired in October in our acquisition of Lev

(3) Fouth quarter 2008 includes a one time impairment charge related to our previous Corporate headquarters which is currently held for sale.

**Exhibit 31.1**

**CHIEF EXECUTIVE OFFICER'S**
**CERTIFICATION UNDER**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Vincent J. Milano, President, Chief Executive Officer and Chairman of the Board of Directors of the registrant, certify that:

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

/s/ Vincent J. Milano

Vincent J. Milano
President, Chief Executive Officer and Chairman of
the Board of Directors

February 27, 2009

**Exhibit 31.2**

**CHIEF FINANCIAL OFFICER'S**
**CERTIFICATION UNDER**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Charles A. Rowland, Jr., Vice President, Chief Financial Officer of the registrant, certify that:

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

/s/ Charles A. Rowland, Jr.

Charles A. Rowland, Jr.
Vice President, Chief Financial Officer

February 27, 2009

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of ViroPharma Incorporated (the "Company") on Form 10-K for the period ending December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Vincent J. Milano

Vincent J. Milano
President, Chief Executive Officer and Chairman of the Board of Directors
February 27, 2009

/s/ Charles A. Rowland, Jr.

Charles A. Rowland, Jr.
Vice President, Chief Financial Officer
February 27, 2009

## STOCKHOLDERS' INFORMATION

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**Business Development**
R. Clayton Fletcher
*Vice President, Business Development*
610-321-6789
Clayton.fletcher@viropharma.com

**Independent Auditors**
KPMG LLP
150 John F. Kennedy Parkway
Short Hills, NJ 07078

**Annual Shareholders' Meeting**
The shareholders' meeting will be held on Friday, May 22, 2009 at 10:00 AM at The Desmond Hotel and Conference Center, One Liberty Boulevard, Malvern, PA, 19355.

**Securities Information**
NASDAQ Global Select Market
Symbol: VPHM

**Transfer Agent**
For shareholder questions regarding lost certificates, address changes, and change of ownership or name in which the shares are held, please direct inquiries to:

**StockTrans, Inc.**
44 West Lancaster Avenue
Ardmore, PA 19003
Voice: (610) 649-7300
http://www.stocktrans.com

# TOGETHER

We're bringing innovative treatments to life-threatening diseases.


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