

UNSUNG HEROES

VIROPHARMA INCORPORATED
2009 ANNUAL REPORT

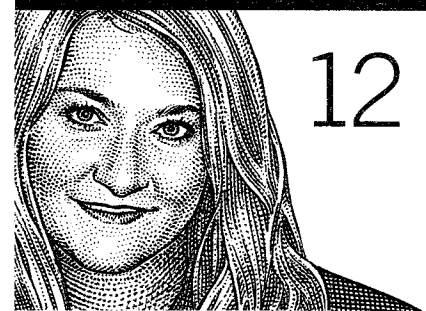
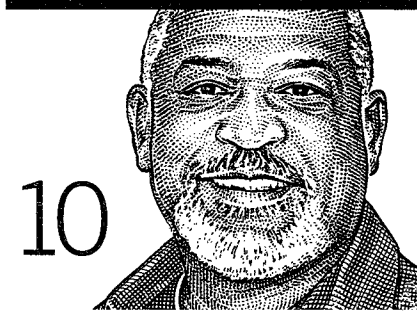
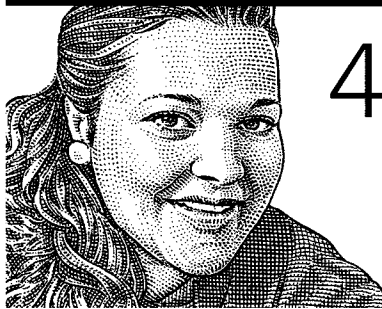


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WE'D LIKE YOU TO MEET SOME AMAZING PEOPLE.

STORIES



At ViroPharma, nothing inspires us more than the stories of real people and their feats of courage, determination and generosity. These people may not be celebrities...their stories might not be in the newspaper. But to us, they are true heroes. And reading their stories is the first step to understanding the essence of ViroPharma.

ViroPharma Incorporated is an international biopharmaceutical company committed to developing and commercializing innovative products that address unmet medical needs. We focus on serious disorders for which there are few, if any, therapeutic options, including diseases caused by C1 esterase inhibitor deficiency and *C. difficile*.

In everything we do, throughout our organization, we are committed to meeting the needs of patients and physicians, as we work to transform the promise of biotechnology into therapies that have the power to restore health and save lives.

2009 BUSINESS HIGHLIGHTS

- 1 DELIVERED RECORD \$310 MILLION IN NET PRODUCT SALES**
Highlighted by \$97 million in net Cinryze™ (C1 Esterase Inhibitor [Human]) sales in first 12 months.
- 2 CONVERTED OVER 400 HAE PATIENTS ONTO PROPHYLACTIC CINRYZE**
Over 200 plans covering at least one patient.
- 3 CONTINUED TO ENSURE THAT PATIENTS SUFFERING *C. DIFFICILE* INFECTIONS HAD ACCESS TO VANCOCIN**
- 4 ADVANCED OUR NON-TOXIGENIC *C. DIFFICILE* PROGRAM INTO PHASE 1 CLINICAL DEVELOPMENT**
Data expected in 2010.

2009 FINANCIAL HIGHLIGHTS

(Dollars in thousands, except per share data.)

	2009	2008	2007	2006	2005
Consolidated Statement of Operations Data					
Net Product Sales	\$310,449	\$232,307	\$203,770	\$166,617	\$125,853
Total Revenue	310,449	232,307	203,770	167,181	132,417
Total Operating Expenses ⁽¹⁾	278,319	153,652	87,974	68,375	44,272
Operating Income	32,130	78,655	115,796	98,806	88,145
Net (Loss) Income	(11,077)	63,960	92,105	66,666	113,705
Diluted (Loss) Income Per Share	(0.14)	0.84	1.21	0.95	2.02
Consolidated Balance Sheet Data					
Cash, Cash Equivalents and Short-term Investments	\$331,672	\$275,839	\$584,328	\$255,409	\$233,413
Working Capital	406,375	317,413	596,819	266,443	166,666
Total Assets	1,084,451	1,086,129	771,605	429,694	435,525
Long-term Debt	138,614	161,003	153,572	—	—
Total Stockholders' Equity	750,387	749,334	558,530	411,899	326,977

(1) Includes \$69 million and \$2 million in 2009 and 2008, respectively, for non-recurring impairment charges.

TO OUR SHAREHOLDERS

2009 WAS A YEAR OF MOMENTUM. AS ANYONE FAMILIAR WITH NEWTON'S LAWS OF MOTION CAN TELL YOU, MOMENTUM DOESN'T JUST HAPPEN.

In our case, we were propelled by a powerful force: the courage of patients battling a terrible disease, the perseverance of their doctors, and the hard work of their families, friends and advocates.

Together, these unsung heroes have inspired us to keep moving — with more focus and determination than ever before.

From a financial perspective, our balance sheet continues to strengthen, and we ended 2009 with over \$400 million in working capital, including cash and cash equivalents of over \$330 million. This strong financial momentum enables us to continue our efforts to find new solutions for unmet medical needs, both through internal development and through acquisitions. For example, our non-toxicogenic *C. difficile* program, which advanced to clinical testing in 2009, may one day provide a solution for recurrent episodes of *C. difficile*. We expect to complete the Phase 1 trial and potentially proceed into Phase 2 clinical testing later this year.

CINRYZE™ (C1 ESTERASE INHIBITOR [HUMAN])

The big story of 2009, of course, was the early launch success of Cinryze, which is approved to prevent attacks of hereditary angioedema, or HAE — a potentially life-threatening swelling disorder that affects a small population of patients.

As we have traveled around the country, meeting these patients and their families, we've begun to realize that this is no ordinary group of people. The frightening and unpredictable nature of their disease has caused them to develop a deeply resilient spirit, while the rarity of the condition has produced a close-knit community fiercely devoted to finding a solution. We look to them for inspiration every day. They deserve much of the credit for what we have achieved.

2010 finds us moving into a new phase of the launch of Cinryze. While we are pleased that we have made great progress in 2009, we know that there are many more HAE patients in the United States who may benefit from Cinryze. There are still a significant number of patients who are preventing attacks of HAE with anabolic steroids, which bring with them a well-documented history of safety implications. In 2010 we will continue to educate physicians about the benefits that Cinryze may offer as a therapeutic option for these patients. We also are focused on continuing to identify new patients coping with HAE.

IT'S ALL ABOUT ACCESS

Our top priority for 2010 is to ensure that anyone suffering from HAE has access to Cinryze for prophylaxis. That means educating doctors, communicating with the HAE community, helping patients acquire reimbursement, and of course, ensuring that our scale-up efforts keep pace with our momentum.

We've already made tremendous progress. During 2009 alone, over 400 patients' lives were transformed by Cinryze therapy. For these patients, taking Cinryze means the beginning of an entirely new prevention-oriented life. They may no longer live with the dread that an HAE attack will ruin an important event, or force them to sit on the sidelines. For the first time ever, they can travel without having to know where to find the closest emergency room. For parents, it means relief from the constant worry that their child's throat will swell shut at a friend's house or on a field trip.

In other words, Cinryze is doing more than saving lives. It's allowing more people to live.

CINRYZESOLUTIONS®

CINRYZESolutions, our patient support program, is dedicated to helping patients through benefit coverage investigations, prior authorizations, appeals assistance and broad based reimbursement assistance at no charge to health care providers or their patients. Today, thanks to this program, well over 200 healthcare plans are now covering at least one prophylactic patient. And for patients without sufficient insurance coverage, or those who need co-pay assistance, or even full drug coverage, CINRYZESolutions can help. We don't want cost to be a hurdle for a patient seeking prophylaxis with Cinryze; nor should it be a concern for health care providers.

OPPORTUNITIES FOR GROWTH

While our focus on U.S. HAE patients will remain a top priority, we also intend to pursue a number of different initiatives with Cinryze and C1 esterase inhibitor as the foundation for future growth. One of the most important steps toward that goal occurred earlier this year, when we expanded our global licensing, commercialization and development rights for Cinryze. This will allow us to bring Cinryze to additional countries around the world, explore new methods for administering the drug, and study C1 esterase inhibitor in other conditions in which it is implicated as an important regulatory protein. To support both the global expansion and our U.S. efforts, we are actively scaling up our manufacturing capacity

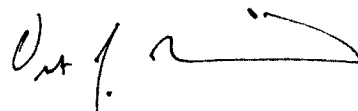
through the implementation of a parallel chromatography process and industrial scale expansion. We've made great progress on these efforts so far and continue to be on track to meet our goals in 2010.

THE MOMENTUM CONTINUES

Naturally, we are thrilled to give our investors such positive feedback on 2009, and such a bright outlook for 2010. Our team has never worked with such passion and precision, and today we are being rewarded with real-world results. I personally am very proud of and thankful for the efforts of our entire global team.

For us however, the most gratifying reward for our hard work has been the impact we've already made on so many patients' lives.

And of course, what we're most grateful for, on a professional and personal level, is the extraordinary impact they've had on ours.



Vincent J. Milano

March 31, 2010

President, Chief Executive Officer
and Chairman of the Board of Directors

MANAGEMENT TEAM

THOMAS F. DOYLE
Vice President
Strategic Initiatives

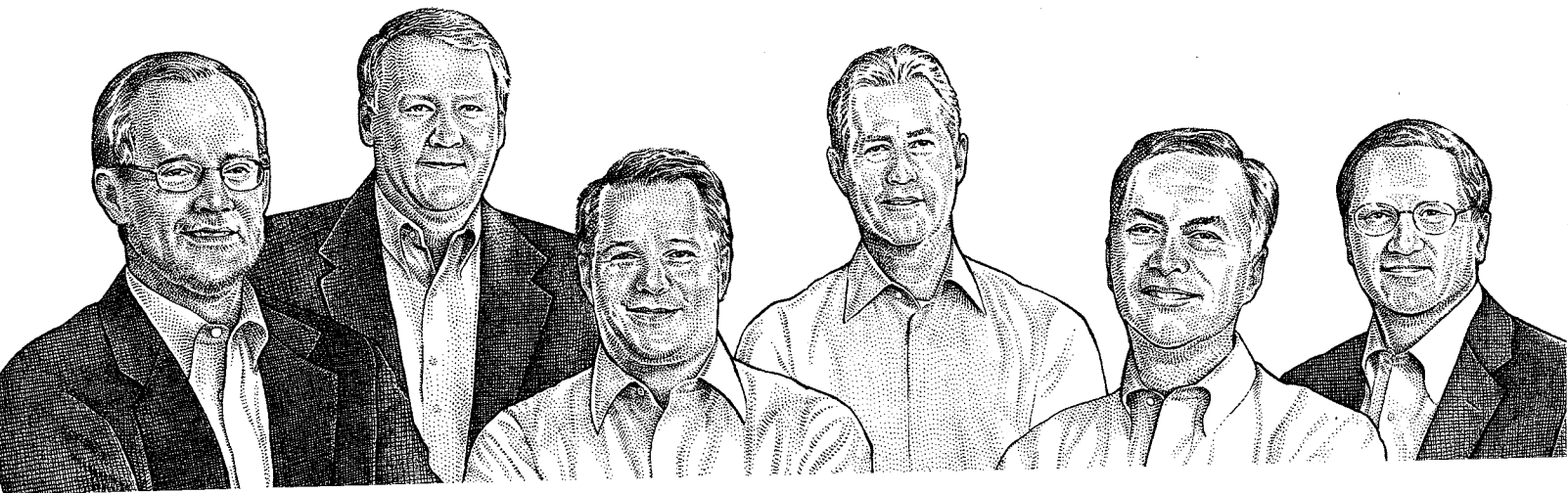
DANIEL B. SOLAND
Vice President and
Chief Operating Officer

VINCENT J. MILANO
President,
Chief Executive Officer
and Chairman of the
Board of Directors

COLIN BROOM
Vice President and
Chief Scientific Officer

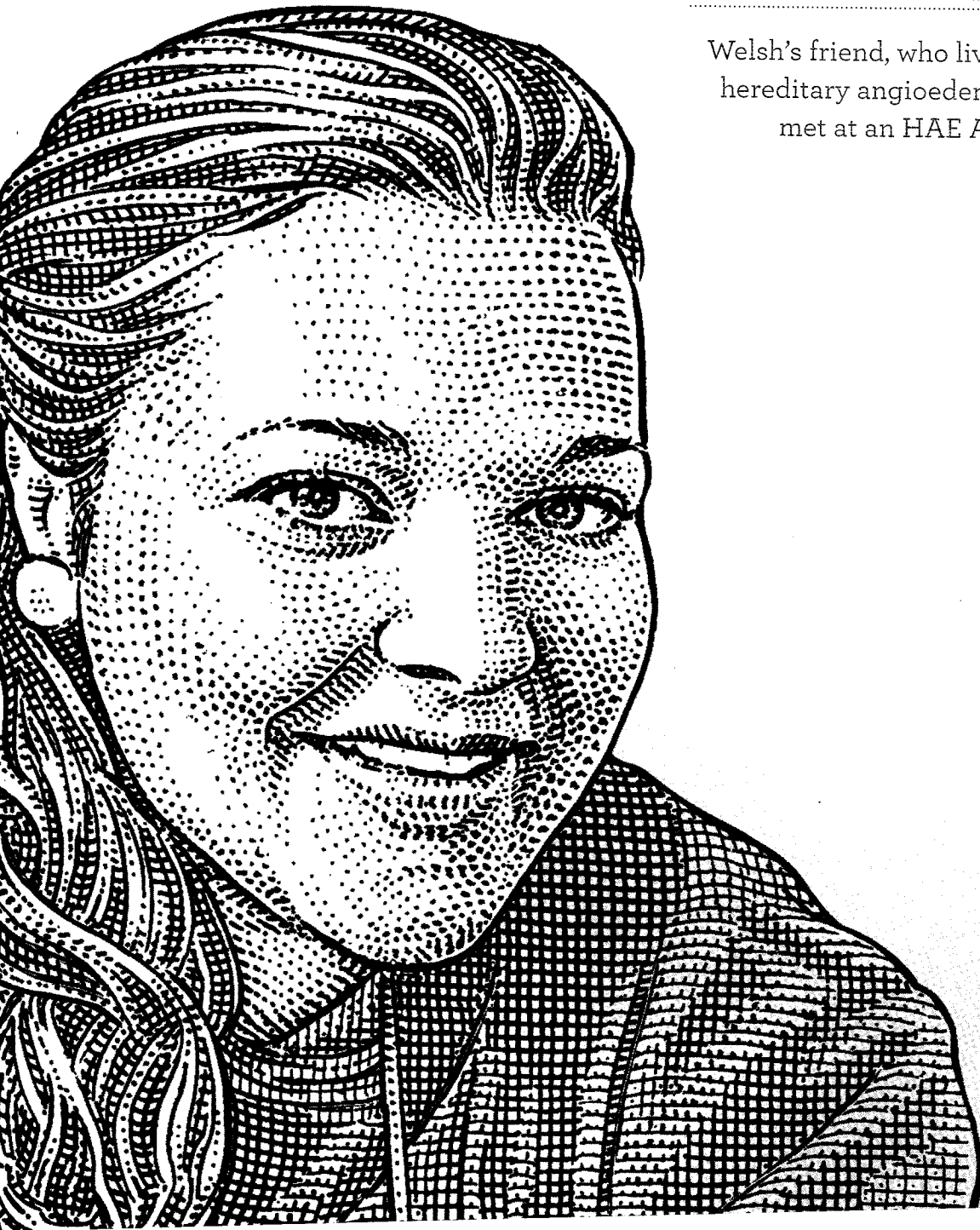
ROBERT G. PIETRUSKO
Vice President
Global Regulatory
Affairs and Quality

CHARLES A. ROWLAND
Vice President and
Chief Financial Officer



**WHEN KYLYNN WELSH'S
FRIEND CALLED,
HER VOICE WAS SHAKING.
"I THINK I NEED HELP,"
SHE SAID.**

Welsh's friend, who lived in Kentucky, had hereditary angioedema; the two girls had met at an HAE Association meeting.



It turns out that Welsh's friend was about to give herself her first infusion of Cinryze™ (C1 Esterase Inhibitor [Human]). "Her doctor had already shown her how to do it," explains Welsh. "But she was really nervous about infusing for the first time, so she called me." Welsh, who is 20, also uses Cinryze to prevent attacks of HAE. "I had to support her and talk her through it, step by step, how to mix the medicine, how to clean it, you know, how to put the butterfly needle in and infuse yourself."

It's a role Welsh seems comfortable with; helping younger patients cope with their disease. Getting them through the scary times. Telling them about her own experience — and survival. When she travels to HAE Association conferences, she tells her story and makes friends with young patients, later staying in touch by phone or email.

Of course, it wasn't so long ago that Welsh was the one who needed help. When she was seventeen years old, before the approval of Cinryze, an HAE attack landed her in the hospital, where she slipped into a coma. Her mother called another patient, a member of the HAE Association, who happened to be using a C1-inhibitor brought from Europe through an importation program. "She dropped everything she was doing and worked with my doctors to help arrange for me to get doses overnight," says Welsh. "It probably saved my life.

"We're definitely...a tight community," she says today. "If one person needs help, everybody pulls together to do what they can to help that person."

*"If one person needs help,
everybody pulls together
to do what they can to
help that person."*

KYLYNN WELSH

Hereditary Angioedema Patient

For Welsh, that community was critical during her teenage years, when few of her peers understood her struggle. "It was amazing," she remembers about her first patient conference. "I didn't think that I would ever find anybody, you know, my age who was going through what I'm going through. So the first time I went to a conference, I met other kids who knew exactly what I was talking about. And I didn't have to explain myself. They didn't treat me differently. I felt, finally, like I fit in.

"I loved every minute of it."

Today, Welsh is a junior at Widener University near Philadelphia. "I never, ever thought I'd be able to go away to school," she says. "The only reason that I'm able to go to school and live there is because Cinryze helps prevent those attacks I had in the past. I'm not worrying as much, is my throat going to swell tonight? You know, am I going to wake up tomorrow? I'm really grateful that I'm able to go to college."

Her dream is to become a traveling emergency room nurse. "I want to be able to go to work and know that...I'm going to make a difference in somebody's life," she says.

If you ask her friend in Kentucky, or any of the other young patients Welsh has helped over the years, she's already well on her way.

HAE PATIENTS WOULD ASK DR. MICHAEL FRANK IF THEY SHOULD HAVE KIDS. HE ALWAYS SAID YES.

In the early days of his work with hereditary angioedema, Dr. Frank knew very little about the disease. But one thing he did know was that a parent had a 50% chance of handing it down to her child.

“And the truth is,” says Dr. Frank today, “I told them that I thought that things would change and that they should go ahead and plan a family, just as if they didn’t have the disease, and that things would be better in the future.”

It was a statement filled with Dr. Frank’s signature blend of confidence, optimism and determination — qualities that have never failed him during his pursuit of a cure for HAE. It was a pursuit that could be discouraging and even a little lonely, in a field increasingly focused on blockbuster drugs and global epidemics.

“But I had accumulated this group of patients, and they were miserable,” he explains. “I had people who were having attacks. And they wanted help. And that’s why I went into medicine in the first place.”

Dr. Frank had always wanted to be a medical investigator. He began his career at the National Institutes of Health, where he studied autoimmune disease at the National Institutes of Allergy and Infectious Diseases. One day in the 1970s, he got a call about an interesting case.

“A young man in his twenties had what was thought to be Irritable Bowel Syndrome,” remembers Dr. Frank. “Then he noticed some funny feelings in his mouth, and he went to his dentist in downtown Washington.” The dentist put the man on penicillin, suspecting an abscess. The patient left the dentist’s office, and as he walked down the hall, his throat swelled shut and he stopped breathing.

“As luck would have it,” explains Dr. Frank, “there was an ear, nose and throat (ENT) doctor who had an office right across the hall. A passerby carried him into the ENT’s office, and they did an emergency tracheotomy.”

The young man survived, and Dr. Frank began working on his case after diagnosing him with HAE. This led to more cases, and before long Dr. Frank became known as “the HAE doctor.”

After some early work with aminocaproic acid, which had debilitating side effects, Dr. Frank and his team of researchers turned their focus to estrogen. They had noticed that HAE seemed to worsen in girls during puberty, and appeared to improve during pregnancy. “So I looked around for a drug that...would lower estrogen levels in men and women,” remembers Dr. Frank. “There was a drug in development called danazol, which was being developed as a female contraceptive...and so we decided to do a double-blind study.”

The drug worked. And for many years after that, steroids such as danazol were the only effective treatment available to HAE patients in the United States. “To have the reward of thinking through a problem and trying something out of the clear blue sky and having it be effective...is a highly rewarding experience,” Dr. Frank says. “It was really surprising.”

While Dr. Frank and his team were studying the effects of danazol, they noticed something unexpected: it raised the level of C1 esterase inhibitor. Dr. Frank asked the American Red Cross to make some C1-inhibitor from plasma for study purposes, and in 1980 he published a report in *The New England Journal of Medicine* showing the effectiveness of C1-inhibitor in the treatment of HAE.

Then the AIDS epidemic hit. “The Red Cross...turned all of its research attention to developing ways of...identifying blood products that were contaminated [with HIV],” explains Dr. Frank. They stopped making C1-inhibitor, so Dr. Frank had to find another supply. He began working with European suppliers, and in the late 1980s published another study showing the drug’s effectiveness.

Eventually, his team’s work helped bring about trials in the United States, and many years later, FDA approval.

“Well, it feels wonderful,” he says now. “I mean...we were able to take a disease that really had no complete clinical description and no method of therapy...and go from that point to this point in one professional lifetime. There aren’t many diseases that you can say that about.”

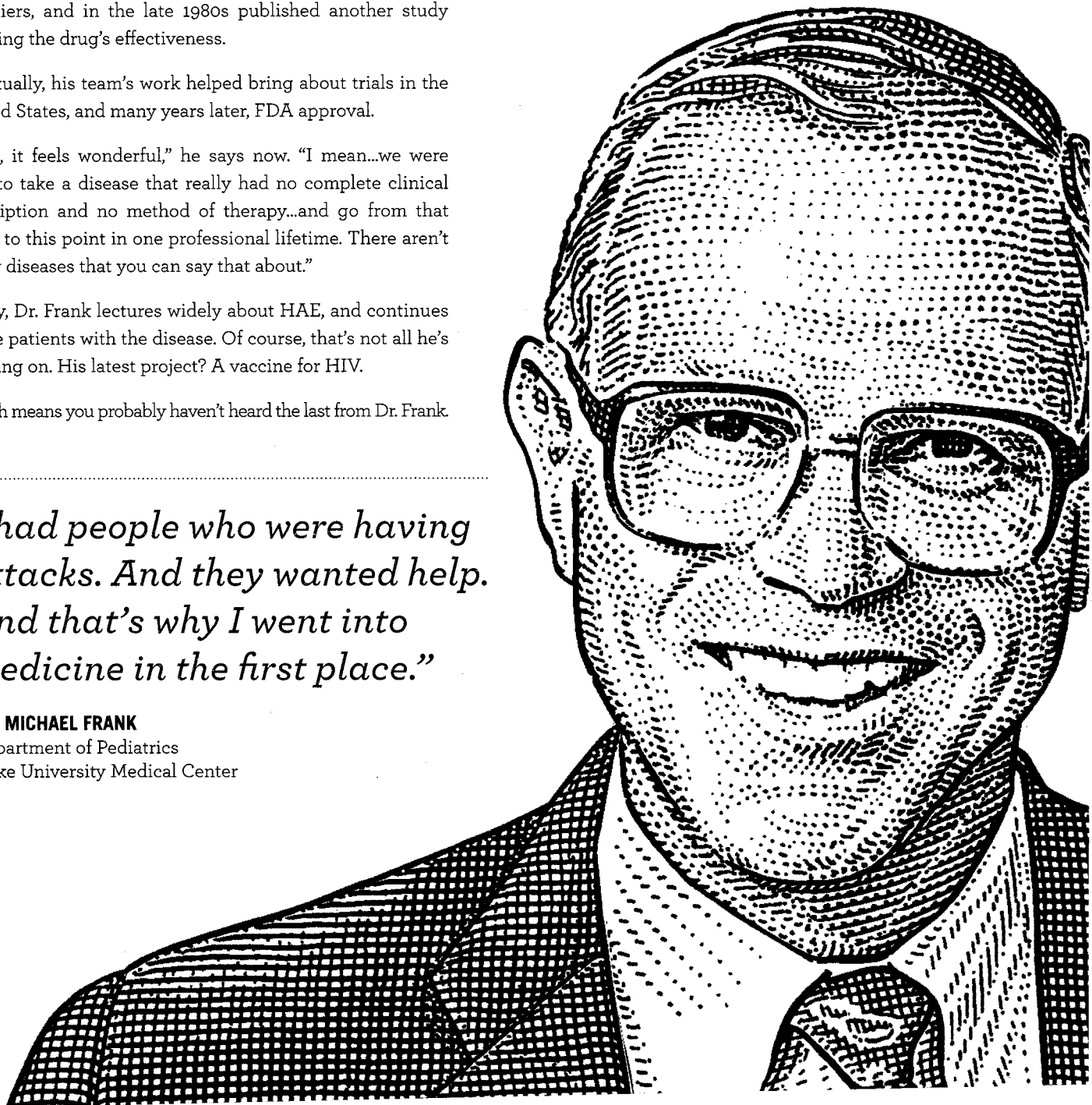
Today, Dr. Frank lectures widely about HAE, and continues to see patients with the disease. Of course, that’s not all he’s working on. His latest project? A vaccine for HIV.

Which means you probably haven’t heard the last from Dr. Frank.

“I had people who were having attacks. And they wanted help. And that’s why I went into medicine in the first place.”

DR. MICHAEL FRANK

Department of Pediatrics
Duke University Medical Center



TONY CASTALDO'S DAUGHTER HAD TO GIVE A SPEECH ABOUT THE SCARIEST MOMENT IN HER LIFE.

The story she told in speech class was about an attack of hereditary angioedema, but it didn't have anything to do with the excruciating abdominal swelling that had landed her in the hospital. For her, the scariest moment came when an attending physician turned to her father and said, "So, Mr. Castaldo, what do you think we should do?"

It must have been unsettling for 14-year-old Leigh to realize that her father actually knew more about HAE than most members of the medical establishment. But by that time, Tony Castaldo knew quite a bit about how to help his daughter — and what he didn't know, he was bound and determined to find out.

It all started when Leigh began experiencing extreme abdominal swelling and pain at the age of four. Despite the frequency and severity of her agonizing attacks, doctors told Castaldo that nothing could be done. And Castaldo refused to believe them.

Armed with little more than the name of the disease, Castaldo headed to the National Library of Medicine at the National Institutes of Health. He began spending his weekends immersed in medical literature, learning the principles of genetics and immunology, then biochemistry and hematology, searching for clues to his daughter's disease.

That's how he learned that anabolic steroids had been used in Europe to treat extremely severe cases of HAE in children. He persuaded his daughter's doctor to administer a very low dose of danazol, accompanied with aggressive medical surveillance. The treatment seemed to help, and Leigh's attacks became more manageable. Until she turned twelve.

"That's when all hell broke loose," says Castaldo. The attacks returned, and the steroids stopped working at any dose. Once again, like a recurring nightmare, Leigh was struck with excruciating abdominal pain and swelling every three or four days.

Leigh's pediatrician referred her to the pediatric hematology department at Georgetown University Hospital, where doctors would treat her at least twice a week with pain medication and fresh frozen plasma. It helped her endure the attacks, but it wasn't enough. Tony Castaldo wanted better for his child.

"I knew there was a clinical trial going on in the United States, using a treatment called a C1 esterase inhibitor," Castaldo remembers. "I did everything I could to get her on it through a compassionate use protocol. It took a year, but we finally got it." Leigh started a C1-inhibitor therapy for acute attacks on December 6, 2000.

Meanwhile, the Information Age had begun. Castaldo immediately grasped the usefulness of the Internet for research and, perhaps more importantly, for communicating with other families coping with HAE. He and several other patients developed a loose network, and in 2000 they formed the United States Hereditary Angioedema Association, with Tony Castaldo as President.

"I basically had three full-time jobs," says Castaldo; his day job working for the Federal Reserve, his work for the Hereditary Angioedema Association, and the time he spent caring for his daughter. He estimates that he flew at least 125,000 miles a year, visiting international HAE experts and attending conferences around the world, traveling on weekends and often going without very much sleep.

But no matter how hard he worked, Leigh was still missing her high school years. Since the C1-inhibitor trial was only for acute treatment, she had to go to the hospital during each attack to receive therapy — something that happened several times a week, at all hours of the day or night.

And then the C1-inhibitor trial ended. Because of unfavorable trial results, the medicine would no longer be available.

Castaldo was undeterred. "We have always had this philosophy at the HAE Association," he says. "You can't tell us it can't be done, because there's always a way. You just have to be creative."

Castaldo found a manufacturer of C1-inhibitor in Holland. The company was called Sanquin Blood Foundation, and they were producing a small amount of a drug that would one day become Cinryze™ (C1 Esterase Inhibitor [Human]). In October 2002, on the day that Leigh went to Georgetown University Hospital to receive the very last clinical trial dose of C1-inhibitor, Castaldo flew to the Netherlands to finalize his deal with Sanquin.

In a remarkable feat of international negotiations, legal wrangling and personal financial sacrifice, Castaldo was able to buy enough C1-inhibitor for his daughter to begin C1-inhibitor therapy at home.

“And all of the sudden,” he says, “she blossomed. Overnight. It was amazing. Here’s a kid who was totally disabled, and suddenly she wasn’t getting sick any more. I’m thinking, oh my God, this is amazing.”

At this point, most people would have taken a break. They would have settled down to enjoy, at long last, a normal life with their child. But Tony Castaldo is not like most people.

Castaldo wanted everyone with HAE to have access to C1-inhibitor. So he worked with the Food and Drug Administration to allow people to buy the drug internationally and bring it to the U.S. through the Personal Importation Program. For several years, until the approval of Cinryze, Castaldo and the HAE Association made it possible for patients to import a lifesaving medication that had been previously unavailable to residents of the United States.

“We have always had this philosophy at the HAE Association. You can’t tell us it can’t be done, because there’s always a way. You just have to be creative.”

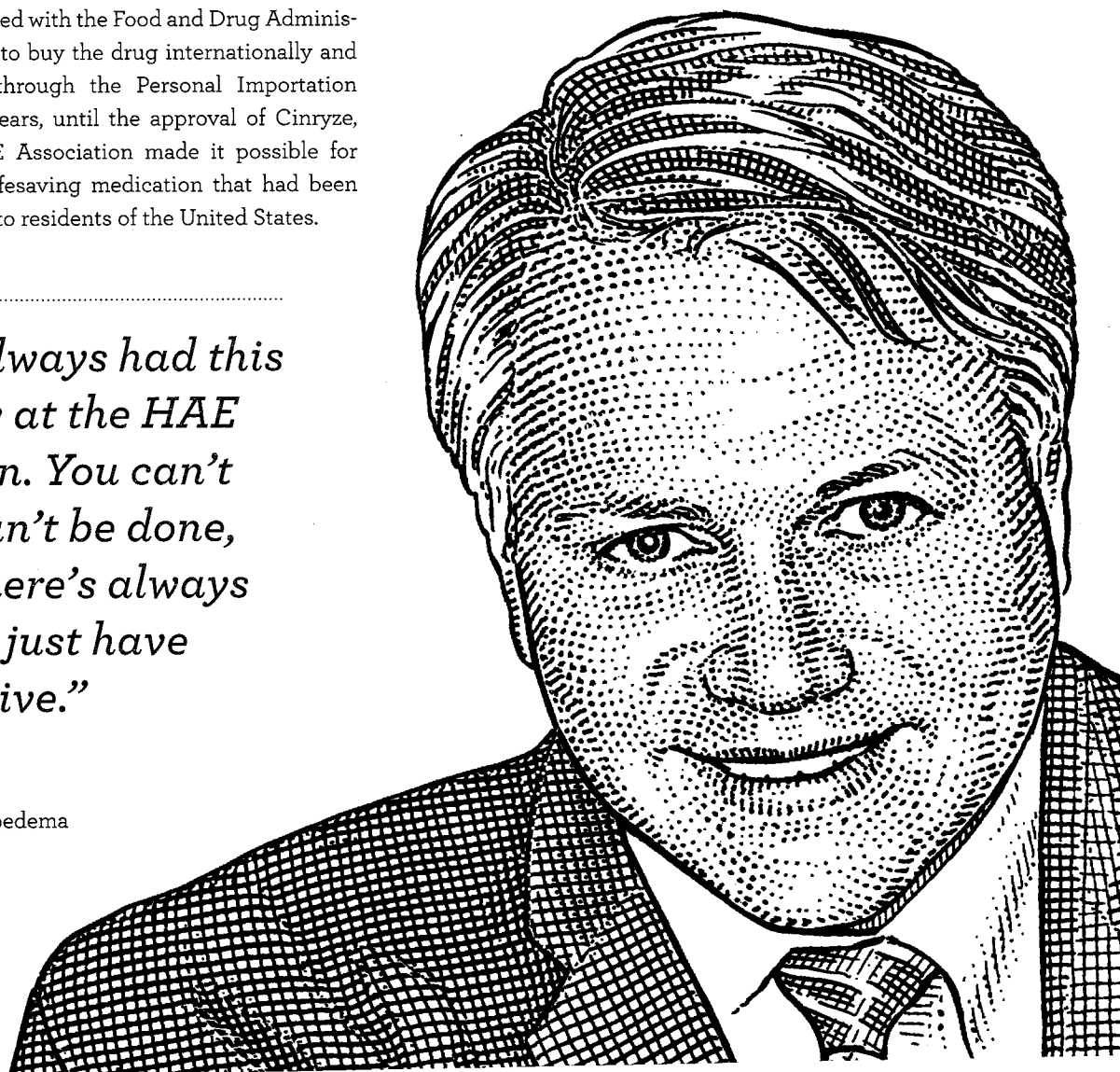
TONY CASTALDO
President
U.S. Hereditary Angioedema
Association

Soon Castaldo began working with investors and pharmaceutical companies, making a business case for developing medicines targeting HAE. He was influential in the formation of Lev Pharmaceuticals, later acquired by ViroPharma. And finally, on October 10, 2008, Cinryze was approved for routine prophylaxis in adolescents and adults against HAE in the United States.

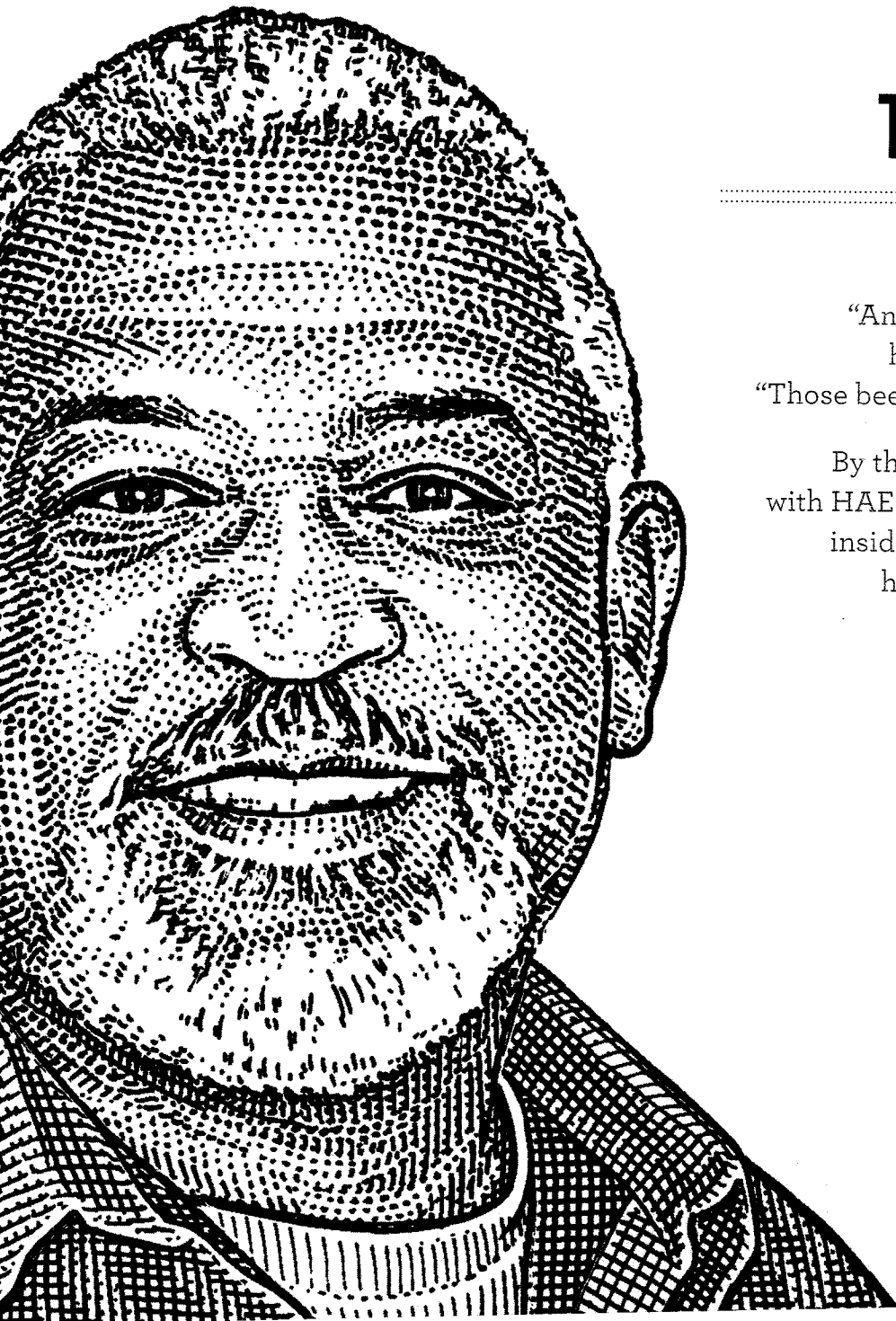
In the meantime, Leigh graduated from George Mason University, with a degree in finance and economics. Today, Castaldo continues to lead the HAE Association, and also serves as President of Hereditary Angioedema International.

“We’re more motivated than ever,” he says. “Now that we’ve got new products available for treating HAE, we’re redoubling our efforts to make sure patients have access to them.”

In other words, Tony Castaldo has only just begun.



WHEN EIGHT-YEAR-OLD KEN LEWIS SAW THE BEEHIVE ON HIS WAY HOME FROM SCHOOL, THERE WAS ONLY ONE THING HE COULD THINK TO DO.



He whacked it with a stick.

“And boy, those bees jumped me,”
he remembers today, laughing.
“Those bees jumped me and tore me up.”

By that time, Lewis had been living
with HAE for four years, and deep down
inside, he knew exactly what would
happen if he got stung by bees.

But Ken Lewis was an eight-year-old kid who never let his disease get in the way of doing what eight-year-old kids do. Sure, the bee stings led to an attack of facial swelling that lasted for several days. But Lewis took it in stride. Sometimes he even found ways to use it to his advantage.

“I can remember times when my face was so swollen, when I walked out into the living room and all my family was there, two or three of them jumped up and ran away,” he recalls. “But then I would take advantage of that, and I’d chase them, and scare them.”

Other moments were less enjoyable. Kids teased Lewis when he went out in public during an attack. “They used to call me a whole bunch of names, which was very embarrassing. But I mean, as a young kid, all you can do is laugh, and go home, and cry once you get home.”

Lewis loved sports as a kid, and refused to let HAE stop him from running track or playing baseball, basketball and football. “I’d come home and my foot would be swollen,” he says. “And I’d go right back out the next day, even with a swollen foot, and play again.”

The youngest of eleven children, Lewis had the most severe case of HAE in his family, suffering from attacks more frequently than his older two sisters and brother who shared the condition. For years, his mother treated his swollen face and limbs with hot towels and antihistamines. It wasn’t until he was eighteen that Lewis began taking steroids to control his condition. He stayed on them for 41 years, dealing with the attendant side effects along the way; the weight gain, the heart problems. In 2009, he had his right thyroid removed because of a nodule.

*“As a young kid,
all you can do is laugh,
and go home,
and cry once you
get home.”*

KEN LEWIS

Hereditary Angioedema Patient

“The doctors told us at the time, taking steroids is the only option you have right now,” Lewis explains. “They said, there are some side effects; it could be fatal. But you really don’t have any other options.”

Lewis graduated from high school and went to Concordia College in St. Paul, Minnesota. He became a machinist, eventually rising to the position of maintenance supervisor at Northwest Airlines. In 2000, he retired after 25 years with the company.

Today, Lewis is taking Cinryze™ (C1 Esterase Inhibitor [Human]) for his HAE, and for the first time in his life, he’s living without worry. He credits his family with getting him through the tough times.

“Well, you know, being the 11th child, I got spoiled pretty good,” he recalls. “I always had somebody there to look after me. I can even remember some of my older brothers and sisters getting in fights because of kids calling me names.”

Ultimately, of course, Lewis is the one who fought harder than anyone.

And in the end, he came out on top.

KRISTINA BROADBELT NEVER IMAGINED THAT HER TASTE IN MUSIC WOULD END UP HELPING HER CAREER.

As Associate Director of Public Relations and Advocacy at ViroPharma, Broadbelt's official role includes spreading the word about her company's work to treat hereditary angioedema. But her unofficial job often involves long talks about history homework, platform shoes and the latest Coldplay CD.

"It definitely helps that I have the same taste in music as my patients," laughs Broadbelt, who works with people of all ages, but feels especially close to the teenagers. "They're the most inspiring patients," she explains. "It's hard enough to be a teenage girl — I know. I have three sisters and a 21-year-old daughter. But their resilience, their positive attitude...the fact that they want to be ambassadors to other teens across the country who are suffering from this — I find it absolutely inspirational."

As a patient advocate, Broadbelt travels the country to meet with HAE patients and their families, attend medical conferences and act as a liaison between ViroPharma and patient organizations. Her goal is to make sure Cinryze™ (C1 Esterase Inhibitor [Human]) is getting to the people who need it most, but she also helps patients cope with their situation in any way she can.

Broadbelt explains that her job fits perfectly with her philosophy about life. "I feel very blessed. I was a seventeen-year-old mother. If I didn't have people help me in my life, I wouldn't be where I am now. So I feel it's my duty to give back. And frankly, I get a lot of joy, satisfaction and fulfillment out of it."

Broadbelt has always loved helping people, but she didn't always know there was a job that would allow her to do it full-time. She started her career in public relations, working on behalf of pharmaceutical companies. In the mid-nineties she noticed that some of her larger clients were starting to hire patient advocates, and it occurred to her that she would love to do that kind of job. "Building relationships, nurturing relationships — that's what I really care about," she explains.

"But when hard times hit the pharmaceutical industry, around 2000, those jobs mostly went away. So I couldn't pursue this idea of being a patient advocate anymore."

Then one day, out of the blue, her old friend Bob Doody, ViroPharma's Assistant Director of Investor Relations, called to say hello. Broadbelt found herself telling him about her dream to work as a patient advocate, and her frustration that the job only seemed to exist at a few large, well-funded companies.

"And that's when a light bulb went off in his head," she remembers. "And he said, 'You know what? I think we need somebody like that here.'"

Broadbelt wrote a job description to help ViroPharma Management understand why the position was needed, and within a few weeks, she was hired.

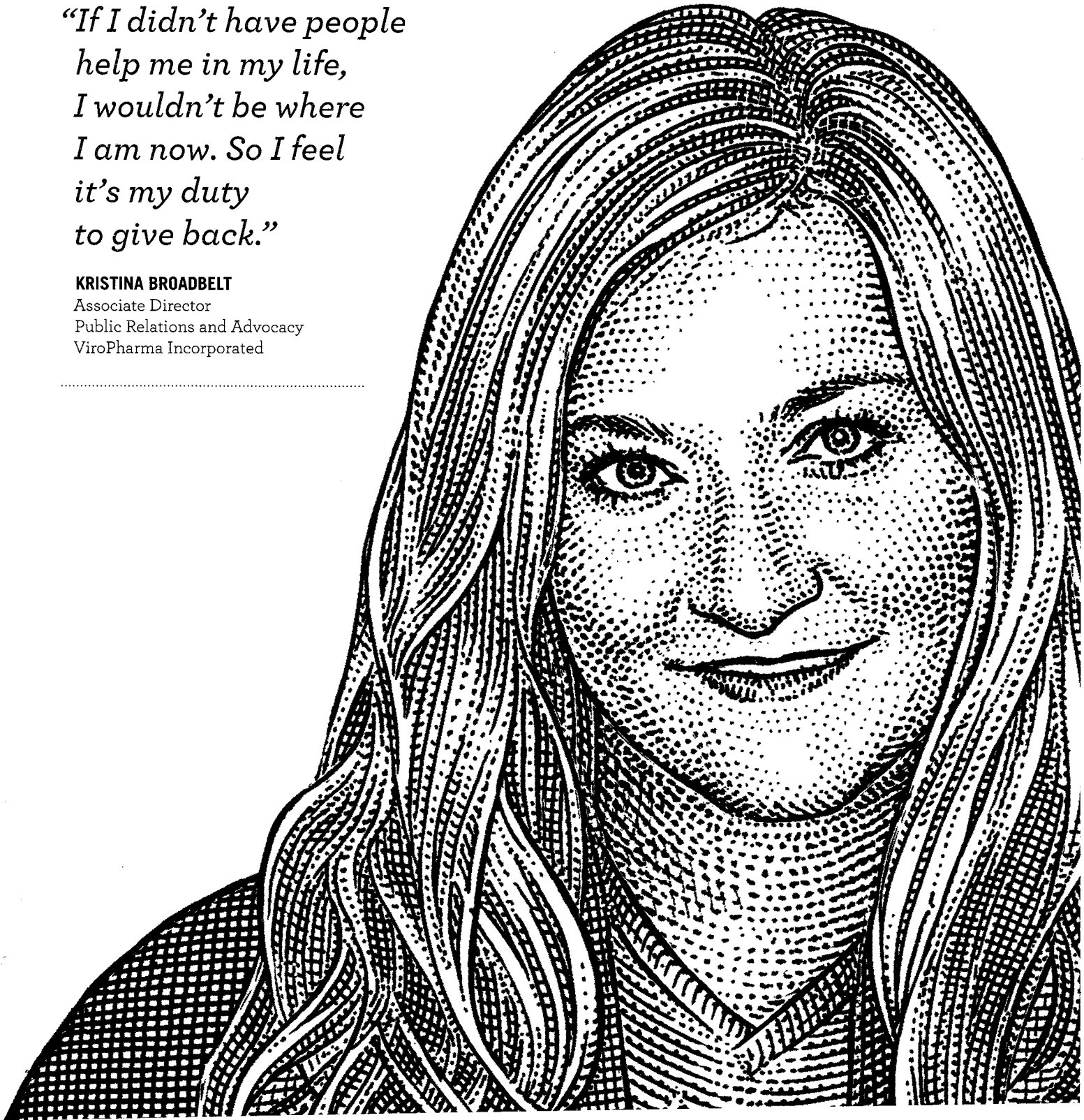
"ViroPharma has given me the tools to make a difference in people's lives," she says now. "It's very atypical for a company of this size to have a person like me on the team. But ViroPharma has made the commitment to be a patient-focused company and do whatever it takes to deliver on that."

Even if that means listening to Lady GaGa.

*“If I didn’t have people
help me in my life,
I wouldn’t be where
I am now. So I feel
it’s my duty
to give back.”*

KRISTINA BROADBELT

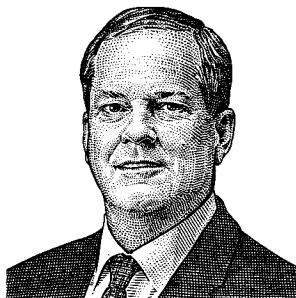
Associate Director
Public Relations and Advocacy
ViroPharma Incorporated



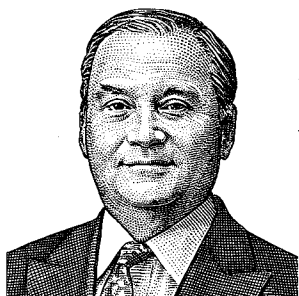
BOARD OF DIRECTORS



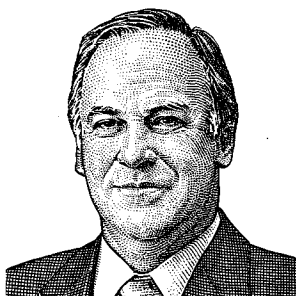
FRANK BALDINO, JR., PH.D.
CEO and Chairman
Cephalon Inc.



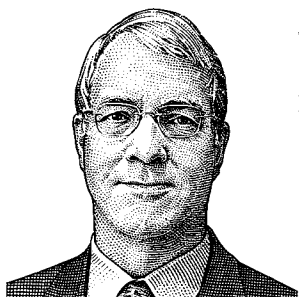
ROBERT J. GLASER⁽²⁾
Senior Partner
Pennmark Associates, LLC



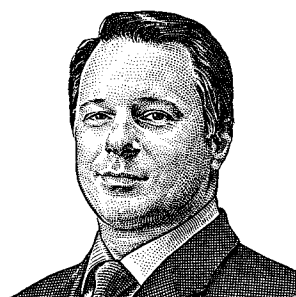
PAUL A. BROOKE⁽¹⁾
Managing Director
and Co-Founder
venBio



JOHN R. LEONE⁽¹⁾
Partner
Paul Capital Partners

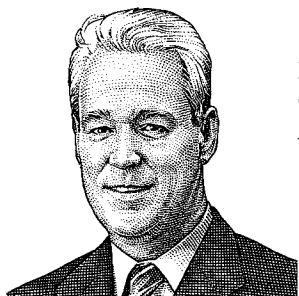


WILLIAM D. CLAYPOOL, M.D.⁽²⁾
Senior Partner
Pennmark Associates, LLC

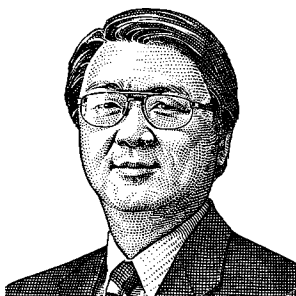


VINCENT J. MILANO
Chairman of the
Board of Directors
ViroPharma Incorporated

President and
Chief Executive Officer
ViroPharma Incorporated



MICHAEL R. DOUGHERTY⁽¹⁾⁽³⁾
President and
Chief Executive Officer
Adolor Corporation



HOWARD H. PIEN⁽³⁾
Lead Independent Director
of Board of Directors
ViroPharma Incorporated

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(2) MEMBER OF COMPENSATION COMMITTEE

(3) MEMBER OF NOMINATING AND GOVERNANCE COMMITTEE

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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 and Project Management

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 and Facilities

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.

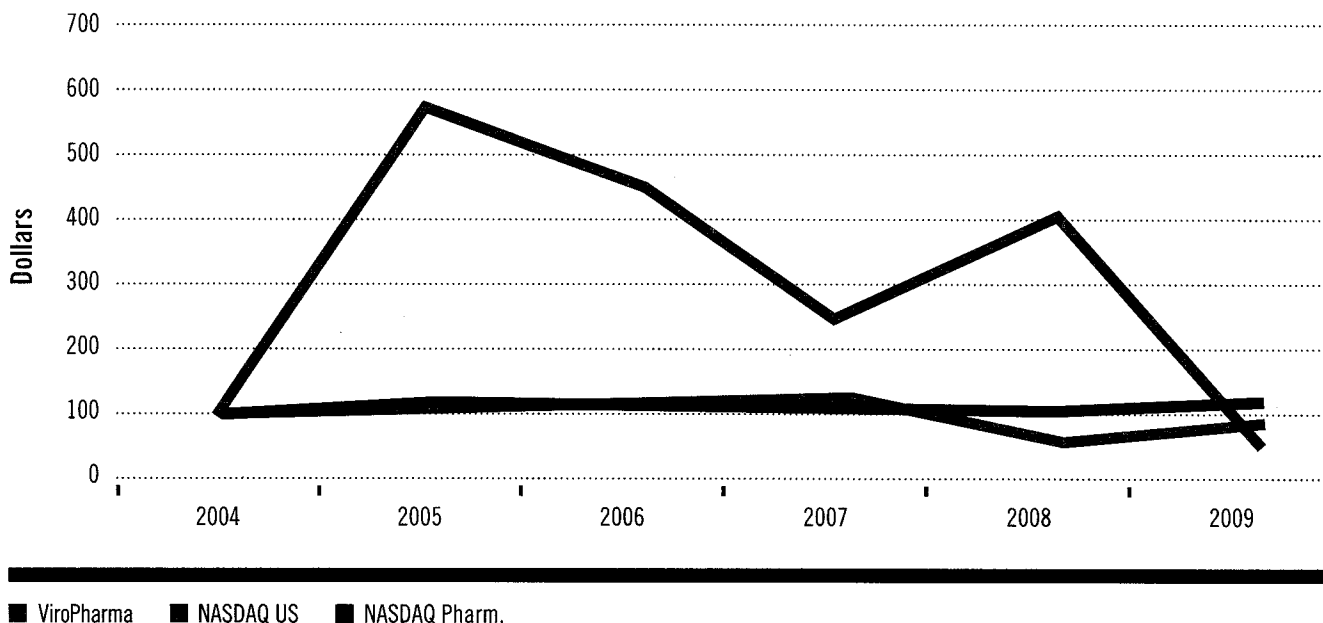
Vice President
General Counsel and Secretary

This annual report contains forward looking statements relating to our goals of developing and commercializing innovative products addressing life threatening unmet medical needs and improving the lives of patients suffering from serious diseases. Forwarding looking statements include, but are not limited to, those related to, the goals, timing, and potential indications and markets of our clinical and preclinical development programs; our ability to achieve commercial success with Cinryze in the U.S., E.U. or other territories; our ability to assure that every patient who needs Cinryze will have access; regulatory approval timelines, including our ability to receive regulatory approval for Cinryze in the E.U. and approvals related to the expansion of manufacturing capabilities in the capacities and timeframes currently 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, including NTCD. The FDA or other regulatory authorities may require additional or unanticipated studies or clinical trial outcomes before granting regulatory approval of NTCD or Cinryze. 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 U.S. and E.U.; cost effectiveness of HAE treatment using Cinryze; relative convenience and ease of administration of Cinryze; potential advantages of Cinryze over alternative treatments; the market acceptance of other products approved to treat acute HAE such as Berinert and Kalbitor; patients' ability to obtain sufficient coverage or reimbursement by third-party payors; sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze; manufacturing or supply interruptions and capacity which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product; and our ability to achieve expansion of manufacturing capabilities in the capacities and timeframes currently anticipated. In addition, our ability to develop life cycle management plans for Cinryze, including designing and commencing clinical studies for additional indications and methods of administration, commercializing Cinryze in additional geographic territories and pursuing regulatory approvals in such territories will impact our ability to generate future revenues from Cinryze. There can be no assurance that our efforts to oppose the FDA's bioequivalence guidance for Vancocin will be successful. 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. 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 comparative total return performance graph above compares the cumulative stockholder return on our common stock for the period from December 31, 2004 through the year ending December 31, 2009 with the cumulative Total Return Index for (I) the NASDAQ Stock Market (U.S. Companies), which we refer to as the NASDAQ Composite Index and (II) the NASDAQ Pharmaceutical Index. This graph assumes the investment of \$100 on December 31, 2004 in our common stock, the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index and assumes that all dividends are reinvested. Measurement points are the last trading days of each of the years ended December 31, 2004, 2005, 2006, 2007, 2008 and 2009.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

SEC Mail Processing
Division

APR 16 2010

FORM 10-K

Washington, DC
110

(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, 2009

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

VIOPHARMA INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

730 Stockton Drive,
Exton, Pennsylvania
(Address of principal executive offices)

19341
(Zip Code)

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

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

<u>Title of each class:</u>	<u>Name of each exchange on which registered:</u>
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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 \$401.7 million as of June 30, 2009, 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 19, 2010 was 77,480,094 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 24, 2010 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, 2009
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“ViroPharma,” “ViroPharma” plus the design, “Cinryze”, CinryzeSolutions and “Vancocin” are trademarks and service marks of ViroPharma or its licensors. We have obtained trademark registration in the United States for the marks in connection with certain products and services. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of others.

Unless the context requires otherwise, references in this report to “we,” “our,” “us,” “Company” and “ViroPharma” refer to ViroPharma Incorporated and its subsidiaries.

PART I

ITEM 1. BUSINESS

ViroPharma Incorporated and subsidiaries is a global biotechnology 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 have two marketed products and two development programs. We intend to grow through sales of our marketed products, Cinryze™ and Vancocin®, through continued development of our product pipeline, expansion of sales of Cinryze into additional territories and through potential acquisition or licensing of products or acquisition of companies.

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze is a C1 esterase inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor (C1-INH) deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was obtained in October 2008, when we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev). On January 8, 2010 we obtained expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world (as described in the strategic relationships section) as well as rights to develop future C1-INH derived products for additional indications. We intend to seek to commercialize Cinryze in Europe in 2011 in countries which we have distribution rights. We are currently evaluating our commercialization plans in additional territories. We also intend to conduct studies to identify further therapeutic uses and expand the labeled indication for Cinryze to potentially include other C1 mediated diseases as well as new modes of administration.

We also 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 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.

We currently have two development programs, C1 esterase inhibitor [human] to identify further therapeutic uses and potential additional indications and other modes of administration for the treatment of HAE and other C1 mediated diseases and a non-toxic strain of *C. difficile* (NTCD) for the treatment and prevention of CDI. On August 6, 2009 we announced that dosing has begun in the Phase 1 clinical trial for NTCD. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as a single and repeat escalating doses in healthy young and older adults. 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 the current standard of care. We continue to evaluate our maribavir program in light of the Phase 3 clinical trial results.

We licensed the U.S. and Canadian rights for a further product development candidate, an intranasal formulation of pleconaril, to Merck & Co., Inc. (Merck) 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 or life threatening illnesses, which treat high unmet medical needs, which require limited commercial infrastructure, and that have the potential to provide both top and bottom line growth.

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.

The following chart generally describes our approved products:

<u>Product</u>	<u>Marketplace</u>	<u>Disease</u>	<u>Program Indication</u>	<u>Product Status</u>
Cinryze – IV	US	HAE	Prophylaxis	Marketed
Vancocin	US	CDI	Treatment	Marketed

The following chart generally describes our investigational products:

<u>Product</u>	<u>Marketplace</u>	<u>Disease</u>	<u>Proposed Indication</u>	<u>Product Status</u>
C1 esterase inhibitor [human] – IV	EU	HAE	Prophylaxis and acute	Prefiling
C1 esterase inhibitor [human] – IV	ROW*	HAE	Prophylaxis and acute	Prefiling
Non-toxigenic strain of C. difficile (NTCD)	Worldwide	CDI	Treatment and prevention	Phase 1
C1 esterase inhibitor [human] – subcutaneous administration	Worldwide	HAE	Prophylaxis	Phase 1
C1 esterase inhibitor [human] – IV	Worldwide	Additional indications under evaluation		Preclinical
Maribavir	Worldwide, other than Japan	CMV	Treatment and prevention	Evaluating Program

* ROW is defined in the Strategic Relationships section of the document.

Marketed Products

Cinryze

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 40% 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 as many as 11,000 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. This genetic defect results in the production of either inadequate levels or poorly functioning C1-INH protein.

C1-INH is a normal constituent of human blood and primarily regulates activation of key inflammatory and coagulation biochemical pathways, specifically the contact and complement pathways in addition to the fibrinolytic system. Regulation of these systems is performed through the formation of complexes between pathway proteinase enzyme and C1-INH, resulting in inactivation of both and consumption of C1-INH. HAE patients have low levels of endogenous or functional C1-INH. Although the events that induce angioedema

attacks in HAE patients are not well defined, it is thought that increased blood vessel permeability leading to swelling and the clinical manifestations of HAE attacks are mediated primarily through contact system activation. Administration of Cinryze increases plasma levels of C1-INH activity. Increased levels of functional C1-INH are thought to suppress contact system activation through the inactivation of plasma kallikrein and factor XIIa, preventing the generation of bradykinin, a natural peptide thought to be responsible for modulation of blood vessel permeability.

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 poorly functioning 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.

Current therapies primarily focus upon treating the symptoms of an acute attack. Two therapeutic agents that can be used for treatment of acute attacks were approved by the FDA in 2009, a kallikrein inhibitor and a C1-INH. For swelling of the intestinal wall, which can cause debilitating pain, narcotics such as morphine and antiemetics for nausea are often given. 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.

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. We are currently conducting a phase 4 study to evaluate the safety and effect of escalating doses of Cinryze as prophylactic therapy which was a post approval requirement of the FDA.

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; accordingly, 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 toxic megacolon 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 Disease Control and Prevention (CDC) and peer-reviewed publications, we estimate that at least 500,000 patients were affected by CDI in 2008. In recent years, many clinicians reported 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 overall incidence of CDI may have plateaued or even decreased in 2009 relative to 2008, however reliable data on current incidence are limited.

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 December 2008, FDA changed OGD's 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, 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 in vitro 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. On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the portion of the OGD's 2008 draft guidelines on bioequivalence for Vancocin that restricts in vitro bioequivalence testing for generic products that are, among other things, Q1 and Q2 the same as Vancocin.

Product Pipeline

We currently have two development programs. Our C1 esterase inhibitor [human] related development program focuses on our efforts to commercialize Cinryze in Europe and certain other countries, conduct clinical studies to identify additional therapeutic uses to expand the labeled indication for C1 esterase inhibitors to potentially include other C1 mediated diseases as well as new modes of administration of C1 esterase inhibitors. We are also conducting Phase 1 clinical studies targeting the treatment and prevention of CDI utilizing the spore form of a non-toxin producing strain of *C. difficile* (NTCD). We continue to evaluate our maribavir program in light of the Phase 3 clinical trial results.

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

HAE Program

Cinryze IV—EU and ROW

In January 2010, we obtained expanded rights to commercialize Cinryze in certain countries in Europe and ROW as well as rights to develop future C1-INH derived products for additional indications. We intend to commercialize Cinryze in Europe when the product has received the EMA commission approval which we anticipate during 2011. HAE affects between 1 in 30,000 and 1 in 50,000 individuals in Europe. We are seeking approval to market Cinryze IV to patients in Europe for the treatment and routine prophylaxis against attacks in adolescent and adult patients with HAE. Part of this commercialization plan was obtaining Orphan Drug designation for Europe which was granted in October 2009.

C1-INH concentrate has been marketed to HAE patients for acute treatment in Europe for 25 years. Our ability to compete in this marketplace is contingent upon our success in differentiating Cinryze IV over existing C1-INH products.

We are currently in the early stages of identifying the steps necessary to launch in territories outside of the US and EU.

Cinryze IV—Other C1 mediated diseases and Cinryze—other formulations

We are currently evaluating with our partner Sanquin, the feasibility of additional therapeutic uses and potential indications in addition to other formulations and modes of administration for Cinryze. We have conducted a Phase 1 study utilizing subcutaneous administration and expect to commence a Phase 2 study in 2010. We also intend to conduct studies to identify further therapeutic uses and additional potential indications for other C1 mediated diseases. Our initial focus includes investigating C1-INH in transplant patients. Finally, we are currently evaluating a recombinant C1-INH technology which may be incorporated in the treatment of C1 mediated diseases.

CDI Program

NTCD

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*. According to published literature, approximately 20 to 30 percent of patients suffering from CDI will have at least one episode of relapse of disease. The goal of our NTCD program is to prevent such recurrence of disease. There is also the potential for NTCD to be used as primary prevention for CDI.

Over the past several years, CDI has increased in severity and incidence. As such, the number of recurrent infections has also increased. According to a recent survey, 55 percent of participating US hospitals reported an increase in the number of treatment relapses over a recent 12 month period. Because of this dramatic increase, finding new alternatives to prevent recurrent CDI remains an important medical goal. 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.

In August 2009, dosing began in the Phase 1 clinical trial for NTCD. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as single and repeat escalating doses in healthy young (18-45 years of age) and older (60 years of age and older) adults. The study is being conducted in Switzerland. Should the therapy be well tolerated, we plan to initiate NTCD repeat dosing in older adults following exposure to oral antibiotics.

Antibiotic use is associated with disruption of gastrointestinal flora which renders individuals susceptible to *C. difficile* colonization. The goal of NTCD dosing following antibiotic exposure is to colonize with this non-toxicogenic strain of *C. difficile* and to prevent colonization by toxicogenic strains, thereby preventing disease. We expect the results of this Phase 1 clinical trial in the second half of 2010.

CMV Program

We continue to evaluate our maribavir program in light of the Phase 3 clinical trial results. 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.

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. Subsequent to our announcements in February 2009, we have continued to wind down our two Phase 3 studies evaluating maribavir.

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.

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 or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and that have the potential to provide both top and bottom line growth over time.

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.

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.

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. As of December 31, 2009, only the second CVR as described below remains achievable. The target for the first CVR payment of \$0.50 per share (or \$87.5 million) is no longer achievable and will not be paid as during the fourth quarter of 2009, a third party's human C1 inhibitor product was approved for the acute treatment of HAE and granted orphan exclusivity. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018.

Strategic Relationships

Cinryze and Sanquin

Pursuant to the terms of an existing Distribution and Manufacturing Services Agreement between our subsidiary ViroPharma Biologics, Inc. ("VP Biologics") with Stichting Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation) ("Sanquin") (the "Original Sanquin Agreement"), we held (i) the exclusive right to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma (including Cinryze) manufactured by Sanquin for the treatment of HAE in all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel, 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.

On January 8, 2010 we obtained the exclusive rights to research, develop, import, use, sell and offer for sale C1-INH derived products (other than Cetor) worldwide, other than the Excluded Territory (as defined below) for all potential indications pursuant to a Manufacturing and Distribution Agreement (Europe and ROW) between our European subsidiary, ViroPharma SPRL ("VP SPRL") and Sanquin (the "ROW Agreement"). The Excluded Territory includes (i) certain countries with existing distributors of Cinryze, Cetor and Cetor NF namely France, Ireland, the United Kingdom, Egypt, Iran, Israel, Indonesia, Turkey, Argentina and Brazil (the "Third Party Distributors") and (ii) countries in which Sanquin has historically operated namely, Belgium, Finland, Luxemburg and The Netherlands (including the Dutch Overseas Territories) (the "Precedent Countries" and collectively, the "Excluded Territory"). In the event that any agreement with a Third Party Distributor in the Excluded Territory is terminated, we have a right of first refusal to obtain the foregoing exclusive licenses to the C1-INH derived products with respect to such terminated country.

Also on January 8, 2010, we amended and restated the Original Sanquin Agreement (the "Restated US Agreement"). Pursuant to the terms of the Restated US Agreement, we retained the rights to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma (including Cinryze) manufactured by Sanquin for the treatment of HAE in all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel.

The initial term of the Restated US Agreement ends on December 31, 2015. The term will automatically renew for up to eighteen years (comprised of six three-year periods), unless the Restated US Agreement is earlier terminated by either party. Sanquin may terminate this Restated US Agreement by providing written notice to us at least three years prior to the end of the initial term or any subsequent renewal period. We may terminate the Restated US Agreement by providing written notice to Sanquin at least two years prior to the end of the initial term or any subsequent renewal period. Each party may terminate the Restated US Agreement upon written notice in the event of: (i) an uncured material breach of the other party or (ii) the other party is declared insolvent or bankrupt, a voluntary petition of bankruptcy is filed by the other party, the other party makes or executes any assignment for the benefit of creditors or a receiver is appointed to control the business of the other party.

The initial term of the ROW Agreement will end on December 31, 2019, but shall automatically renew for up to eighteen years (comprised of six three-year periods), unless the ROW Agreement is earlier terminated by either party. Sanquin may terminate the ROW Agreement by providing written notice to us at least three years prior to the end of the initial term or any subsequent renewal period. We may terminate the ROW Agreement by

providing written notice to Sanquin at least two years prior to the end of the initial term or any subsequent renewal period. Each party may terminate the ROW Agreement upon written notice to the other in the event of: (i) an uncured material breach of the other party or (ii) in the event that other party (1) applies for or consents to an appointment of a receiver for itself or all or substantially all of its assets, (2) makes an assignment for the benefit of creditors, (3) commences a voluntary case or bankruptcy or consents to any bankruptcy or restructuring relief or the appointment of or taking possession of its property in any such proceeding or (4) takes any corporate action to effect any of the foregoing.

In January 2010, both parties established a Joint Steering Committee comprised of an equal number of representatives from each of the parties to the agreements. The Joint Steering Committee shall serve as a forum to establish and discuss progress under, among others, (i) a global commercialization plan; (ii) clinical development programs of ViroPharma and Sanquin early stage research programs; (iii) manufacturing capacity schedules; (iv) pharmacovigilance matters; (v) quality matters; (vi) manufacturing improvement programs; and (vii) regulatory matters.

Subject to certain terms of each of the Restated US Agreement and the ROW Agreement, if we do not use commercially reasonable efforts to file applications for marketing authorization of Cinryze or launch Cinryze in accordance with a commercialization plan for the applicable territories, as approved by the Joint Steering Committee, Sanquin may (upon prior written notice to us) terminate our rights in the applicable country.

In addition, pursuant to the terms of the ROW Agreement, Sanquin may conduct certain early stage research programs (the "Early Stage Research Programs"), and we will provide to Sanquin €1,000,000 (approximately \$1.4 million) per year for a period of five years to support such Early Stage Research Programs. We have a right of first refusal to further develop and commercialize the subject matter of each such Early Stage Research Program worldwide (except for the Excluded Territory) subject to Sanquin's and its research partners' right to use any such intellectual property for their internal, non-commercial research purposes. Except for the Early Stage Research Programs, we will be solely responsible for conducting all clinical trials and other development activities necessary to support our efforts to obtain regulatory approval of Cinryze in additional territories as well as any future C1-INH derived products developed pursuant to the ROW Agreement. Sanquin has the right to approve any such clinical trials and development activities through the Joint Steering Committee.

Sanquin may include in its regulatory dossiers improvements to Cinryze for the hereditary angioedema ("HAE") indication, solely for the marketing and sale of Cetor or Cetor NF in the Excluded Territory. If there are (i) new indications relating to any C1-INH product or (ii) improvements relating to the HAE-indication that cannot be included in Sanquin's regulatory dossiers, Sanquin will receive a royalty-free license to sell Cinryze or the future product for these new indications or improvements in the Precedent Countries.

Sanquin has agreed to indemnify us and our affiliates for certain losses, except to the extent we have an obligation to indemnify Sanquin. We have agreed to indemnify Sanquin and its affiliates for all losses arising from (i) our infringement of any third party's intellectual property as a result of the sale of Cinryze or any future C1-INH derived products in the territories covered by the agreements, (ii) a breach by us of the terms of the agreements, (iii) certain tax liabilities and (iv) our negligence or willful misconduct, except, in each case, to the extent Sanquin has an obligation to indemnify us.

Without Sanquin's prior written consent, we shall not enter into a merger, be acquired by or sell substantially all of our assets to a manufacturer and/or distributor of a plasma derived C1 esterase inhibitor or another plasma-derived product approved under applicable law for marketing for the same or comparable clinical indications as Cinryze or any future C1-INH derived products. We may not, without the consent of Sanquin, distribute, market, offer for sale, sell, import or promote any competitive product in the territory covered by the Restated US Agreement until December 31, 2018. In addition, we may not, without the consent of Sanquin, distribute, market, offer for sale, sell, import or promote any competitive product in the territories covered by the ROW Agreement until December 31, 2019.

In the event that VP Biologics has become bankrupt or insolvent and has committed an uncured breach of the Restated US Agreement, Sanquin will immediately obtain VP Biologics' rights to the marketing authorizations for Cinryze obtained by us and the applications for marketing authorization of Cinryze filed by us. ViroPharma Incorporated will guarantee VP Biologics' performance under the Restated US Agreement. In the event that VP SPRL becomes bankrupt or insolvent and commits an uncured breach of the ROW Agreement, Sanquin will immediately obtain our rights to the regulatory approvals for the products obtained by us under the ROW Agreement and the applications for regulatory approval of the product filed by us under the ROW Agreement. ViroPharma Incorporated will guarantee VP SPRL's performance under the ROW Agreement in the event of a bankruptcy.

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 and we are obligated to pay additional purchase price consideration based on annual net sales of Vancocin through 2011. As of December 31, 2009, we have paid an aggregate of \$37.1 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 2009.

For annual net sales during 2010 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 6 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.

Picornaviruses and Merck

In November 2004, we entered into a license agreement with Merck under which Merck has assumed responsibility for all future development and commercialization of pleconaril in the U.S. and Canada. Merck paid us an upfront option fee of \$3.0 million in November 2003. In August 2004, Merck exercised its option to enter into a full license agreement with us following its assessment of the product's performance in characterization studies. Merck 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 Merck's sales of intranasal pleconaril in the licensed territories. Merck 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 Merck in respect of intranasal pleconaril. As a result of Merck'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 Merck'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 Merck 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.

Cinryze

In conjunction with the Lev acquisition, we acquired a Distribution and Manufacturing Services Agreement with Sanquin, which was amended and restated in January 2010 as described above. Additionally, in January 2010, we entered into the ROW Agreement as described above.

Restated U.S. Agreement

The terms of the Restated US Agreement related to manufacturing provide that Sanquin shall manufacture Cinryze for us on a toll manufacturing basis, using plasma supplied by us, for a manufacturing fee. During the term, we shall purchase from Sanquin an annual minimum quantity of Cinryze established by the parties for such calendar year.

Sanquin is implementing structural and equipment changes to its Amsterdam and Brussels manufacturing facilities. We previously funded such changes to the Brussels manufacturing facility and a portion of such changes to the Amsterdam manufacturing facility, each through a loan facility of an aggregate amount of €7,500,000 (approximately \$10.4 million). Pursuant to the Restated US Agreement, Sanquin will implement additional structural and equipment changes to the Brussels manufacturing facility, financed through an additional €5,000,000 (approximately \$7.2 million) loan facility provided by us. Sanquin will repay all such loan amounts by January 1, 2015 by providing us with a discount to the per unit purchase price of product.

Sanquin will use commercially reasonable efforts to obtain regulatory approval to manufacture Cinryze in the Amsterdam manufacturing facility prior to a date agreed to by the parties. Sanquin will enter into manufacturing agreements with one or more third party manufacturers, which may include affiliates of Sanquin, (reasonably acceptable to us) pursuant to which such third party manufacturers shall provide certain back-up manufacturing facilities for Cinryze. In the event that certain events occur which result in Sanquin permanently ceasing to manufacture Cinryze, Sanquin will grant us a perpetual license under its intellectual property related to Cinryze and assign to us each of the agreements with such third party manufacturers. In consideration thereof, we will pay a one-time fee to Sanquin as well as a royalty on future sales of Cinryze or any future C1-INH product.

ROW Agreement

The terms of the ROW Agreement related to manufacturing provide that Sanquin will manufacture Cinryze either based on a supply of plasma provided by Sanquin or on a toll-manufacturing basis using plasma supplied by us for a manufacturing fee. The manufacturing fee will be comprised of a base fee and a royalty which shall vary based upon the source of the plasma utilized. The parties will negotiate in good faith a new purchase price and manufacturing fee for any additional new products developed in accordance with the terms of the ROW Agreement. Beginning in 2015, we shall purchase at least a minimum quantity of Cinryze or future C1-INH product from Sanquin annually, which quantities shall be determined by the Joint Steering Committee in 2013.

Sanquin will enter into manufacturing agreements with one or more third party manufacturers, which may include affiliates of Sanquin, (reasonably acceptable to us) pursuant to which such third party manufacturers shall provide certain back-up manufacturing facilities for the products. In the event that certain events occur which result in Sanquin permanently ceasing to manufacture Cinryze or future C1-INH derived products, Sanquin will grant us a perpetual license under its intellectual property related to Cinryze or any future C1-INH product and assign to us each of the agreements with such third party manufacturers. In consideration thereof, we will pay a one-time fee to Sanquin as well as a royalty on future sales of Cinryze or any future C1-INH product.

Plasma

Cinryze is derived from human plasma sourced from commercial plasma suppliers. 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 a combination of sources for plasma including (i) long term supply agreements, (ii) periodic “spot purchases” of plasma from third party plasma suppliers, and (iii) we are exploring options to acquire our own plasma centers.

Supply Agreement with DCI Management Group, LLC

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. In July 2009 we amended the terms of the agreement. Under the amended agreement, the supplier agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices. Our annual purchase commitment is between \$19.3 million and \$25.4 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 \$139.0 million.

The amended agreement expires December 31, 2015, 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.

Intermediate Supply Agreement with Biotest AG

On June 19, 2009, we entered into an intermediate supply agreement (the “Supply Agreement”) with Biotest AG (“Biotest”) pursuant to which we will sell to Biotest all excess output of specific intermediate plasma products (the “Intermediates”) derived from the plasma processed by Sanquin in manufacturing Cinryze. 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 Intermediates. The Supply Agreement has an initial term expiring December 31, 2014, unless sooner terminated. In addition we established pricing for a pre-determined volume of source plasma (the “Target Volume”), provided that the parties shall renegotiate pricing terms upon achievement of the Target Volume. 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 Supply Agreement by Biotest, Biotest shall be liable to purchase all amounts of Intermediates deliverable under the Supply Agreement during its remaining term.

Purchase Agreement with Plasma Centers of America, LLC

On April 3, 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 the three new 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.

On October 20, 2009, we and PCA entered into a letter agreement providing for the termination of the purchase agreement with PCA dated April 3, 2008. Pursuant to the Letter Agreement, the Purchase Agreement was immediately terminated and ViroPharma is no longer obligated to perform its obligations under the Purchase Agreement. The Letter Agreement provides that PCA shall not be obligated to refund any payments previously made by ViroPharma to PCA, and also contains mutual releases between the parties. The parties determined to mutually terminate the Purchase Agreement following disagreements regarding project timelines.

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.

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, 2009, 2008 and 2007 are as follows:

	<u>Percentage of total revenues</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Customer A	29%	39%	37%
Customer B	25%	38%	40%
Customer C	13%	17%	16%
Customer D	12%	—	—
Total	<u>79%</u>	<u>94%</u>	<u>93%</u>

In 2009, four wholesalers represented 79% 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. We have entered into distribution service agreements with the parties identified in the table above.

Marketing and Sales

Our initial sales organization was established in 2008 in the Northeastern U.S. to target doctors and hospitals to promote Vancocin. With the commercial launch of Cinryze, we have transitioned our existing sales force and expanded our sales force to target doctors who treat patients who have been diagnosed with HAE. Given the relatively limited HAE patient population, our U.S. sales force is small compared to other drugs with similar gross revenues. Our sales force primarily focuses its efforts towards allergists, immunologists and home healthcare providers.

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. In anticipation of our commercial sales launch of Cinryze in Europe and certain other countries, we intend to expand our own commercial organizations in such territories and markets and sell Cinryze through our own sales force in these territories. This infrastructure expansion will result in additional costs in future periods. Outside of the United States and European territories, we will evaluate sales efforts on a country-by-country basis, and it is possible that we will rely on relationships with one or more companies with established distribution systems and direct sales forces in such countries.

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 three pending U.S. patent applications covering vancomycin related technology. One issued U.S. patent and two pending U.S. patent applications describing compounds, compositions and methods for treating respiratory syncytial virus (RSV) diseases have been transferred to another party. We have two issued U.S. patents and one pending U.S. patent application 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 three issued U.S. patents, six non-U.S. patents and four pending U.S. patent applications that we co-own with a single development collaborator 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 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.

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, marketing, 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 or BLA; and
- obtaining FDA approval of the NDA or BLA prior to any commercial sale or shipment of the drug or biologic 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 or BLA 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 or biologic product may be marketed only in those dosage forms and for those indications approved in the NDA or BLA.

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 or BLA 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.

Congress and regulatory authorities, including the FDA, are considering whether an abbreviated approval process for so-called generic or “follow-on” biological products should be adopted. An abbreviated approval process is currently available under the Federal Food, Drug and Cosmetic Act for generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, but not for biological products approved under the Public Health Service Act through a BLA. Currently, an applicant for a generic version of a small molecule compound only has to reference in its application an approved product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use; demonstrate that its product has the same active ingredients, dosage form, strength, route of administration and conditions of use and is absorbed in the body at the same rate and to the same extent as the referenced approved drug; include certifications to non-infringement of valid patents listed with the FDA for the referenced approved drug; and await the expiration of any non-patent exclusivity. Various proposals have been made to establish an abbreviated approval process to permit approval of generic or follow-on versions of biological products. It is unclear as to when, or if, any such proposals may be adopted but any such abbreviated approval process could have a material impact on our business as follow-on products may be significantly less costly to bring to market and may be priced significantly lower than our products would be.

In addition to obtaining FDA approval for each indication to be treated with each product, each drug or biologic 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 or biologic 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 or biologic 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 esterase inhibitor [human]) for routine prophylaxis in adolescent and adult patients with 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.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific

regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

For example, under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions, and the holder of a national marketing authorization may submit an application to the remaining member states. We submitted our Marketing Authorization Application for Cinryze for the acute treatment and prophylaxis of HAE to the European Medicines Agency (EMA), using the centralized procedure.

Before submitting a Marketing Authorization Application (MAA) in the EU, a company must obtain approval of a Paediatric Investigation Plan (PIP) from the EMA's Paediatric Committee (PDCO). The PIP describes the pediatric development of a product and may include pharmaceutical development, non-clinical and clinical activities. The PIP will also define the age ranges of the children for whom the product must be developed and the timelines that the sponsor must meet, including, for example, the deferral of some studies. The PIP is updated as new information is obtained. The incentives for completing the PIP include 6 months patent extension and, for orphan medicinal products, an additional 2 years orphan exclusivity. In October 2009 and March 2009 PIPs were approved for Cinryze and maribavir, respectively.

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. In October 2009 and December 2007, the Company was granted orphan medical product designation for Cinryze and maribavir, respectively, by the Committee for Orphan Medicinal Products of the EMA.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. A member state may approve a specific price or level of reimbursement for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In the event we receive regulatory approval of Cinryze in the EU, we will need to engage with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required in each country.

Competition

Other companies are developing treatments for the disease states for which we market products or are developing product candidates, including compounds in preclinical and clinical development for HAE, *C. difficile*, and CMV. These companies include both public and private entities, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions. 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.

HAE

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. Steroid based products are currently used for prophylaxis of HAE. In the fourth quarter of 2009 the FDA has granted marketing approval of CSL Behring's product, Berinert® C1-Esterase Inhibitor, Human, for the treatment of acute abdominal or facial attacks of hereditary angioedema and Berinert has received exclusivity pursuant to the Orphan Drug Act. This approval will prevent us from obtaining FDA licensure and marketing our C1-INH product for the treatment of acute abdominal or facial attacks HAE for up to seven years. Additionally, in the fourth quarter of 2009, Dyax received approval for their product candidate for the acute treatment of HAE. In addition, Pharming NV and Shire are currently developing products for the acute treatment of HAE.

CDI

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.

In December 2008, FDA changed OGD's 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, 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 in vitro 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.

On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD's 2008 draft guidelines on bioequivalence for Vancocin. If FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also 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, and the number of generics and the timing of their market entry is unknown.

Additionally, 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. Vancocin sales for treatment of antibiotic-associated pseudomembranous colitis caused by *C. difficile* have decreased over the past 12 months and Vancocin's share of the U.S. market for this indication may continue to 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.

CMV

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 cidofvir 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. We believe that there are a number of 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.

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 or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and that provide both top and bottom line growth over time.

Many of our competitors have substantially greater financial, research and development, manufacturing, marketing and human resources than we do.

Employees

As of February 19, 2010, we had 188 employees of which 169 were employed in the United States and 19 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

<u>Name</u>	<u>Age</u>	<u>Position</u>
Vincent J. Milano	46	President, Chief Executive Officer and Chairman of the Board of Directors
Charles A. Rowland, Jr. . .	51	Vice President, Chief Financial Officer
Colin Broom, M.D.	54	Vice President, Chief Scientific Officer
Thomas F. Doyle	49	Vice President, Strategic Initiatives
Daniel B. Soland	51	Vice President, Chief Operating Officer
Robert G. Pietrusko	61	Vice President, Regulatory Affairs and Quality
J. Peter Wolf	40	Vice President, General Counsel and Secretary
Richard S. Morris	36	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 served on the board of directors of Verticalnet, Inc. from August 2003 until the company was acquired by BravoSolution S.p.A. in January 2008. 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. Prior thereto, Mr. Rowland was Senior Vice President and CFO of Biovail Pharmaceuticals, Inc. from 2004 to 2006. 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 1984 until 1998, Dr. Broom was with Glaxo and then SmithKline Beecham, where he held positions of increasing seniority in clinical pharmacology in Europe before moving to the U.S. to head global oncology and subsequently becoming Vice President of CNS/GI. 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. Dr. Broom has been a director of NPS Pharmaceuticals since July 2009.

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 joined ViroPharma in November 2006 as our Vice President, Chief Commercial Officer and has served as our Chief Operating Officer since March 2008. 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, Phm.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 and as an associate at two other private law firms. 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.viopharma.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.

PART II—OTHER INFORMATION

ITEM 1A. RISK FACTORS

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 sales of Vancocin represented 69 percent of our revenue in 2009. 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 or declined during 2008 and 2009. A decrease in sales of Vancocin could have a material adverse effect on our business, financial condition, results of operations and liquidity.

If we are unable to continue to successfully commercialize Cinryze in the United States, or are delayed in our ability to commercialize Cinryze in Europe and additional territories or are significantly 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. We are in the process of seeking regulatory approval for Cinryze in Europe and anticipate that our Marketing Authorization Application (MAA) will be accepted by the European Medicines Agency (EMA) in the first half of 2010. 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;

- our ability to receive regulatory approvals to market Cinryze in Europe and other territories in the timeframes we anticipate;
- manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product;
- 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, Europe and additional territories;
- 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 in the U.S. and our ability to receive sufficient reimbursement and price approvals that are separately required in each country of Europe; and
- sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze.

If we are not able to continue to successfully commercialize Cinryze in the U.S., Europe and additional territories, 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.

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 maintain a significant market share in order to increase revenue and maintain profitability.

The prevalence of HAE patients has not been definitively determined but has been estimated, through market research we have conducted, at up to 11,000 total patients in the U.S. Additionally, we believe that HAE affects between 1 in 10,000 and 1 in 50,000 individuals in Europe and other territories worldwide. 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. or other territories 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 additional HAE patients to increase revenue and 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 FDA convened a meeting of its Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products on August 4, 2009. The Advisory Committee was asked if the proposed guidelines are sufficient for establishing bioequivalence for generic vancomycin oral capsules. The Advisory Committee voted unanimously in favor of the component of the proposed OGD recommendation that requires bioequivalence to be demonstrated through comparable dissolution in media of pH 1.2, 4.5 and 6.8 for potential vancomycin HCl capsule generic products

that (a) contain the same active and inactive ingredients in the same amounts as Vancocin HCl capsules; (b) meet currently accepted standards for assay, potency, purity, and stability (equivalent to those in place for Vancocin HCl capsules); and (c) are manufactured according to cGMP.

We have opposed 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 and voted upon by the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, the threat of generic competition will be high.

We do not have patent protection for the composition of Cinryze and we rely on the exclusivity provided by the Orphan Drug Act.

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 FDA granted Cinryze seven years of marketing exclusivity to Cinryze C1 inhibitor (human) for routine prophylaxis of HAE pursuant to the Orphan Drug Act. The FDA has granted marketing approval of CSL Behring's product, Berinert® C1-Esterase Inhibitor, Human, for the treatment of acute abdominal or facial attacks of hereditary angioedema and Berinert has received exclusivity pursuant to the Orphan Drug Act. In addition, the EMEA has enacted similar orphan drug legislation and we have received an orphan drug designation under this legislation for Cinryze. We believe Pharming NV is currently developing products that the EMEA may determine to be in the same class as Cinryze for the acute treatment of HAE in Europe.

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. In the event we are unable to fill demand for Cinryze, it is possible that the FDA may view such unmet demand as a market shortage which could impact the market exclusivity provided by the Orphan Drug Act. Additionally, 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.

We do not know whether Vancocin and Cinryze will continue to be competitive in the markets which they 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* decreased in 2009 from the sales achieved in 2008. Vancocin's share of the U.S. market for this indication may decrease further 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 and Optimer Pharmaceuticals, 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 in the U.S., CSL Behring and Dyax had products approved for the treatment of acute attacks of HAE during 2009 and steroid based products are currently used for prophylaxis of HAE. In addition, Pharming NV and Jerini/Shire are currently developing products for the acute treatment of HAE. Approval of new products, or expanded use of currently available products, to prophylax or treat HAE, could materially and adversely affect our U.S. sales of Cinryze. In addition, there are currently several products approved for the acute treatment of HAE in Europe. Even if we are successful in receiving regulatory approval for Cinryze in Europe there can be no assurance that we will be able to achieve market share in accordance with our expectations.

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 current Good Manufacturing Practice regulations, or cGMPs required by the FDA and other regulatory agencies. 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. As such, 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. For example, Cinryze is a biologic which requires processing steps that are more difficult than those required for most chemical pharmaceuticals and therefore the third party contracts must have additional technical skills and multiple steps to attempt to control the manufacturing processes.

Problems with these manufacturing processes such as equipment malfunctions, facility contamination, labor problems, raw material shortages or contamination, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers and even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and insufficient inventory.

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 and other regulatory agencies routinely inspect manufacturing facilities before approving a new drug application, or NDA, or biologic application, or BLA, for a drug or biologic manufactured at those sites. If any of our manufacturers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our products and product candidates may be delayed.

In addition, regulatory agencies subject a marketed therapy, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. The discovery of previously unknown problems with a therapy or the facility or process used to produce the therapy could prompt a regulatory authority to impose restrictions on us or

delay approvals for new products or could cause us to voluntarily adopt restrictions, including withdrawal of one or more of our products or services from the market. The FDA recently inspected two sites maintained by our contract manufacturer for Cinryze and issued a notice of observations at the close of the inspection on FDA Form 483 for each site. The observations at one site were subsequently remedied and a notice to this effect was issued by the FDA. Responses to the observations made at the second site have been provided to the FDA. If any of our manufacturers or processors fails to satisfy regulatory requirements, operations at such facility may be halted which could result in our inability to supply product to patients and reduce our revenues.

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 depend on single manufacturers for certain components used in Vancocin and Cinryze and the loss of either of these suppliers or any supplier in general would have a negative impact on our operations.

We rely on a single supplier 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 and 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 CINRYZE. We and Sanquin are undertaking process improvements and facility expansions to increase the capacity of the facilities involved in manufacturing Cinryze. In the event that certain events occur which result in Sanquin permanently ceasing to manufacture Cinryze, Sanquin will grant us a perpetual license under its intellectual property related to the Product and assign to us each of the agreements with such third party manufacturers. In consideration thereof, we will pay a one-time fee to Sanquin as well as a royalty on future sales of products. In the event demand for Cinryze is greater than the amount supplied by Sanquin, we will not be able to meet such demand as there are no other sources of supply of Cinryze available to us. In the event Sanquin permanently ceases to manufacture Cinryze, we will need to find an alternate manufacturer of Cinryze. Currently, to our knowledge, there is only one other commercial supplier of C1 esterase inhibitor and that supplier has recently received marketing approval for their product in the U.S. Accordingly, in the event Sanquin permanently ceases to manufacture Cinryze, we cannot be certain that we would be able to locate another willing supplier for our product on the terms we require.

The risks associated with the numerous factors that could cause interruptions in the supply of our products, including manufacturing capacity limitations, regulatory reviews, changes in our sources for manufacturing, disputes with a manufacturer, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials, are magnified when the suppliers are limited in number. 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.

During time periods that patient demand approaches our manufacturing capacity we will manage the rate at which additional new patients will receive Cinryze and will limit the number of doses provided to patients. This would result in a reduction of potential future revenues.

Pursuant to our distribution agreement, Sanquin Blood Supply Foundation supplies us with certain annual minimum and maximum amounts of C1 INH. We and Sanquin are undertaking process improvements and facility expansions to increase the capacity of the facilities involved in manufacturing Cinryze. Our manufacturing scale up effort is a two-tiered approach including a parallel chromatography process, which we anticipate will be completed in the first quarter of 2010, with the additional product becoming available for commercial sale in the second quarter of 2010. The second phase of our scale up plan involves a larger scale construction project to significantly increase the production facilities of Sanquin. Pursuant to an agreement with Sanquin we have financed a portion of the costs of the project to increase the manufacturing capacity of its facilities. Following 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 at an increased capacity. We anticipate that the approvals could be received by the end of 2010.

The number of patients enrolling into our treatment support service for patients with HAE and their healthcare providers, *CinryzeSolutions* is above our expectations. As a result, we began to temporarily limit the rate at which additional patients are started on drug to ensure that those already receiving commercial drug continue with a supply of Cinryze until capacity increases. If the manufacturing capacity expansion projects at Sanquin are delayed, or do not result in the capacity we anticipate, or if Sanquin cannot obtain necessary regulatory approvals for the contemplated facility expansions in the time frames we anticipate, we may not be able to satisfy patient demand. Our inability to obtain adequate product supplies to satisfy our patient demand may create opportunities for our competitors and we will suffer a loss of potential future revenues.

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 Vancocin from two warehouses located in the central U.S. and western U.S. and Cinryze from one of these warehouses. A disaster occurring at or near these facilities 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 percent 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 our products to patients could be disrupted; and
- we may not achieve the sales of our products 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 2009 we experienced from any one wholesaler was approximately \$12.9 million and we anticipate that this amount could

increase if Vancocin sales 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.

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 CinryzeSolutions™ program, a treatment support service for patients with HAE and their healthcare providers. CinryzeSolutions 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.

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 sources to supply U.S. human plasma for Cinryze. In connection with our commercial sales of Cinryze and our ongoing and future clinical trials, we will need increased supplies of plasma.

We have a contract for the purchase and sale of plasma with DCI Management Group, LLC, pursuant to which we purchase specified 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. We have also made periodic spot purchases of plasma.

Plasma markets have historically been subject to price fluctuations as a result of changes in the production capacity available in the industry, the availability and pricing of plasma, development of competing products and the availability of alternative therapies. In recent years, there has been consolidation in the industry as several plasma derivatives manufacturers have acquired plasma collectors and reduced capacity. As a result, it could be difficult to resolve any significant disruption in the supply of plasma. In addition, concern over the safety of blood products (which has led to increased domestic and foreign regulatory control over the collection and testing of plasma and the disqualification of certain segments of the population from the donor pool), have reduced the potential donor pool.

If we are unable to obtain or maintain the level of plasma supply we require, 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 or biologics 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 that treat serious or life threatening illnesses, which treat high unmet medical needs, which require limited commercial infrastructure, and that have the potential to provide both top and bottom line growth. 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.

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

We are currently evaluating with our partner Sanquin, the feasibility of additional indications and/or other formulations for Cinryze. We plan to initially focus on C-1 mediated diseases affecting transplant patients. In addition, we have submitted a MAA for Cinryze for acute treatment of HAE and prophylaxis of HAE to the EMA and anticipate that the filing will be accepted in the first half of 2010. We also intend to seek approval to market Cinryze in certain additional territories throughout the world outside of the U.S. and Europe.

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. We began a Phase 1 clinical trial for NTCD during the third quarter of 2009. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as a single and repeat escalating doses in healthy young and older adults. Following completion of the phase 1 study, a phase 2 study is planned although the results of the clinical trials may not support further clinical development.

Maribavir

We continue to evaluate our maribavir program in light of the phase 3 trial results. 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. In the event we are unable to develop a path forward to develop maribavir, we will not generate any future revenue from maribavir.

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 us to initiate or continue testing of the product candidates in human clinical trials;
- the product candidate cannot be developed into a commercially viable product;
- the product candidate is difficult and/or costly to manufacture;
- the product candidate later is discovered to cause adverse effects that prevent widespread use, require withdrawal from the market, or serve as the basis for product liability claims;
- third party competitors hold proprietary rights that preclude us from marketing the product candidate; and
- third party competitors market a more clinically effective, 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.

The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Even if we receive regulatory approval for our product candidates, or acquire the rights to additional products which have received regulatory approvals, 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 subject to a risk evaluation mitigation strategy 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, NTCD, for the treatment and prevention of CDI in clinical development. In addition, we are currently evaluating with our partner Sanquin, the feasibility of additional therapeutic uses and potential indications as well as other modes of administration for Cinryze. We expect to conduct clinical studies during 2010 to assess at least one additional therapeutic use of Cinryze as well as a study related to another mode of administration. Merck 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. 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 regulatory 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.

Our strategic plan may not achieve the intended results.

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, and do not maintain discovery research or significant internal preclinical development capabilities. Our restructuring efforts have placed, and may continue to place, a 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 in the near term or longer term. 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.

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 in the United States and a separate agreement related to other territories. 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 €25.8 (approximately \$37.0 million) million per year, net of the agreed upon discount.

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.

In November 2004, we announced that we entered into a license agreement with Schering Plough Corporation, since acquired by Merck & Co, Inc. under which Merck 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. Merck will receive a portion of any royalty payments made to us under our license agreement with Sanofi-Aventis for rights to pleconaril. If Merck 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.

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 Sanquin, GSK and Sanofi-Aventis, 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.

Our rights to Cinryze is based upon intellectual property that we have licensed from Sanquin and 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 agreement with Sanquin includes minimum purchase requirements and our license agreement with GSK imposes various obligations on us, including milestone payment requirements and royalties. If we fail to comply with these obligations, Sanquin and GSK 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. 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.

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.

We are aware of several product candidates in clinical development which may compete with NTCD. Optimer Pharmaceuticals is developing a narrow spectrum antibiotic which recently completed a second Phase III clinical trial for treatment and recurrence of CDI infection. Merck & Co., Inc. licensed a monoclonal antibody developed by Massachusetts Biological Labs which is in Phase II clinical trials for treatment of CDI infection. Additionally, SanofiAventis is developing a *C. difficile* vaccine which is in Phase II studies for the prevention and recurrence of CDI. 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 develop and also may prove to be more successful in the manufacturing and marketing of products.

Any product that we successfully develop and for which we gain regulatory approval must then compete for market acceptance and market share. Accordingly, important competitive factors, in addition to completion of clinical testing and the receipt of regulatory approval, will include product efficacy, safety, timing and scope of

regulatory approvals, availability of supply, marketing and sales capacity, reimbursement coverage, pricing and patent protection. Our products could also be rendered obsolete or uneconomical by regulatory or competitive changes.

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, such as acquisitions, may become challenging, which could have a material adverse effect on our business plans, revenues and results of operations.

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 expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of drugs. Continued significant changes in the health care system could have a material adverse effect on our business. Decisions by state regulatory agencies, including state pharmacy boards, and/or retail pharmacies may require substitution of generic for branded products, may prefer competitors' products over our own, and may impair our pricing and thereby constrain our market share and growth. In addition, we believe the increasing emphasis on managed care in the 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. 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 Merck. 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.

Cinryze and Vancocin 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 Cinryze and Vancocin, 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 1000 Units doses of Cinryze every three or four days 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. In addition, in June 2009, we received an untitled letter from the Office of Compliance and Biologics Quality in the FDA Center for Biologics Evaluation and Research alleging promotional materials were false or misleading because they present efficacy claims for Cinryze but failed to reveal, and they minimize, material facts; they make unsubstantiated comparative claims; and they overstate the efficacy of Cinryze. We have revised our marketing materials and the FDA has closed the review of these materials.

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 Hampshire, New Mexico, Vermont, Texas, 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, have established manufacturing relationships, and are seeking approval to market Cinryze in Europe. We have also established our own commercial sales and marketing personnel in Europe and plan to increase the number of personnel in certain European countries. 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.

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, 2009 is \$205.0 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 a future liability in the form of a contingent value payments to the former stockholders of Lev upon the achievement of a commercial target. The 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 the payment may be payable or if it 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, 2009, the market price for our common stock fluctuated between \$14.55 and \$3.79 per share 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 and Cinryze;
- approvals of generic products that compete with Vancocin;

- our ability to successfully manufacture sufficient amounts of Cinryze to meet demand and increase manufacturing capacity;
- 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 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.

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 headquarters located in Exton, Pennsylvania. The lease expires in April 2015. In connection with the 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 U.K. operations. The lease expires in May 2018. We are also a party to a short term lease for a shared services facility in Brussels and anticipate that during 2010 we will evaluate potential opportunities to accommodate our continued expansion in Europe.

On January 30, 2007, we purchased a 33,000 square feet facility located in Exton, PA. We vacated this space in October 2008 when we moved into our new headquarters. In October 2009, we leased this facility to a third party for an initial term of five years.

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 2008 and 2009 and through February 19, 2010.

	<u>High</u>	<u>Low</u>
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
Year ended December 31, 2009	\$14.15	\$3.98
First Quarter	\$ 7.08	\$4.73
Second Quarter	\$ 9.98	\$5.53
Third Quarter	\$ 9.80	\$7.30
Fourth Quarter		
First Quarter 2010 (through February 19, 2010)	\$10.49	\$8.63

Holdings and Dividends

There were approximately 694 record holders of our common stock as of February 19, 2010. 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 24, 2010, 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, 2009, 2008, 2007, 2006 and 2005 and under the caption “Consolidated Balance Sheet Data” as of December 31, 2009, 2008, 2007, 2006 and 2005 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). Additionally, in October 2008, we acquired Lev Pharmaceuticals, Inc. See Note 10 of the Consolidated Financial Statements.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
<i>(in thousands, except per share amounts)</i>					
Consolidated Statement of Operations Data:					
Net product sales	\$310,449	\$232,307	\$203,770	\$166,617	\$125,853
Total revenues	310,449	232,307	203,770	167,181	132,417
Operating expenses:					
Cost of sales (excluding amortization of product rights)	40,214	8,874	8,934	18,984	18,029
Research and development (1)	52,083	64,434	33,925	17,890	9,994
Selling, general and administrative (1)	89,316	67,270	38,995	25,832	11,091
Intangible amortization and acquisition of technology rights	28,183	10,809	6,120	5,669	5,158
Goodwill impairment	65,099	—	—	—	—
Impairment loss	3,424	2,265	—	—	—
Total operating expenses	278,319	153,652	87,974	68,375	44,272
Operating income	32,130	78,655	115,796	98,806	88,145
Interest income	352	14,296	24,265	9,853	2,008
Interest expense	(11,609)	(12,951)	(9,612)	(686)	(11,304)
Other income (expense)	9,079	—	—	555	(2,949)
Income tax expense (benefit) (2)	41,029	16,040	38,344	41,862	(37,805)
Net (loss) income from continuing operations	<u>\$ (11,077)</u>	<u>\$ 63,960</u>	<u>\$ 92,105</u>	<u>\$ 66,666</u>	<u>\$113,705</u>
Net (loss) income per share from continuing operations:					
Basic	\$ (0.14)	\$ 0.90	\$ 1.32	\$ 0.97	\$ 2.56
Diluted	\$ (0.14)	\$ 0.84	\$ 1.21	\$ 0.95	\$ 2.02
Shares used in computing net income from continuing operations per share:					
Basic	77,423	71,391	69,827	68,990	44,334
Diluted	77,423	85,712	80,891	70,338	57,610

	As of December 31,				
	2009	2008	2007	2006	2005
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 331,672	\$ 275,839	\$584,328	\$255,409	\$233,413
Working capital	406,375	317,413	596,819	266,443	166,666
Total assets	1,084,451	1,086,129	771,605	429,694	435,525
Long-term debt (2)(3)	138,614	161,003	153,572	—	—
Total stockholders’ equity (3)	750,387	749,334	558,530	411,899	326,977

(1) Certain prior year amounts related to our medical education and medical affairs costs have been reclassified within operating expenses to conform to the current year presentation.

- (2) We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. The adoption is discussed further in Note 3 of the Consolidated Financial Statements.
- (3) At December 31, 2005, \$78.9 million of the subordinated convertible notes were 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 Incorporated and subsidiaries is a global biotechnology 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 have two marketed products and two development programs. We intend to grow through sales of our marketed products, Cinryze™ and Vancocin®, through continued development of our product pipeline, expansion of sales of Cinryze into additional territories and through potential acquisition or licensing of products or acquisition of companies.

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze is a C1 esterase inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor (C1-INH) deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was obtained in October 2008, when we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev). On January 8, 2010 we acquired expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world (as described in the strategic relationships section) as well as rights to develop future C1-INH derived products for additional indications. We intend to seek to commercialize Cinryze in Europe in 2011 in countries which we have distribution rights. We are currently evaluating our commercialization plans in additional territories. We also intend to conduct studies to identify further therapeutic uses and expand the labeled indication for Cinryze to potentially include other C1 mediated diseases as well as new modes of administration.

We also 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 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.

We currently have two development programs, C1 esterase inhibitor [human] to identify further therapeutic uses and potential additional indications and other modes of administration for the treatment of HAE and other C1 mediated diseases and a non-toxicogenic strain of *C. difficile* (NTCD) for the treatment and prevention of CDI. On August 6, 2009 we announced that dosing has begun in the Phase 1 clinical trial for NTCD. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as a single and repeat escalating doses in healthy young and older adults. 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 the current standard of care. We continue to evaluate our maribavir program in light of the Phase 3 clinical trial results.

We licensed the U.S. and Canadian rights for a further product development candidate, an intranasal formulation of pleconaril, to Merck & Co., Inc. 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 or life threatening illnesses with a high unmet medical need, require limited commercial infrastructure to market, and that provide both top and bottom line growth over time.

Executive Summary

Since December 31, 2008, we experienced the following:

Business Activities

Cinryze:

- Shipped approximately 26,000 doses of Cinryze to specialty pharmacy/specialty distributors (SP/SD's);
- Secured rights to develop, file regulatory dossiers, and commercialize Cinryze for HAE as well as potential new indications in certain European and rest of world countries; and
- Began enrollment in a Phase 4 study to evaluate the safety and effect of escalating doses of Cinryze as prophylactic therapy (a post approval requirement of the FDA);

C. difficile infection (CDI):

- Initiated Phase 1 clinical trial for NTCD;
- Vancocin scripts decreased 9.3% in 2009 as compared to 2008; and
- The Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted to support a component of the FDA's Office of Generic Drugs draft guidelines on bioequivalence for Vancocin;

CMV:

- Recorded expenses of \$19.1 million for the year ended December 31, 2009 related to costs incurred prior to and in connection with the wind-down of our Phase 3 clinical trials for maribavir;

Financial Results

- Recorded net sales of Cinryze of \$97.3 million;
- Net sales of Vancocin decreased to \$213.1 million for the year ended December 31, 2009 from \$232.3 million for the year ended December 31, 2008; and
- Reported net loss of \$11.1 million;

Liquidity

- Generated net cash from operations of \$84.8 million; and
- Ended 2009 with working capital of \$406.4 million, which includes cash and cash equivalents of \$331.7 million.

During 2010 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.

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.

The FDA convened a meeting of its Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products on August 4, 2009. The Advisory Committee was asked if the proposed guidelines are sufficient for establishing

bioequivalence for generic vancomycin oral capsules. The Advisory Committee voted unanimously in favor of the component of the proposed OGD recommendation that requires bioequivalence to be demonstrated through comparable dissolution in media of pH 1.2, 4.5 and 6.8 for potential vancomycin HCl capsule generic products that (a) contain the same active and inactive ingredients in the same amounts as Vancocin HCl capsules; (b) meet currently accepted standards for assay, potency, purity, and stability (equivalent to those in place for Vancocin HCl capsules); and (c) are manufactured according to cGMP. We have opposed 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 and voted upon by the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, 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; the market acceptance of competing approved products such as Berinert; 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 and capacity which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product; and our ability to achieve expansion of manufacturing capabilities in the capacities and timeframes currently anticipated. In addition, our ability to develop life cycle management plans for Cinryze, including designing and commencing clinical studies for additional indications, seeking rights to additional geographic territories and pursuing regulatory approvals in such territories will impact our ability to generate 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 greater resources to conduct 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. We continue to evaluate our potential development strategy for the maribavir program in light of the Phase 3 clinical trials results and evolving information.

We cannot assure you that our current cash and cash equivalents 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 our outstanding 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, 2009 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

We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. The adoption is discussed further in Note 3 of the Consolidated Financial Statements.

Years ended December 31, 2009 and 2008

(in thousands, except per share data)	For the years ended December 31,	
	2009	2008
Net product sales	\$310,449	\$232,307
Cost of sales (excluding amortization of product rights)	\$ 40,214	\$ 8,874
Operating income	\$ 32,130	\$ 78,655
Net (loss) income	\$(11,077)	\$ 63,960
Net (loss) income per share:		
Basic	\$ (0.14)	\$ 0.90
Diluted	\$ (0.14)	\$ 0.84

The \$32.1 million in operating income for the year ended December 31, 2009 decreased as compared to \$78.7 million in the same period in 2008 which resulted primarily from the impairment of goodwill in the first quarter of 2009 (\$65.1 million), increased cost of sales (\$31.3 million), increased intangible amortization associated with our acquisition of Lev (\$17.4 million) and increased SG&A costs related to the launch of Cinryze (\$22.0 million), partially offset by increased net sales of Vancocin and Cinryze (\$78.1 million).

Revenues

Revenues consisted of the following:

(in thousands)	For the years ended December 31,	
	2009	2008
Net product sales		
Vancocin	\$213,138	\$232,284
Cinryze	97,311	23
Total revenues	<u>\$310,449</u>	<u>\$232,307</u>

Revenue—Vancocin and Cinryze product sales

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 sell and distribute to physicians, hospitals and patients, among others. Beginning in the second quarter of 2009, we recognized revenue based upon shipments of Cinryze to SP/SD's due to our ability to meet the revenue recognition criteria specifically our ability to estimate our payor mix. We previously recognized revenue upon shipment of Cinryze from SP/SD's to patients. We are temporarily managing the rate at which additional patients are started on drug to ensure that those already receiving commercial drug, and those new patients who start their routine prophylaxis will continue with a reliable uninterrupted supply of Cinryze. Our team is working with Sanquin to complete a two tiered scale up process that is intended to significantly increase available supply in the second quarter of 2010 and beyond. When the additional supply enters the market, we will then return to adding new patients at a normal rate.

During the year ended December 31, 2009, net sales of Vancocin decreased 8.2% compared to the same period in 2008. The decrease for the year ended December 31, 2009 is primarily due to lower sales volumes driven by lower rates of severe disease, as compared to last year at this time, and a suspected increase in compounding seen both in the hospital and long-term care marketplace, partially offset by the price increases in 2009. Based upon data reported by IMS Health Incorporated, prescriptions during the year ended December 31, 2009 decreased from the same period in 2008 period by 9.3%. The units sold for the year ended December 31, 2009 decreased by 17.0% compared to the same period in 2008.

Vancocin product sales are influenced by prescriptions and wholesaler forecasts of prescription demand, which could be at different levels from period to period. Cinryze product sales are influenced by prescriptions. In the third quarter of 2009, we began to manage patients added to Cinryze therapy to ensure patients on drug will continue to receive Cinryze in future periods. We receive inventory data from our three largest wholesalers through our fee for service agreements and our two SP/SD's through service agreements. We do not independently verify this data. Based on this inventory data and our estimates, we believe that as of December 31, 2009, the wholesalers and SP/SD's did not have excess channel inventory.

Cost of sales (excluding amortization of product rights)

Cost of sales increased for the year ended December 31, 2009 by \$31.3 million as compared to the same period in the prior year due to Cinryze which was launched in December 2008. Included in the Cost of sales for the year ended December 31, 2009 was \$1.8 million that was previously deferred. Cost of sales during the year ended December 31, 2008 did not include Cinryze as we acquired Lev Pharmaceuticals in October 2008. Vancocin and Cinryze cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights. As part of our October 2008 purchase of Lev, we acquired Cinryze inventory which was recorded at fair value in purchase accounting. This step-up of inventory value increased the cost of sales during the year ended December 31, 2009 by \$6.9 million. We have utilized all inventory that was recorded at fair value as part of the Lev purchase in 2009.

Since units are shipped based upon earliest expiration date, we would expect the cost of product sales of both Vancocin and Cinryze to fluctuate from quarter to quarter as we may experience fluctuations in quarterly manufacturing yields.

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 advancements in our NTCD preclinical program, the start of our Phase 4 commitment for Cinryze, and our plan to conduct additional clinical studies using Cinryze we expect costs in these programs to exceed current costs. We are evaluating our maribavir program which was discontinued in February 2009.

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

(in thousands)	For the years ended December 31,	
	2009	2008
Direct—Core programs		
CMV	\$15,715	\$35,200
Non-toxicogenic strains of C. difficile (NTCD)	9,801	4,702
Cinryze	7,067	5,226
Vancocin	675	603
HCV	8	762
Indirect		
Development	18,817	17,941
Total	<u>\$52,083</u>	<u>\$64,434</u>

Direct Expenses—Core Development Programs

Our direct expenses related to our CMV program decreased during the year ended December 31, 2009 as we wound-down our stem cell and liver transplant studies. Costs incurred during 2009 include enrollment in our solid organ (liver) study through February 2009, conducting follow-up visits and continuing to evaluate the results of our Phase 3 programs. 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 the current standard of care. During 2008, we continued recruitment and site initiations into ongoing phase 3 studies of maribavir in patients undergoing allogeneic stem cell transplant at transplant centers in the U.S., Canada and several European Countries and patients undergoing liver transplantation in the U.S. and Europe. Additionally, we began executing on our pre-launch plans for our clinical, regulatory and commercial activities for maribavir in the U.S. and Europe.

In April 2008, we announced that ViroPharma and Wyeth jointly discontinued the development of HCV-796 due to the safety issue that emerged in the 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 and the agreement expired in accordance with its terms during the third quarter of 2009.

In October 2008, we acquired Cinryze, a C1 inhibitor, which has been approved by the FDA for routine prophylaxis of HAE. During 2009, we incurred costs related to the Cinryze open label trials which closed on March 31, 2009 and for our Phase 4 clinical trial.

The increase in costs of NTCD in 2009 over 2008 relate to increased research and development activities, costs associated with manufacturing NTCD spores and costs associated with our Phase 1 clinical trial.

Vancocin costs in 2009 and 2008 related to additional research activities.

Anticipated fluctuations in future direct expenses are discussed under “**Liquidity—Development Programs.**”

Indirect Expenses

These costs primarily relate to the compensation of and overhead attributable to our development team. During the second half of 2009, our development team has shifted its focus from our CMV program to our Cinryze and NTCD programs.

Selling, general and administrative expenses

Selling, general and administrative expenses (SG&A) increased for the year December 31, 2009 by \$22.0 million over the same period in 2008. This increase was driven by the expansion of our Cinryze field force (\$13.2 million), increased professional fees (\$2.7 million), and increased marketing efforts (\$2.6 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 \$5.5 million and \$4.0 million in the year of 2009 and 2008, respectively. We anticipate that these additional legal and consulting costs will gradually diminish in future periods. We anticipate continued increased spending in selling, general and administrative expenses in future periods as we continue the commercial launch of Cinryze.

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 Cinryze product rights 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 6 of the Consolidated Financial Statements.

Intangible amortization for the year ended December 31, 2009 was \$28.2 million, as compared to \$10.8 million in 2008. Amortization increased in 2009 as compared to 2008 due to the full year inclusion of the intangible asset acquired in our acquisition of Lev Pharmaceuticals.

On an ongoing periodic basis, we evaluate the useful life of our 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 quarter ended December 31, 2009. We will continue to monitor the actions of the FDA and OGD surrounding the bioequivalence recommendation for Vancocin and consider the effects of our opposition efforts, any announcements by generic competitors or other adverse events for additional impairment indicators. We will reevaluate the expected cash flows and fair value of our Vancocin-related assets, as well as estimated useful lives, at such time.

Impairment losses

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. This situation required us to test for impairment of our goodwill and other intangible assets which lead to a goodwill impairment charge of \$65.1 million.

During 2009 and 2008, we incurred impairment charges related to our previous corporate headquarters of \$3.4 million and \$2.3 million, respectively due to the down turn in the real estate market.

Other Income (Expense)

Interest Income

Interest income for year ended December 31, 2009 was \$0.4 million as compared to \$14.3 million in 2008. Interest income in 2009 as compared to 2008 decreased due to lower amounts of cash on hand and lower interest rates.

Interest Expense

We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. The adoption is discussed further in Note 3 of the Consolidated Financial Statements.

(in thousands)	For the years ended December 31,	
	2009	2008
Interest expense on senior convertible notes	\$ 4,343	\$ 4,980
Amortization of debt discount	6,854	7,181
Amortization of finance costs	412	790
Total interest expense	<u>\$11,609</u>	<u>\$12,951</u>

Interest expense and amortization of finance costs in 2009 and 2008 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 income tax expense was \$41.0 million and \$16.0 million for the year ended December 31, 2009 and 2008, respectively. Our income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences. The income tax expense for 2009 reflects the full impact of our gain on the repurchase of a portion of our convertible notes. In addition, our tax expense for the year includes our current estimate of the impact of the orphan drug credit for maribavir. The increase in the 2009 expense as compared to 2008 is primarily due to the decrease in our orphan drug qualified expenses, offset by the decrease in our taxable income from 2008.

During the twelve months ended December 31, 2009, we paid approximately \$1.2 million as a result of the IRS audit of our 2006 federal income tax return and results in a reduction of our taxes payable liability. We also have various state returns currently under audit. The final outcome of these audits are not yet determinable.

Results of Operations

We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. The adoption is discussed further in Note 3 of the Consolidated Financial Statements.

Years ended December 31, 2008 and 2007

(in thousands, except per share data)	For the years ended December 31,	
	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	\$ 63,960	\$ 92,105
Net income per share:		
Basic	\$ 0.90	\$ 1.32
Diluted	\$ 0.84	\$ 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 NTC 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, compared to \$7.6 million for share-based compensation expense and \$3.3 million of costs associated with our opposition to the OGD's change in approach for the year ended December 31, 2007.

Revenues

Revenues consisted of the following:

(in thousands)	For the years ended December 31,	
	2008	2007
Net product sales	\$232,307	\$203,770

Revenue

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 (excluding amortization of product rights)

Vancocin and Cinryze cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights. 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
<i>Direct—Core programs</i>		
CMV	\$35,200	\$22,068
Cinryze	5,226	—
Non-toxigenic strains of C. difficile (NTCD)	4,702	1,023
Vancocin	603	14
HCV	762	951
<i>Indirect</i>		
Development	17,941	9,869
Total	\$64,434	\$33,925

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. During 2007 we continued recruitment into a 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. In the third quarter of 2009 the collaboration agreement expired pursuant to its terms.

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 Merck.

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 \$67.3 million from 39.0 million in 2007. For 2008, the largest contributors to these increases was additional headcount for 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 6 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.

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.

Other Income (Expense)

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 20.1% and 29.4% 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.

Liquidity

We expect that our sources of revenue will continue to arise from Cinryze and Vancocin product sales. However, we cannot predict what the actual sales of Vancocin will be in the future based on the number of generic competitors that could enter the market if approved by the FDA, the timing of entry into the market of those generic competitors and/or the sales we may generate from an authorized generic version of Vancocin. In addition, there are no assurances that demand for Vancocin will continue at historical or current levels.

Our ability to generate positive cash flow is also impacted by the timing of anticipated events in our Cinryze, NTCD and CMV programs, including the timing of our expansion as we intend to seek to commercialize Cinryze in Europe and certain other countries, 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.

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 the majority of 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, we anticipate we will continue to invest in

our pipeline on our initiative to develop non-toxicogenic strains of *C. difficile*, our phase 4 program for Cinryze, and our maribavir program, future costs may exceed current costs. Also, we will incur additional costs as we intend to seek to commercialize Cinryze in Europe in countries we have distribution rights and certain other countries beginning in 2011 as well as conduct studies to identify additional C1 mediated diseases which may be of interest for further clinical development, and to evaluate new forms of administration for Cinryze. Additionally, our operating expenses will not decrease significantly due to the introduction of copies of generic Vancocin. We are also required to pay contingent consideration to Lev shareholders upon certain regulatory and commercial milestones. The most significant of our near-term operating development cash outflows are as described under “*Development Programs*” as set forth below.

While we anticipate that cash flows from Cinryze and Vancocin, as well as our current cash and cash equivalents, will allow us to fund substantially all of our ongoing development and operating costs, as well as the interest payments on our senior convertible notes, we may need additional financing in order to expand our product portfolio. At December 31, 2009, we had cash and cash equivalents of \$331.7 million.

Overall Cash Flows

During the year ended December 31, 2009, we were provided with \$84.8 million of net cash from operating activities, primarily from our operating income plus our non-cash items such as our goodwill impairment, depreciation and amortization expense and our deferred tax provision, partially offset by changes in working capital, specifically increases in accounts receivable and inventory due to the Cinryze launch. We used \$8.9 million of cash for investing activities primarily related to the additional purchase price consideration for Vancocin and our net cash used in financing activities for the year ended December 31, 2009 was \$20.5 million, mainly for the repurchase of a portion of our senior convertible notes.

Direct Expenses—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

Cinryze—We acquired Cinryze in October 2008 and through December 31, 2009 have spent approximately \$12.3 million in direct research and development costs related to Cinryze since acquisition. During 2010, we continue to expect research and development costs related to Cinryze as we complete our Phase 4 commitment. Additionally, we will incur costs related to evaluating additional indications, formulations and territories as we develop our life cycle program related to Cinryze. We are solely responsible for the costs of Cinryze development.

NTCD—We acquired NTCD in February 2006 and through December 31, 2009 have spent approximately \$16.3 million in direct research and development costs. During 2010, we expect our research and development activities related to NTCD to increase significantly as we commenced clinical studies with NTCD during the third quarter of 2009.

CMV program—From the date we in-licensed maribavir through December 31, 2009, we paid \$98.5 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 and a \$3.0 million milestone payment in February 2007.

During 2010, we will continue to analyze the study results for the Phase 3 trials evaluating maribavir used as prophylaxis in stem cell and bone marrow transplant patients that did not achieve their primary endpoints.

Should we achieve certain product development events, we are obligated to make certain milestone payments to GSK, the licensor of maribavir.

Vancocin—We acquired Vancocin in November 2004 and through December 31, 2009, we have spent approximately \$1.7 million in direct research and development costs related to Vancocin activities since acquisition.

HCV program—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 and the agreement expired in accordance with its terms during the third quarter of 2009.

Business development activities

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. As of December 31, 2009, only one of the contingent consideration payments is still achievable which is \$0.50 per Lev share. We used approximately \$385 million of existing cash and cash equivalents to fund the acquisition, including deal related expenses, and issued 7,359,667 shares in conjunction with the merger.

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.

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. 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.

We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities are bifurcated and accounted for separately. Under this new method of accounting, the convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value. See Note 3 of the Consolidated Financial Statements for further explanation.

On March 24, 2009, we repurchased, in a privately negotiated transaction, \$45.0 million in principal amount of our senior convertible notes due March 2017 for total consideration of approximately \$21.2 million. The repurchase represented 18% of our then outstanding debt and was executed at a price equal to 47% of par value.

Following these repurchases, senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$138.6 million as of December 31, 2009. Additionally, in negotiated transactions, we sold approximately 2.38 million call options for approximately \$1.8 million and repurchased approximately 2.38 million warrants for approximately \$1.5 million which terminated the call options and warrants that were previously entered into by us in March 2007. We recognized a \$9.1 million gain in the first quarter of 2009 as a result of this debt extinguishment. For tax purposes, the gain qualifies for deferral until 2014 in accordance with the provisions of the American Recovery and Reinvestment Act.

As of December 31, 2009, we have accrued \$1.2 million in interest payable to holders of the senior convertible notes. Debt issuance costs of \$4.8 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, 2009 being \$2.8 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 our 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, 2009, the fair value of the principal of the \$205.0 million convertible senior notes outstanding was approximately \$149.4 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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 allowed ViroPharma to receive up to approximately 13.25 million shares of its common stock at \$18.87 per share 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 our 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 our on the pricing date. If the market price per share of our 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 our 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 our 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. We are entitled to receive approximately 10.87 million shares of its common stock at \$18.87 from the call option holders and if the market price of our common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), will owe the counterparties an aggregate of approximately 10.87 million shares of our common stock.

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. These instruments have been determined to be indexed to our own stock and have been recorded in stockholders' equity in our Consolidated Balance Sheet. As long as the instruments are classified in stockholders' equity they are not subject to the mark to market requirements of US GAAP.

From time to time, we make seek approval from our board of directors to evaluate additional opportunities to repurchase our common stock or convertible notes, including through open market purchases or individually negotiated transactions.

Contractual Obligations

Future contractual obligations and commercial commitments at December 31, 2009 are as follows:

(in thousands)

<u>Contractual Obligations (1)(2)</u>	<u>Total</u>	<u>1 year or less</u>	<u>2-3 years</u>	<u>4-5 years</u>	<u>More than 5 years</u>
Operating leases (3)	\$ 12,438	\$ 1,656	\$ 3,581	\$ 3,731	\$ 3,470
Senior convertible notes (4)	235,750	4,100	8,200	8,200	215,250
Collaboration agreements (5)	7,165	1,433	2,866	2,866	—
Purchase obligations (6)	371,025	62,591	115,668	126,992	65,774
Total	<u>\$626,378</u>	<u>\$69,780</u>	<u>\$130,315</u>	<u>\$141,789</u>	<u>\$284,494</u>

(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 2010 and 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 \$1.6 million, \$2.1 million and \$2.7 million in the years ended December 31, 2010, 2011 and 2012, 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. As of December 31, 2009, only the second CVR as described below remains achievable. The first CVR payment was \$0.50 per share (or \$87.5 million). During the fourth quarter of 2009, a third party's human C1 inhibitor product was approved for the acute treatment of HAE and granted orphan exclusivity, therefore the first CVR is no longer achievable and will not be paid. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales within 10 years of closing of the acquisition.

- (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 \$23.0 million will be payable in future periods under arrangements in place at December 31, 2009. Of this amount, approximately \$4.2 million has been accrued for work estimated to have been completed as of December 31, 2009 and approximately \$18.8 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) Pursuant to the terms of the ROW Agreement, Sanquin may conduct certain early stage research programs for which we will provide to Sanquin €1,000,000 (approximately \$1.4 million) per year for a period of five years.
- (6) In conjunction with our acquisition of Lev, we acquired purchase obligations related to the supply and manufacturing of Cinryze. We have committed to purchase up to 140,000 liters of plasma per year through 2015 from our supplier. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer. Excluded from these amounts is the manufacturing fee for Cinryze produced under the EU and ROW agreement as the minimum purchase shall be determined by the Joint Steering Committee in 2013. Also, the additional €5.0 million (approximately \$7.2 million) loan that will be made to Sanquin in 2010 has been excluded from the table above.

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 contained in our Annual Report on Form 10-K for the year ended December 31, 2009. 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.
- At the end of each reporting period we analyze our estimated channel inventory and we would 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. Further, 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 and for Cinryze they are based on information on payee's obtained from our SP/SD's 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 5%, 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 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.

- **Impairment of Long-lived Assets**—We review our fixed and intangible assets for possible impairment annually and whenever events occur or circumstances indicate that the carrying amount of an asset may not be recoverable. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include, 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 6 of the Consolidated Financial Statements for further information. Additionally in the fourth quarter of 2009, we reviewed the fair value of our property and building held for sale and have determined that an additional impairment charge was required. See Note 5 of the Consolidated Financial Statements for further information.

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. See Note 6 of the Consolidated Financial Statements for further information.

On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD's 2008 draft guidelines on bioequivalence for Vancocin. If FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also 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, and the number of generics and the timing of their market entry is unknown.

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. We will continue to monitor the actions of the OGD and consider the effects of our opposition actions and any announcements by generic competitors or other adverse events for additional impairment indicators. We will reevaluate the expected cash flows and fair value of our Vancocin-related assets at such time a triggering event occurs.

- **Impairment of Goodwill**— We reviewed the carrying value of goodwill, to determine whether impairment may exist. Based on accounting standards, it is required that goodwill be assessed annually for impairment using fair value measurement techniques, unless a triggering event occurs between annual assessments which would then require an assessment at the end of the quarter in which a triggering event occurred.

During the first quarter of 2009, our market capitalization dropped below the carrying value of our net assets due to the results of our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem

cell or bone marrow transplant patients. We concluded that the drop in our market cap was a triggering event which required us to perform an impairment test of our intangible assets and a step 2 test for goodwill impairment. As part of this process, we also assessed our intangible and fixed assets for impairment. Based on the analysis performed under step two, there was no remaining implied value attributable to goodwill and accordingly, we wrote off the entire goodwill balance and recognized a goodwill impairment charge in the first quarter of 2009.

- **Share-Based Employee Compensation**—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.

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, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax examinations. 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 our income taxes 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 were accounted for in accordance with SFAS No. 141, *Business Combinations* and the total purchase price was 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.

Businesses acquired subsequent to January 1, 2009 will be accounted for in accordance with the new accounting standards regarding business combinations. Under the new standards, the total purchase price will be allocated to the net tangible assets or identifiable intangible assets based on their fair values as of the date of the acquisition. Additionally, acquired IPR&D projects will initially be capitalized and considered indefinite-lived assets subject to annual impairment reviews or more often upon the occurrence of certain events. For those compounds that reach commercialization, the assets are amortized over the expected useful lives.

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 our

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 October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Topic 605. This consensus provides accounting principles and application guidance on how the arrangement should be separated, and the consideration allocated. This guidance changes how to determine the fair value of undelivered products and services for separate revenue recognition. Allocation of consideration is now based on management's estimate of the selling price for an undelivered item where there is no other means to determine the fair value of that undelivered item. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010.

On December 29, 2009, the FASB issued a proposed Accounting Standards Update to address potential practice issues associated with FASB ASC Topic 855, Subsequent Events. The proposed ASU would no longer require entities that file or furnish financial statements with the SEC to disclose the date through which subsequent events have been evaluated in originally issued and reissued financial statements. The proposed ASU has a 30-day comment period that ends January 28, 2010 and based on the proposal, final guidance would be effective on issuance. Accordingly, we will adopt the guidance when finalized.

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 a minimum number of liters of plasma per year through 2015 from our supplier. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer. In October 2009, we terminated our agreement with Plasma Centers of America (PCA) and our obligation to purchase plasma collected from centers own by PCA. The total minimum purchase commitments for these continuing arrangements as of December 31, 2009 are approximately \$371.0 million.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our holdings of financial instruments are primarily comprised of money mark funds holding only U.S. government securities. 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 optimizing the generation of investment income. We seek reasonable assuredness of the safety of principal and market liquidity by investing in cash equivalents (such as Treasury bills and money market funds) and fixed income securities (such as U.S. government and agency securities, municipal securities, taxable municipals, and corporate notes) while at the same time seeking to achieve a favorable rate of return. Our market risk exposure

consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. Historically, we have typically invested in financial instruments with maturities of less than one year. The carrying amount, which approximates fair value, and the annualized weighted average nominal interest rate of our investment portfolio at December 31, 2009, was approximately \$323.7 million and 0.03%, respectively. A one percent change in the interest rate would have resulted in a \$0.8 million impact to interest income for the quarter ended December 31, 2009.

At December 31, 2009, we had principal outstanding of \$205.0 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 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 our 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, 2009, the fair value of the principal of the \$205.0 million convertible senior notes outstanding was approximately \$149.4 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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 us to counterparty credit risk for nonperformance. We manage our exposure to counterparty credit risk through specific minimum credit standards, and diversification of counterparties.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements required by this item are attached to this Report beginning on page 71.

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, 2009. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2009 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, 2009, 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 have materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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, our principal executive and principal financial officers and effected by our 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.

Our management assessed the effectiveness of its internal control over financial reporting as of December 31, 2009. 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, 2009, 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, 2009, 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 policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by COSO.

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, 2009 and 2008, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2009, and our report dated February 24, 2010 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Short Hills, New Jersey
February 24, 2010

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

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, 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

<u>Exhibit No.</u>	<u>Description</u>
3.1*	Amended and Restated Certificate of Incorporation of the Company, as amended by a Certificate of Amendment of Amended and Restated Certificate of Incorporation dated May 18, 1999, as further amended by a Certificate of Amendment of Amended and Restated Certificate of Incorporation dated May 24, 2000. (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. (21) (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. (21) (Exhibit 4.2)
10.1††	Form of Employment Agreement. (14) (Exhibit 10.1)
10.2	Form of Indemnification Agreement. (14) (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)
10.5†	First Amended and Restated Agreement dated February 27, 2001 between Sanofi-Synthelabo and ViroPharma Incorporated. (7) (Exhibit 10.32)
10.6††	2001 Equity Incentive Plan. (8) (Exhibit 10.33)
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. (9) (Exhibit 10.34)
10.14†	Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004.(10) (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.(10) (Exhibit 2.2)
10.16†	License Agreement between ViroPharma Incorporated and Schering Corporation dated November 3, 2004. (11) (Exhibit 2.1)
10.17††	ViroPharma Severance Plan. (14) (Exhibit 10.37)
10.18††	ViroPharma Cash Bonus Plan. (22) (Exhibit 10.2)
10.19††	ViroPharma Board Compensation Policy.(31) (Exhibit 10.19)
10.20††	Amended and Restated 1995 ViroPharma Stock Option and Restricted Share Plan. (13)
10.21††	2005 Equity Incentive Plan. (19)
10.22††	Form Of Non-Qualified Stock Option Agreement For Member Of The Board Of Director. (15) (Exhibit 10.2)
10.23††	Form Of Non-Qualified Stock Option Agreement. (15) (Exhibit 10.3)
10.24††	Form of Incentive Stock Option Agreement. (15) (Exhibit 10.4)

<u>Exhibit No.</u>	<u>Description</u>
10.25†	Master Agreement by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated effective as of December 1, 2005. (16) (Exhibit 10.41)
10.26†	Project Agreement No. 1 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated. (16) (Exhibit 10.42)
10.27†	Bulk Supply Agreement between ViroPharma and Alpharma Inc. dated April 13, 2006. (17) (Exhibit 10.1)
10.28†	Project Agreement No. 2 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated dated May 15, 2006. (17) (Exhibit 10.2)
10.29	Real Estate Purchase Agreement between LV Associates, L.P. and the Company dated December 22, 2006. (22) (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. (21) (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. (21) (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. (21) (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.(21) (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. (21) (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. (21) (Exhibit 10.5)
10.36†	Amended and Restated Bulk Supply Agreement between ViroPharma and Alpharma Inc. dated October 26, 2007.(18) (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)
10.45†	Plasma Supply Agreement dated April 12, 2007 (24) (Exhibit 10.4)
10.46†	Agreement for the Purchase and Sale of Blood Plasma dated July 12, 2007 (25)(Exhibit 10.1)
10.50	Lease Agreement with 730 Stockton Drive Associates, L.P. dated March 14, 2008. (27) (Exhibit 10.1)

<u>Exhibit No.</u>	<u>Description</u>
10.51††	Letter Agreement with Michel de Rosen dated March 30, 2008 (28) (Exhibit 10.1)
10.52††	Letter Agreement between the Company and Robert Pietrusko dated January 9, 2009 (22) (Exhibit 10.1)
10.53	Form of Partial Unwind Agreement with respect to the Note Hedge Transaction Confirmation between ViroPharma Incorporated and Credit Suisse International (32) (Exhibit 10.1)
10.54	Form of Partial Unwind Agreement with respect to the Warrant Confirmation between ViroPharma Incorporated and Credit Suisse International (32) (Exhibit 10.2)
10.55	Form of Partial Unwind Agreement with respect to the Note Hedge Transaction Confirmation between ViroPharma Incorporated and Wells Fargo Bank, National Association (32) (Exhibit 10.3)
10.56	Form of Partial Unwind Agreement with respect to the Warrant Confirmation, dated July 11, 2007 between ViroPharma Incorporated and Wells Fargo Bank, National Association (32) (Exhibit 10.4)
10.57††	Amended and Restated ViroPharma Incorporated 2000 Employee Stock Purchase Plan. (33) (Annex A)
10.58††	Form of Amended and Restated Change of Control Agreement with the Executive Officers. (34) (Exhibit 10.1)
10.59††	Form of Amended and Restated Change of Control Agreement with the General Counsel. (34) (Exhibit 10.2)
10.60†	Intermediate Supply Agreement with Biotest AG dated as of June 19, 2009 by and between ViroPharma SPRL, a wholly owned subsidiary of ViroPharma Incorporated, and Biotest AG. (35) (Exhibit 10.1)
10.62†	First Amendment to the Agreement for the Purchase and Sale of Blood Plasma, dated as of July 9, 2009 by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated, and DCI Management Group LLC. (36) (Exhibit 10.1)
10.63†*	Manufacturing and Distribution Agreement (Europe and ROW) dated as of January 8, 2010, by and between ViroPharma SPRL, a wholly-owned subsidiary of ViroPharma Incorporated, and Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation)
10.64†*	Distribution and Manufacturing Services Agreement For the Americas and Israel dated as of January 8, 2010, by and between ViroPharma Biologics, Inc., a wholly-owned subsidiary of ViroPharma Incorporated, and Sanquin Bloedvoorziening (Sanquin Blood Supply Foundation)
10.65†*	Exclusive License Agreement dated as of February 20, 2006 by and between ViroPharma Incorporated and Dale N. Gerding, M.D.
14	Code of Conduct and Ethics. (23)(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.

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- * 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-Q for the quarter ended March 31, 2001.
 - (8) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2001.
 - (9) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on April 11, 2008.
 - (10) Filed as an Exhibit to the Company's Current Report on Form 8-K/A filed with the Commission on November 24, 2004.
 - (11) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 29, 2004.
 - (12) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 15, 2005.
 - (13) Filed as an Annex to Registrant's Proxy Statement filed with the Commission on April 8, 2002.
 - (14) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2004.
 - (15) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2005.
 - (16) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2005.
 - (17) Filed as an Exhibit to Registrant's Form 10-Q for the quarter ended June 30, 2006.
 - (18) Filed as an Exhibit to Registrant's Form 10-K for the year ended December 31, 2008.
 - (19) Filed as Annex to Registrant's Proxy Statement filed with the Commission on April 11, 2008.
 - (20) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (333-141411) filed with the Commission on March 19, 2007.
 - (21) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 26, 2007.
 - (22) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on January 8, 2009.
 - (23) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 24, 2010.
 - (24) Filed as an Exhibit to Form 10-QSB/A filed by Lev Pharmaceuticals, Inc. on August 27, 2007.
 - (25) Filed as an Exhibit to Form 8-K filed by Lev Pharmaceuticals, Inc. on July 25, 2007.
 - (26) Filed as an Exhibit to Form 10-Q filed by Lev Pharmaceuticals, Inc. on April 30, 2008.
 - (27) Filed as an Exhibit Registrant's Form 10-Q for the quarter ended March 31, 2008.
 - (28) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the Commission on April 3, 2008.
 - (29) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006 .
 - (30) Filed as an Exhibit to Form 10-KSB filed by Lev Pharmaceuticals, Inc. on March 31, 2006 .
 - (31) Filed as an Exhibit to the Company's Annual Report on Form 10-K filed with the Commission on March 2, 2009.
 - (32) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 24, 2009.
 - (33) Filed as Annex A to the Company's Proxy Statement filed with the Commission on April 10, 2009.

- (34) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on June 17, 2009.
- (35) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2009.
- (36) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on October 29, 2009.

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:

<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ VINCENT J. MILANO</u> Vincent J. Milano	President, Chief Executive Officer (Principal Executive Officer)	February 24, 2010
<u>/s/ CHARLES A. ROWLAND, JR.</u> Charles A. Rowland, Jr.	Chief Financial Officer (Principal Financial Officer)	February 24, 2010
<u>/s/ RICHARD S. MORRIS</u> Richard S. Morris	Chief Accounting Officer and Controller (Principal Accounting Officer)	February 24, 2010
<u>/s/ VINCENT J. MILANO</u> Vincent J. Milano	Chairman of the Board	February 24, 2010
<u>/s/ PAUL A. BROOKE</u> Paul A. Brooke	Director	February 24, 2010
<u>/s/ WILLIAM CLAYPOOL, M.D.</u> William Claypool, M.D.	Director	February 24, 2010
<u>/s/ MICHAEL R. DOUGHERTY</u> Michael R. Dougherty	Director	February 24, 2010
<u>/s/ ROBERT J. GLASER</u> Robert J. Glaser	Director	February 24, 2010
<u>/s/ JOHN R. LEONE</u> John R. Leone	Director	February 24, 2010
<u>/s/ HOWARD H. PIEN</u> Howard H. Pien	Director	February 24, 2010
<u>/s/ FRANK BALDINO, JR.</u> Frank Baldino, Jr.	Director	February 24, 2010

VIROPHARMA INCORPORATED
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
ViroPharma Incorporated:

We have audited the accompanying consolidated balance sheets of ViroPharma Incorporated as of December 31, 2009 and 2008, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2009. 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, 2009 and 2008, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2009, in conformity with U.S generally accepted accounting principles.

As discussed in Notes 3 and 9 to the consolidated financial statements, the Company retrospectively changed its method of accounting for convertible debt instruments that may be settled in cash upon conversion due to the adoption of a new accounting standard issued by the FASB, as of January 1, 2009.

As discussed in Note 15 to the consolidated financial statements, the Company changed its method of measuring the fair value of assets and liabilities as of January 1, 2008.

As discussed in Note 13 to the consolidated financial statements, the Company changed its method of recognizing and measuring the tax effects related to uncertain tax positions due to the adoption of a new accounting standard issued by the FASB, as of January 1, 2007.

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, 2009, 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 24, 2010 expressed an unqualified opinion on the effective operation of internal control over financial reporting.

/s/ KPMG LLP

Short Hills, New Jersey
February 24, 2010

ViroPharma Incorporated
Consolidated Balance Sheets

(in thousands, except share and per share data)	<u>December 31,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 331,672	\$ 275,839
Accounts receivable, net	41,243	15,058
Inventory	41,582	27,168
Prepaid expenses and other current assets	9,546	5,120
Prepaid income taxes	2,256	6,867
Property and building held for sale	—	6,734
Deferred income taxes	20,065	24,094
Total current assets	<u>446,364</u>	<u>360,880</u>
Intangible assets, net	618,510	639,693
Property, equipment and building improvements, net	10,508	6,853
Goodwill	—	65,099
Debt issue costs, net	2,784	3,892
Other assets	6,285	9,712
Total assets	<u>\$1,084,451</u>	<u>\$1,086,129</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,866	\$ 5,719
Due to partners	—	1,278
Accrued expenses and other current liabilities	33,354	35,650
Income tax payable	769	820
Total current liabilities	<u>39,989</u>	<u>43,467</u>
Non-current income tax payable and other non-current liabilities	2,958	4,071
Deferred tax liabilities	152,503	128,254
Long-term debt	138,614	161,003
Total liabilities	<u>334,064</u>	<u>336,795</u>
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	—	—
Common stock, par value \$0.002 per share. 175,000,000 shares authorized; issued and outstanding 77,442,716 shares at December 31, 2009 and 77,397,621 shares at December 31, 2008	156	156
Additional paid-in capital	701,063	690,502
Accumulated other comprehensive gain (loss)	914	(655)
Retained earnings	48,254	59,331
Total stockholders' equity	<u>750,387</u>	<u>749,334</u>
Total liabilities and stockholders' equity	<u>\$1,084,451</u>	<u>\$1,086,129</u>

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated
Consolidated Statements of Operations

(in thousands, except per share data)	Years ended December 31,		
	2009	2008	2007
Revenues:			
Net product sales	\$310,449	\$232,307	\$203,770
Costs and Expenses:			
Cost of sales (excluding amortization of product rights)	40,214	8,874	8,934
Research and development	52,083	64,434	33,925
Selling, general and administrative	89,316	67,270	38,995
Intangible amortization	28,183	10,809	6,120
Goodwill impairment	65,099	—	—
Impairment loss	3,424	2,265	—
Total costs and expenses	278,319	153,652	87,974
Operating income	32,130	78,655	115,796
Other Income (Expense):			
Interest income	352	14,296	24,265
Interest expense	(11,609)	(12,951)	(9,612)
Gain on long-term debt repurchase	9,079	—	—
Income before income tax expense	29,952	80,000	130,449
Income tax expense	41,029	16,040	38,344
Net (loss) income	(11,077)	63,960	92,105
Net (loss) income per share:			
Basic	\$ (0.14)	\$ 0.90	\$ 1.32
Diluted	\$ (0.14)	\$ 0.84	\$ 1.21
Shares used in computing net (loss) income per share:			
Basic	77,423	71,391	69,827
Diluted	77,423	85,712	80,891

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated
Consolidated Statements of Comprehensive Income (Loss)

(in thousands)	Year ended December 31,		
	2009	2008	2007
Net (loss) income	\$(11,077)	\$63,960	\$92,105
Other comprehensive income:			
Unrealized holding gains (losses) arising during period, net of income taxes of \$300 in 2008 and \$(326) in 2007	—	550	(608)
Foreign currency translation adjustment	1,569	(659)	5
Comprehensive (loss) income	\$ (9,508)	\$63,851	\$91,502

See accompanying notes to consolidated financial statements

ViroPharma Incorporated

Consolidated Statements of Stockholders' Equity

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained Earnings	Total stockholders' equity
	Number of shares	Amount	Number of shares	Amount				
(in thousands)								
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 options, net	—	—	—	—	(23,250)	—	—	(23,250)
Issuance of senior convertible notes (as adjusted, see Note 3)	—	—	—	—	95,215	—	—	95,215
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	—	—	—	—	—	—	92,105	92,105
Balance, December 31, 2007	—	—	69,905	140	593,565	(546)	(4,629)	588,530
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 Pharmaceuticals, Inc.	—	—	7,360	15	86,020	—	—	86,035
Net income	—	—	—	—	—	—	63,960	63,960
Balance, December 31, 2008	—	—	77,398	156	690,502	(655)	59,331	749,334
Exercise of common stock options	—	—	13	—	22	—	—	22
Employee stock purchase plan	—	—	32	—	356	—	—	356
Share-based compensation	—	—	—	—	11,828	—	—	11,828
Cumulative translation adjustment	—	—	—	—	—	1,569	—	1,569
Stock option tax benefits	—	—	—	—	44	—	—	44
Termination of call spread options, net	—	—	—	—	274	—	—	274
Repurchase of conversion options on long-term debt	—	—	—	—	(1,963)	—	—	(1,963)
Net income	—	—	—	—	—	—	(11,077)	(11,077)
Balance, December 31, 2009	—	\$—	77,443	\$156	\$701,063	\$ 914	\$ 48,254	\$750,387

See accompanying notes to consolidated financial statements.

ViroPharma Incorporated
Consolidated Statements of Cash Flows

(in thousands)	For the years ended December 31,		
	2009	2008	2007
Cash flows from operating activities:			
Net (loss) income	\$(11,077)	\$ 63,960	\$ 92,105
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Non-cash share-based compensation expense	11,817	8,938	7,600
Non-cash building impairment	3,424	2,265	—
Non-cash interest expense	7,291	7,888	2,462
Gain on long-term debt repurchase	(9,079)	—	—
Non-cash goodwill impairment	65,099	—	—
Deferred tax provision	28,161	10,389	12,875
Depreciation and amortization expense	29,660	11,989	6,924
Changes in assets and liabilities:			
Accounts receivable	(26,000)	2,991	(8,237)
Inventory	(13,622)	(3,129)	57
Prepaid expenses and other current assets	(4,447)	4,977	(1,916)
Prepaid income taxes/ income taxes payable	4,447	(6,084)	(23)
Other assets	3,432	(8,279)	10
Due to partners	(1,278)	270	225
Accounts payable	(211)	1,573	(726)
Accrued expenses and other current liabilities	(2,456)	(6,387)	10,378
Non-current income tax payable and other non-current liabilities	(382)	76	1,133
Net cash provided by operating activities	84,779	91,437	122,867
Cash flows from investing activities:			
Purchase of Lev Pharmaceuticals, Inc., net of cash acquired	—	(380,218)	—
Purchase of Vancocin assets	(7,000)	(7,000)	(5,950)
Purchase of property, plant and equipment	(1,929)	(2,529)	(8,866)
Purchase of short-term investments	—	—	(789,707)
Maturities of short-term investments	—	405,187	588,347
Net cash (used in) provided by investing activities	(8,929)	15,440	(216,176)
Cash flows from financing activities:			
Long-term debt repurchase	(21,150)	—	—
Repayment of acquired debt	—	(12,056)	—
Net proceeds from issuance of senior convertible notes	—	—	241,825
Net purchase of call spread options	—	—	(23,250)
Termination of call spread options, net	274	—	—
Net proceeds from issuance of common stock	378	540	712
Excess tax benefits from share-based payment arrangements	44	184	304
Tax benefit on convertible note hedge	—	1,262	1,880
Net cash (used in) provided by financing activities	(20,454)	(10,070)	221,471
Effect of exchange rate changes on cash	437	(659)	5
Net increase in cash and cash equivalents	55,833	96,148	128,167
Cash and cash equivalents at beginning of period	275,839	179,691	51,524
Cash and cash equivalents at end of period	\$331,672	\$ 275,839	\$ 179,691

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 is a global biotechnology 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 have two marketed products and two development programs. We intend to grow through sales of our marketed products, Cinryze™ and Vancocin®, through continued development of our product pipeline, expansion of sales of Cinryze into additional territories and through potential acquisition or licensing of products or acquisition of companies.

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze is a C1 esterase inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor (C1-INH) deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was obtained in October 2008, when we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev). On January 8, 2010 we acquired expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world (as described in the strategic relationships section) as well as rights to develop future C1-INH derived products for additional indications. We intend to seek to commercialize Cinryze in Europe in 2011 in countries which we have distribution rights. We are currently evaluating our commercialization plans in additional territories. We also intend to conduct studies to identify further therapeutic uses and expand the labeled indication for Cinryze to potentially include other C1 mediated diseases as well as new modes of administration.

We also 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 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.

We currently have two development programs, C1 esterase inhibitor [human] to identify further therapeutic uses and potential additional indications and other modes of administration for the treatment of HAE and other C1 mediated diseases and a non-toxic strain of *C. difficile* (NTCD) for the treatment and prevention of CDI. On August 6, 2009 we announced that dosing has begun in the Phase 1 clinical trial for NTCD. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as a single and repeat escalating doses in healthy young and older adults. 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 the current standard of care. We continue to evaluate our maribavir program in light of the Phase 3 clinical trial results.

Note 2. Basis of Presentation

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.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

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 and Cinryze. Vancocin is distributed through wholesalers that sell the product to pharmacies and hospitals and Cinryze is distributed through specialty pharmacy/ specialty distributors (SP/SD's) who then sell and distribute to physicians, hospitals and patients, among others. These three wholesalers and two SP/SD's represent approximately 88% of our trade accounts receivable at December 31, 2009 and approximately 83% of our 2009 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, 2009 and 2008, 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 or market using actual cost. At December 31, 2009 and 2008, inventory consists of finished goods, work-in-process (WIP) and certain starting materials required to produce inventory of Vancocin and Cinryze.

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, whichever 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.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements—(Continued)

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 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.

During the first quarter of 2009 and as of March 31, 2009, the market capitalization of ViroPharma fell below the carrying value of the our net assets due to the results of our Phase 3 clinical trial evaluating maribavir used as prophylaxis in allogeneic stem cell transplant patients and our decision to discontinue dosing in our Phase 3 trial of maribavir in solid organ (liver) transplant patients. The fact that our market capitalization fell below our carrying value required us to test for impairment of our goodwill and other intangible assets. See Note 7 for further discussion of this impairment test.

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. 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. See Note 5 for discussion of impairments of our previous Company headquarters in 2009 and 2008.

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 and Cinryze is recorded upon delivery to either the wholesaler or specialty pharmacy/specialty distributor (SP/SD), 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 2009, 2008 and 2007, the Company did not defer any Vancocin product sales. Product revenue for Cinryze was deferred until the product was shipped to the end customer by the specialty pharmacy until the 2nd quarter of 2009. Beginning in the 2nd quarter of 2009, Cinryze revenue is recorded upon delivery to the wholesaler.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

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. For Cinryze, our customers are specialty pharmacy and specialty distributors (SP/SD) who will distribute the product to physicians, hospitals and patients.

Four wholesalers and/or SP/SD's represent the majority of the Company's consolidated total revenue, as approximated below:

	Percentage of total revenues		
	2009	2008	2007
Customer A	29%	39%	37%
Customer B	25%	38%	40%
Customer C	13%	17%	16%
Customer D	12%	—	—
Total	79%	94%	93%

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.

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

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

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 the new accounting for share-based payments using the modified prospective approach effective January 1, 2006. This pronouncement 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 the standard 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.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

Foreign Currency Translation

The financial statements of the Company's international subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date for assets and liabilities, the historical exchange rate for stockholders' equity and an average exchange rate for each period of revenues, expenses, and gain and losses. The functional currency of the Company's non-U.S. subsidiaries is the local currency. Adjustments resulting from the translation of financial statements are reflected in accumulated other comprehensive income. Transaction gains and losses are charged to operations.

Subsequent Events

We have evaluated all subsequent events through the date the financial statements were issued.

Reclassification

Certain prior year amounts related to our medical education and medical affairs costs have been reclassified within operating expenses to conform to the current year presentation.

New Accounting Standards

In June 2009, the Financial Accounting Standards Board (FASB) issued ASC Topic 105, Generally Accepted Accounting Principles, which became the single source of authoritative nongovernmental U.S. generally accepted accounting principles (GAAP), superseding existing FASB, American Institute of Certified Public Accountants (AICPA), Emerging Issues Task Force (EITF), and related accounting literature. This pronouncement reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections and is effective for financial statements issued for reporting periods that end after September 15, 2009. We adopted this pronouncement in 2009 and modified our financial disclosures to authoritative accounting literature that will be references in accordance with ASC Topic 105.

In August 2009, the FASB issued a new accounting pronouncement that provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted market price of the identical liability when trades as an asset or b) quoted prices for similar liabilities or similar liabilities when trades as assets and/or 2) a valuation technique that is consistent with the principles of ASC Topic 820. The new accounting pronouncement also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust inputs relating to the existence of transfer restrictions on that liability. The adoption of this standard did not have an impact on our financial position or results of operations; however, this standard may impact us in future periods.

In May 2009, the FASB released a new accounting pronouncement which establishes the accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The adoption this pronouncement did not have a material impact on our financial statements.

In April 2009, the FASB released a new pronouncement which requires certain disclosures about fair value of financial instruments in interim financial statements and in annual financial statements. We adopted this pronouncement on June 30, 2009 and have provided the necessary additional disclosures.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

In April 2009, the FASB issued guidance in determining whether impairments in debt securities are other than temporary, and modifies the presentation and disclosures surrounding such instruments. This guidance is effective for interim periods ending after June 15, 2009. We adopted the provisions of this guidance during second quarter 2009, with no impact on our financial position, cash flows, or disclosures.

In May 2008, the FASB issued a new pronouncement that 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. This pronouncement which is part of ASC Topic 470 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. We adopted this pronouncement on January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt. The adoption is discussed further in Note 3.

Effective January 1, 2009, we adopted a newly issued accounting standard for fair value measurements of all nonfinancial assets and nonfinancial liabilities not recognized or disclosed at fair value in the financial statements on a recurring basis. The adoption of the accounting standard for these assets and liabilities did not have an impact on our financial statements other than additional disclosures, which are included in the footnotes.

Effective January 1, 2009, we adopted a newly issued accounting standard for business combinations. This standard requires an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize IPR&D and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. The standard also amended accounting for uncertainty in income taxes in a business combination. Previously, accounting standards generally required post-acquisition adjustments related to business combination deferred tax asset valuation allowances and liabilities for uncertain tax positions to be recorded as an increase or decrease to goodwill. This new standard does not permit this accounting and, generally, requires any such changes to be recorded in current period income tax expense. Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in acquisition accounting are accounted for under this guidance and will be recognized in current period income tax expense.

In April, 2009, the FASB issued a new accounting standard providing guidance for the accounting of assets acquired and liabilities assumed in a business combination that arise from contingencies. This guidance amends and clarifies previous accounting standards to address application issues regarding the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. Due to the fact that this guidance is applicable to acquisitions completed after January 1, 2009 and we did not have any business combinations in the year ended December 31, 2009, the adoption did not impact our financial position or results of operations.

In March 2008, the FASB issued guidance 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 the Derivatives and Hedging Topic of the ASC (ASC Topic 815), and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. We adopted this guidance on January 1, 2009 and such disclosures are included herein.

In June 2008, the FASB issued guidance which stated that unvested share-based payment awards that contain rights to receive nonforfeitable dividends (whether paid or unpaid) are participating securities, and should be

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

included in the two-class method of computing EPS. We adopted this pronouncement on January 1, 2009. We do not have share-based payment awards that contain rights to nonforfeitable dividends, thus this pronouncement does not impact our consolidated financial statements.

In June 2008, the FASB ratified guidance which 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. We adopted this guidance on January 1, 2009 with no impact on operating results or financial position.

Note 3. Accounting Change Adopted

We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. In accordance with GAAP all prior periods presented herein have been adjusted to apply the new method retrospectively. Under this new method of accounting, the debt and equity components of our convertible debt securities are bifurcated and accounted for separately based on the value and related interest rate of a non-convertible debt security with the same terms. The fair value of a non-convertible debt instrument at the original issuance date was determined to be \$148.1 million. The equity (conversion options) component of our convertible debt securities is included in Additional paid-in capital on our Consolidated Balance Sheet and, accordingly, the initial carrying value of the debt securities was reduced by \$101.9 million. Our net income for financial reporting purposes was reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amount of \$250.0 million as additional non-cash interest expense. The adoption of this new standard has resulted in a reduction in the carrying value of our convertible debt by approximately \$89.0 million as of December 31, 2008. In addition, the adoption of this standard reduced our deferred debt issuance costs as we were required to allocate the amount related to the conversion option to equity.

Due to the retrospective adoption of the standard, we had to adjust our previously recognized deferred tax asset related to our convertible debt. The bifurcation of the convertible notes caused us to establish a deferred tax liability at issuance. This change in prior period deferred tax assets impacted the deferred tax assets ultimately available to be recognized in the purchase accounting for our acquisition of Lev in October 2008. Accordingly the goodwill resulting from the transaction increased \$35.2 million to \$65.1 million in our adjusted December 31, 2008 balance sheet.

ViroPharma Incorporated
Notes to the Consolidated Financial Statements—(Continued)

Condensed Consolidated Balance Sheet

(in thousands, except share and per share data)	<u>Revised December 31, 2008</u>	<u>Reported December 31, 2008</u>
Assets		
Current assets:		
Total current assets	\$ 360,880	\$ 360,880
Goodwill	65,099	29,936
Debt issue costs, net	3,892	6,610
Total assets	<u>\$1,086,129</u>	<u>\$1,053,684</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accrued expenses and other current liabilities	\$ 35,650	\$ 35,650
Total current liabilities	43,467	43,467
Deferred tax liability	128,254	95,121
Long-term debt	161,003	250,000
Total liabilities	<u>336,795</u>	<u>392,660</u>
Commitments and Contingencies		
Additional paid-in capital	690,502	595,287
Retained earnings	59,331	66,236
Total stockholders' equity	<u>749,334</u>	<u>661,024</u>
Total liabilities and stockholders' equity	<u>\$1,086,129</u>	<u>\$1,053,684</u>

Consolidated Statements of Operations

(in thousands, except per share data)	<u>For the years ended December 31,</u>	
	<u>Revised 2008</u>	<u>Reported 2008</u>
Operating income	\$ 78,655	\$78,655
Other Income (Expense):		
Interest income	14,296	14,296
Interest expense	(12,951)	(5,852)
Income before income tax expense	80,000	87,099
Income tax expense	16,040	19,482
Net income	<u>\$ 63,960</u>	<u>\$67,617</u>
Net income per share:		
Basic	\$ 0.90	\$ 0.95
Diluted	\$ 0.84	\$ 0.83
Shares used in computing net income per share:		
Basic	71,391	71,391
Diluted	85,712	85,712

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

(in thousands, except per share data)	<u>Revised 2007</u>	<u>Reported 2007</u>
Operating income	\$115,796	\$115,796
Other Income (Expense):		
Interest income	24,265	24,265
Interest expense	(9,612)	(4,395)
Income before income tax expense	130,449	135,666
Income tax expense	38,344	40,313
Net income	<u>\$ 92,105</u>	<u>\$ 95,353</u>
Net income per share:		
Basic	\$ 1.32	\$ 1.37
Diluted	\$ 1.21	\$ 1.21
Shares used in computing net income per share:		
Basic	69,827	69,827
Diluted	80,891	80,891

Note 4. Inventory

Inventory is related to Cinryze and Vancocin and is stated at the lower of cost or market using actual cost. The following represents the components of the inventory at December 31, 2009 and December 31, 2008:

(in thousands)	<u>December 31, 2009</u>	<u>December 31, 2008</u>
Raw Materials	\$26,780	\$11,861
Work In Process	8,533	10,802
Finished Goods	6,269	4,505
Total	<u>\$41,582</u>	<u>\$27,168</u>

Note 5. Property, Equipment and Building Improvements

Property, equipment and building improvements consists of the following at December 31, 2009 and 2008:

(in thousands)	<u>2009</u>	<u>2008</u>
Land	\$ 156	\$ —
Building	3,039	—
Computers and equipment	7,176	6,219
Leasehold improvements	5,191	3,388
	15,562	9,607
Less: accumulated depreciation and amortization	5,054	2,754
Property, equipment and building improvements, net	<u>\$10,508</u>	<u>\$6,853</u>

During 2009, we reclassified property and a building that was previously held for sale to a held and use long term asset. This was due to the Company's decision to lease our previous corporate headquarters and take the building off the market. In accordance with the applicable accounting pronouncements, we adjusted the carrying value of the building to fair value at the time of the reclassification and incurred a \$3.4 million impairment to the building. During 2008, we incurred a \$2.3 million impairment related to this building.

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Notes to the Consolidated Financial Statements—(Continued)

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 6. Intangible Assets

The following represents the balance of the intangible assets at December 31, 2009:

(in thousands)	<u>Gross Intangible Assets</u>	<u>Accumulated Amortization</u>	<u>Net Intangible Assets</u>
Cinryze Product rights	\$521,000	\$24,873	\$496,127
Vancocin Intangibles	<u>154,099</u>	<u>31,716</u>	<u>122,383</u>
Total	<u>\$675,099</u>	<u>\$56,589</u>	<u>\$618,510</u>

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

(in thousands)	<u>Gross Intangible Assets</u>	<u>Accumulated Amortization</u>	<u>Net Intangible Assets</u>
Cinryze Product rights	\$521,000	\$ 4,034	\$516,966
Vancocin Intangibles	<u>147,099</u>	<u>24,372</u>	<u>122,727</u>
Total	<u>\$668,099</u>	<u>\$28,406</u>	<u>\$639,693</u>

In December 2008, FDA changed OGD's 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, 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 in vitro 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.

On August 4, 2009 the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD's 2008 draft guidelines on bioequivalence for Vancocin. If FDA's proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also 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, and the number of generics and the timing of their market entry is unknown.

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. 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. We will reevaluate the expected cash flows and fair value of our Vancocin-related assets at such time a triggering event occurs.

We are 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. We account for these additional payments

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Notes to the Consolidated Financial Statements—(Continued)

as additional purchase price which requires that the additional purchase price consideration is recorded as an increase to the intangible asset of Vancocin and is amortized over the remaining estimated useful life of the intangible asset. 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, 2009, we have paid an aggregate of \$37.1 million to Lilly in additional purchase price consideration, as our net sales of Vancocin surpassed the maximum obligation level of \$65 million in 2009, 2008, 2007, 2006 and 2005. The \$37.1 million paid to Lilly was based upon 35% of \$20 million in 2009 and 2008, 35% of \$17 million in 2007, 35% of \$19 million in 2006 and 50% of \$21 million in 2005. We are obligated to pay Lilly additional amounts based on 35% of annual net sales between \$45 and \$65 million of Vancocin during 2010 and 2011.

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

At the time of recording the additional intangible assets, the Company recorded a cumulative adjustment in 2009 and 2008 of approximately \$1.3 million and \$1.0 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, 2009, 2008 and 2007 was \$28.2 million, \$10.8 million and \$6.1 million, respectively. The estimated aggregated amortization expense for each of the next five years will be approximately \$27.0 million, excluding any future increases related to additional purchase price consideration that may be payable to Lilly.

Note 7. Goodwill Impairment

During the first quarter of 2009 and as of March 31, 2009, the market capitalization of ViroPharma fell below the carrying value of the our net assets due to the results of our Phase 3 clinical trial evaluating maribavir used as prophylaxis in allogeneic stem cell transplant patients and our decision to discontinue dosing in our Phase 3 trial of maribavir in solid organ (liver) transplant patients. The fact that our market capitalization fell below our carrying value required us to test for impairment of our goodwill and other intangible assets. We conducted this analysis at March 31, 2009 and concluded that our goodwill was impaired due to our market capitalization being below the carrying value of our net assets for an extended period of time. We incurred a \$65.1 million charge in the first quarter related to this goodwill impairment.

Note 8. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following at December 31, 2009 and 2008:

(in thousands)	<u>2009</u>	<u>2008</u>
Rebates and returns	\$15,460	\$ 7,243
Payroll, bonus and employee benefits liabilities	6,411	4,647
Clinical development and research liabilities	3,365	6,795
Selling and commercial liabilities	2,308	3,046
Interest payable	1,196	1,403
Other current liabilities	4,614	12,516
	<u>\$33,354</u>	<u>\$35,650</u>

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Notes to the Consolidated Financial Statements—(Continued)

Note 9. Long-Term Debt

Long-term debt as of December 31, 2009 and December 31, 2008 (as adjusted by Note 3) is summarized in the following table:

(in thousands)	<u>December 31, 2009</u>	<u>Adjusted December 31, 2008</u>
Senior convertible notes	\$138,614	\$161,003
less: current portion	<u>—</u>	<u>—</u>
Total debt principal	<u>\$138,614</u>	<u>\$161,003</u>

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. 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.

We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities are bifurcated and accounted for separately. Under this new method of accounting, the convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value. See Note 3 for further explanation.

On March 24, 2009 we repurchased, in a privately negotiated transaction, \$45.0 million in principal amount of our senior convertible notes due March 2017 for total consideration of approximately \$21.2 million. The repurchase represented 18% of our then outstanding debt and was executed at a price equal to 47% of par value. Following these repurchases, senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$ 138.6 million as of December 31, 2009. Additionally, in negotiated transactions, we sold approximately 2.38 million call options for approximately \$1.8 million and repurchased approximately 2.38 million warrants for approximately \$1.5 million which terminated the call options and warrants that were previously entered into by us in March 2007. We recognized a \$9.1 million gain in the first quarter of 2009 as a result of this debt extinguishment. For tax purposes, the gain qualifies for deferral until 2014 in accordance with the provisions of the American Recovery and Reinvestment Act.

As of December 31, 2009, we have accrued \$1.2 million in interest payable to holders of the senior convertible notes. Debt issuance costs of \$4.8 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, 2009 being \$2.8 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

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Notes to the Consolidated Financial Statements—(Continued)

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, 2009, the fair value of the principal of the \$205.0 million convertible senior notes outstanding was approximately \$149.4 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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 allowed ViroPharma to receive up to approximately 13.25 million shares of its common stock at \$18.87 per share 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 our 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. We are entitled to receive approximately 10.87 million shares of its common stock at \$18.87 from the call option holders and 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), will owe the counterparties an aggregate of approximately 10.87 million shares of ViroPharma common stock.

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. These instruments have been determined to be indexed to our own stock and have been recorded in stockholders' equity in our Consolidated Balance Sheet. As long as the instruments are classified in stockholders' equity they are not subject to the mark to market provisions.

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Notes to the Consolidated Financial Statements—(Continued)

Note 10. Acquisition, License and Research Agreements

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. As of December 31, 2009, only the second CVR as described below remains achievable. The target for the first CVR payment of \$0.50 per share (or \$87.5 million) is no longer achievable and will not be paid as during the fourth quarter of 2009, a third party's human C1 inhibitor product was approved for the acute treatment of HAE and granted orphan exclusivity. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018.

The purchase price was as follows:

	<u>(in thousands)</u>
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	<u><u>\$494,097</u></u>

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

	<u>(in thousands)</u>
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	<u><u>\$718,601</u></u>
Liabilities assumed:	
Accounts payable	\$ 2,129
Accrued expenses	17,142
Long-term debt	12,056
Deferred tax liabilities	193,177
Total liabilities	<u><u>\$224,504</u></u>
Total purchase price	<u><u>\$494,097</u></u>

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Notes to the Consolidated Financial Statements—(Continued)

The retrospective adoption for the new accounting pronouncement related to our convertible debt eliminated the book and tax basis difference and related deferred tax asset which resulted in an adjustment to the above goodwill and deferred income taxes of \$35.2 million for the recasted December 31, 2008 balance sheet.

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, in accordance with SFAS 141, Accounting for Business Combinations which was the effective GAAP at the time of the acquisition,

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 2009 and 2008 was \$20.8 million and \$4.0 million, respectively.

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.

(in thousands, except per share data)	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

Sanquin Rest of World (ROW) Agreement

On January 8, 2010 we obtained, as part of the Sanquin ROW Agreement, expanded rights to commercialize Cinryze and future C1-INH derived products in certain European countries and other territories throughout the world as well as rights to develop future C1-INH derived products for additional indications. We intend to seek to commercialize Cinryze in Europe in countries which we have distribution rights commencing in 2011 as well as in additional territories.

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.

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Notes to the Consolidated Financial Statements—(Continued)

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. 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 6). In 2009, 2008 and 2007, the Company paid \$7.0 million, \$7.0 million and \$6.0 million, respectively, of these additional payments, which was accounted for as contingent consideration, increasing the carrying amount of the related intangible assets (see Note 6).

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 intangible assets will be amortized over their related useful lives (see Note 6).

Merck Agreement

In November 2003, the Company entered into an agreement granting Merck & Co., Inc. (“Merck”) 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, Merck 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 Merck entered into a license agreement under which Merck has assumed responsibility for all future development and commercialization of pleconaril. Other than transitioning the technology to Merck, 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, Merck 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, Merck 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 Merck’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

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Notes to the Consolidated Financial Statements—(Continued)

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.

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.

Note 12. Share-based Compensation

The Company adopted the new accounting provisions for share-based compensation as of January 1, 2006 using the modified prospective method. This adoption 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. Prior to the adoption of the standard, the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows. The new provisions require 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.

The Company estimates forfeiture rates for all share-based awards. The Company monitors stock options exercises and employee termination patterns in estimating the forfeiture rate.

Additionally, in accordance with GAAP, 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, 2009 and 2008:

(in thousands) <u>Plan</u>	2009			2008		
	<u>R&D</u>	<u>SG&A</u>	<u>Total</u>	<u>R&D</u>	<u>SG&A</u>	<u>Total</u>
Employee Stock Option Plans	\$3,113	8,445	\$11,558	\$2,948	\$5,899	\$8,847
Employee Stock Purchase Plan	90	180	270	57	28	85
Non-employee Stock Options	(11)	—	(11)	6	—	6
Total	<u>\$3,192</u>	<u>\$8,625</u>	<u>\$11,817</u>	<u>\$3,011</u>	<u>\$5,927</u>	<u>\$8,938</u>

No amounts of share-based compensation cost have been capitalized into inventory or other assets during the years ended December 31, 2009 and 2008.

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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 2009, 2008 and 2007 had weighted average fair values of \$6.73, \$7.66 and \$11.30 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:

	<u>2009</u>	<u>2008</u>	<u>2007</u>
Expected dividend yield	—	—	—
Range of risk free interest rate	1.6% – 3.4%	1.9% – 3.7%	3.7% – 5.1%
Weighted-average volatility	77.2%	87.0%	92.7%
Range of volatility	71.5% – 79.9%	76.6% – 90.2%	90.2% – 94.6%
Range of expected option life (in years)	5.50 – 6.25	5.50 – 6.25	5.50 – 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.

On May 23, 2008, the 2005 Plan was amended and an additional 5,000,000 shares of common stock was reserved for issuance upon the exercise of stock options or the grant of restricted shares or restricted share units. This amendment was approved by stockholders at our Annual Meeting of Stockholders. As of December 31, 2009, there were 2,963,028 shares available for grant under the Plans. The following table lists the balances available by Plan at December 31, 2009:

	<u>1995 Plan</u>	<u>2001 Plan</u>	<u>2005 Plan</u>	<u>Combined</u>
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)	(5,425,862)	(13,678,849)
Number of options cancelled since inception	3,004,308	818,094	511,459	4,333,861
Number of shares expired	(506,793)	(6,147)	(29,044)	(541,984)
Number of shares available for grant	<u>—</u>	<u>56,475</u>	<u>2,906,553</u>	<u>2,963,028</u>

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Notes to the Consolidated Financial Statements—(Continued)

The following table lists option grant activity for the year ended December 31, 2009:

	Share Options	Weighted average exercise price per share
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
Granted	1,571,009	9.94
Exercised	(51,125)	10.67
Forfeited	(167,062)	11.72
Expired	(64,341)	16.13
Balance at December 31, 2009	<u>7,590,195</u>	<u>\$10.68</u>

The total intrinsic value of share options exercised during the year ended December 31, 2009, 2008 and 2007 was approximately \$0.1 million, \$0.7 million, and \$0.8 million, respectively.

We have 7,590,195 option grants outstanding at December 31, 2009 with exercise prices ranging from \$0.99 per share to \$38.70 per share and a weighted average remaining contractual life of 6.55 years. The following table lists the outstanding and exercisable option grants as of December 31, 2009:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding	7,590,195	\$10.71	6.55	\$10,619,796
Exercisable	4,272,839	\$10.50	5.06	\$ 8,824,288

As of December 31, 2009, there was \$17.5 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 2.4 years. The total fair value of shares vested in the year ended December 31, 2009 was \$9.7 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 have approved amendments to the plan to increase the number of shares available for issuance under the plan by 600,000 shares. Under this plan, 69,806, 24,478 and 18,908 shares were sold to employees during 2009, 2008 and 2007. As of December 31, 2009 there are approximately 478,969 shares available for issuance under this plan.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

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 \$270,000. The fair value was estimated using the Type B model, with the following assumptions:

	2009 Plan Period Two	2009 Plan Period One
Risk free interest rate	0.28%	0.28%
Volatility	123.30%	76.10%
Expected option life (in years)	0.5	0.5

Under Plan Period Two, 37,378 shares were sold to employees on December 31, 2009 at \$5.08 per share, which represents the closing price on the offer termination date of \$5.98 per share at 85%.

Under Plan Period One, 34,428 shares were sold to employees on June 30, 2009 at \$11.59 per share, which represents the closing price on the offer termination date of \$13.63 per share at 85%.

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, 2009	December 31, 2008	December 31, 2007
Expected dividend yield	—	—	—
Range of risk free interest rate	0.2% – 1.1%	0% – 1.0%	2.6% – 3.5%
Weighted average volatility	67.40%	57.90%	50.30%
Range of volatility	51.8% – 84.4%	44.0% – 66.8%	50.3% – 69.3%
Contractual option life (in years)	0.53 – 2.28	0.04 – 3.29	0.13 – 4.29

There were no non-employee share options vested or exercised during the year ended December 31, 2009 or 2008. Shares issued to non-employees upon exercise of stock options are new shares.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

Note 13. Income Taxes

For the years ended December 31, 2009, 2008 and 2007, the following table summarizes the components of income (loss) before income taxes and the provision (benefit) for income taxes:

(in thousands)	Year ended December 31,		
	2009	2008	2007
Domestic	37,020	79,406	130,371
Foreign	(7,068)	594	78
Income before income taxes	<u>\$29,952</u>	<u>\$80,000</u>	<u>\$130,449</u>
Expense (benefit) for income taxes:			
Current:			
Federal	7,614	145	21,216
State and local	4,018	3,763	4,264
Foreign	16	209	68
Subtotal	<u>11,648</u>	<u>4,117</u>	<u>25,548</u>
Deferred:			
Federal	21,588	11,123	12,268
State and local	10,684	431	576
Foreign	(2,891)	369	(43)
Subtotal	<u>29,381</u>	<u>11,923</u>	<u>12,796</u>
Income tax expense	<u>\$41,029</u>	<u>\$16,040</u>	<u>\$ 38,344</u>
Effective income tax rate	137.0%	20.1%	29.4%

Income tax expense includes federal, state and foreign income tax at statutory rates and the effects of various permanent differences. The increase in the 2009 rate as compared to 2008 is primarily due to the impact of the goodwill impairment recognized in the first quarter of 2009. 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.

For the year ended December 31, 2009, 2008 and 2007, the following table summarizes the principal elements of the difference between the effective income tax rate and the federal statutory income tax rate:

(% of pre-tax income)	Year ended December 31,		
	2009	2008	2007
U.S. federal statutory income tax rate	35.0%	35.0%	35.0%
State and local income tax, net of federal income tax effect	44.3	3.6	2.6
Share-based compensation	5.0	1.3	0.8
Orphan drug credit	(20.5)	(16.0)	(5.8)
Change in valuation allowance	(1.6)	(3.8)	(2.9)
Goodwill impairment	75.8	—	—
Other	(1.0)	—	(0.3)
Effective income tax expense rate	<u>137.0%</u>	<u>20.1%</u>	<u>29.4%</u>

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

In 2009, 2008 and 2007, the Company recorded \$0.1 million, \$0.2 million and \$0.3 million related to current stock option tax benefits allocated directly to stockholders' equity, respectively.

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

(in thousands)	December 31,	
	2009	2008
Deferred tax assets:		
Net operating loss carryforwards	\$ 15,755	\$ 44,409
Capitalized research and development costs	11,339	17,630
Orphan drug credit carryforward	24,036	16,733
Research and development credit carryforward	6,840	6,840
Non-deductible reserves	3,593	1,502
Depreciation	1,518	438
Intangible asset amortization	7,687	7,839
Equity compensation	7,684	4,918
Other	—	3,034
Subtotal	78,452	103,342
Valuation allowance	(5,949)	(6,436)
Deferred tax assets	72,503	96,906
Deferred tax liabilities:		
Intangible asset amortization	197,731	193,846
Convertible note	2,553	3,352
Inventory	—	2,691
Prepaid expenses	1,084	1,071
Other	3,573	—
Deferred tax liabilities	204,941	200,960
Net deferred tax assets (liability)	\$(132,438)	\$(104,054)

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

(in thousands)	December 31,	
	2009	2008
Current assets	\$ 20,065	\$ 24,094
Other non-current liabilities	(152,503)	(128,148)
Net deferred tax assets (liability)	\$(132,438)	\$(104,054)

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

The following table summarizes the change in the valuation allowance:

(in thousands)	Year ended December 31,		
	2009	2008	2007
Valuation allowance at beginning of year	\$6,436	\$ 38,742	\$48,278
Tax expense (benefit)	(487)	(4,087)	(4,028)
Additional paid in capital	—	—	(120)
Reduction of deferred tax asset	—	—	(1,725)
Adoption of new accounting for convertible debt	—	(28,219)	(3,663)
Valuation allowance at end of year	\$5,949	\$ 6,436	\$38,742

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 due to our future projections of taxable income, the reversal of deferred tax liabilities, the utilization of the carryforwards and other factors. We continue to maintain a valuation allowance for state net operating losses that are more likely than not to expire unused based on current limitations.

The Company has a cumulative unremitted loss from foreign subsidiaries. Future unremitted foreign earnings 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.

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2009.

(in thousands)	Amount	Expiration
Federal net operating losses	\$ 11,533	2024-2028
State net operating losses	173,536	2019-2028
Orphan drug credits	24,036	2025-2028
Research and development credits	8,565	2010-2027

On January 1, 2007, the Company adopted the pronouncement for recognizing tax benefits related to uncertain tax positions and the additional financial statement disclosure. This pronouncement 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 this pronouncement 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 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.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

The following is a rollforward of our uncertain tax positions for the year ended December 31, 2009:

	<u>(in thousands)</u>
Balance at January 1, 2007	\$ —
Additions for tax positions of prior years	1,133
Balance at December 31, 2007	1,113
Additions for tax positions of prior years	76
Balance at December 31, 2008	1,209
Additions for tax positions of prior years	—
Payments made to settle uncertain tax position	(1,209)
Balance at December 31, 2009	\$ —

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 2004. The Company's 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 (Loss) per share

	<u>For the years ended December 31,</u>		
<u>(in thousands, except per share data)</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>
<u>Basic Earnings (Loss) Per Share</u>			
Net income (loss)	\$(11,077)	\$63,960	\$92,105
Common stock outstanding (weighted average)	77,423	71,391	69,827
Basic net income (loss) per share	\$ (0.14)	\$ 0.90	\$ 1.32
<u>Diluted Earnings (Loss) Per Share</u>			
Net income (loss)	\$(11,077)	\$63,960	\$92,105
Add interest expense on senior convertible notes, net of income tax	—	7,994	5,982
Diluted net income (loss)	\$(11,077)	\$71,954	\$98,087
Common stock outstanding (weighted average)	77,423	71,391	69,827
Add shares from senior convertible notes	—	13,248	10,200
Add "in-the-money" stock options	—	1,073	864
Common stock assuming conversion and stock option exercises	77,423	85,712	80,891
Diluted net income (loss) per share	\$ (0.14)	\$ 0.84	\$ 1.21

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

The following common shares that are associated with stock options were excluded from the calculations as their effect would be anti-dilutive:

(in thousands)	<u>For the years ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
“Out-of-the-money” stock options	5,034	4,447	4,074
Shares from senior convertible notes	11,406	—	—
“In-the-money” stock options	849	—	—

Note 15. Fair Value Measurement

Valuation Hierarchy—GAAP 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, 2009:

(in millions of dollars)	<u>Total Carrying Value at December 31, 2009</u>	<u>Fair Value Measurements at December 31, 2009 Using</u>		
		<u>(Level 1)</u>	<u>(Level 2)</u>	<u>(Level 3)</u>
Cash and cash equivalents	<u>\$331,672</u>	<u>\$331,672</u>	<u>\$—</u>	<u>\$—</u>
Total	<u>\$331,672</u>	<u>\$331,672</u>	<u>\$—</u>	<u>\$—</u>

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. All of our cash equivalents currently are invested in money market accounts. There were no changes in valuation techniques during the quarter ended December 31, 2009.

During 2009, we adjusted the carrying value of our previous corporate headquarters to its fair value due to the reclassification of the asset from available for sale to held and use due to our decision to lease the building and have taken it off the market. We measured the fair value of the building using level 3 inputs including discounted cash flows for the rental of the building would generate in future periods and residual capitalization rates that a market participant would be willing to pay to purchase the building given an existing lease. In 2008, we measured the fair value of the building based on the then current sales price less cost to sell.

Additionally, during the first quarter of 2009 and as of March 31, 2009, the market capitalization of the Company fell below the carrying value of our net assets due to the results of our Phase 3 clinical trial evaluating. The fact that our market capitalization fell below our carrying value required us to test for impairment of our goodwill and other intangible assets. We conducted this analysis at March 31, 2009 using our then current stock price and level 3 inputs which included a control premium based on market transactions and discounted cash flows for certain assets. We concluded that our goodwill was impaired due to our market capitalization including control premium

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

being below the carrying value of our net assets for an extended period of time. We incurred a \$65.1 million charge in the first quarter related to this goodwill impairment.

We believe that the fair values of our current assets and current liabilities approximate their reported carrying amounts.

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 \$413,000, \$214,000 and \$114,000 to the 401(k) Plan in each of the years ended December 31, 2009, 2008 and 2007, 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

We have committed to purchase up to 140,000 liters of plasma per year through 2015 from our supplier. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer. Also, an additional €5.0 million (approximately \$7.2 million) loan will be made to Sanquin in 2010.

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 began to occupy the space, which was in the fourth quarter of 2008. In connection with the new lease, we also received a leasehold improvement allowance of \$2.3 million.

Our future minimum lease payments under our operating leases related to buildings and equipment for periods subsequent to December 31, 2009 are as follows (in thousands):

<u>Year ending December 31,</u>	<u>Commitments</u>
2010	1,656
2011	1,776
2012	1,805
2013	1,845
2014	1,886
Thereafter	<u>3,470</u>
Total minimum payments	<u>\$12,438</u>

We have severance agreements for certain employees and change of control agreements for executive officers and certain other employees. Under its severance agreements, certain employees may be provided separation benefits from us if they are involuntarily separated from employment. Under our change of control agreements, certain employees are provided separation benefits if they are either terminated or resign for good reason from ViroPharma within 12 months from a change of control.

In addition to the merger consideration paid at closing as described in Note 10, Lev shareholders received the non-transferrable contractual right to two contingent payments (“CVR Payments”) of \$0.50 each that could deliver up to an additional \$174.6 million, or \$1.00 per share in cash, if Cinryze meets certain targets. As of

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

December 31, 2009, only the second CVR as described below remains achievable. The target for the first CVR payment of \$0.50 per share (or \$87.5 million) is no longer achievable and will not be paid as during the fourth quarter of 2009, a third party's human C1 inhibitor product was approved for the acute treatment of HAE and granted orphan exclusivity. The second CVR payment of \$0.50 per share (\$87.5 million) becomes payable if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018.

Note 18. Collaborations

In January 2010, we entered into a collaboration agreement with Sanquin to establish a Joint Steering Committee. The Joint Steering Committee shall serve as a forum to establish and discuss progress under, among others, (i) a Global Commercialization Plan; (ii) clinical development programs of ViroPharma and the Sanquin Early Stage Research Programs; (iii) manufacturing Capacity Schedules; (iv) pharmacovigilance matters; (v) quality matters; (vi) manufacturing improvement programs; and (vii) regulatory matters.

Sanquin may conduct certain early stage research programs and we will provide to Sanquin €1,000,000 (approximately \$1.4 million) per year for a period of five years to support such Early Stage Research Programs. We have a right of first refusal to further develop and commercialize the subject matter of each such Early Stage Research Program worldwide (except for the Excluded Territory) subject to Sanquin's and its research partners' right to use any such intellectual property for their internal, non-commercial research purposes. Except for the Early Stage Research Programs, we will be solely responsible for conducting all clinical trials and other development activities necessary to support our efforts to obtain regulatory approval of Cinryze in additional territories as well as any future C1-INH derived products developed pursuant to the Rest of World Agreement. Sanquin has the right to approve any such clinical trials and development activities through the Joint Steering Committee.

On January 1, 2009, we implemented the new accounting requirements on how 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. In accordance with these requirements, we evaluated our collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments to and from our collaborative partners are not within the scope of other authoritative accounting literature, the income statement classification for these payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due to our collaborative partner related to development activities are reflected as a research and development expense.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

Note 19. Supplemental Cash Flow Information

(in thousands)	For the years ended December 31,	
	2009	2008
Supplemental disclosure of non-cash transactions:		
Employee share-based compensation	\$11,828	\$ 8,932
Liability classified share-based compensation benefit	(11)	6
Unrealized gains on available for sale securities	—	550
Reversal of accrued deferred finance costs	—	151
Change in/ establishment of landlord allowance	104	2,063
Non-cash lease activity	—	573
Debt buy back deferred tax impact	308	—
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$10,466	\$10,348
Cash paid for interest	4,550	5,000
Cash received for stock option exercises	22	360
Cash received for employee stock purchase plan	356	188

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)
2009 Quarter Ended				
Net product sales	\$ 60,190	\$81,873	\$80,551	\$87,835
Total revenues	60,190	81,873	80,551	87,835
Cost of sales (excluding amortization of product rights)	3,929	14,121	10,216	11,948
Operating expenses	51,319	43,503	37,910	40,274
Goodwill Impairment	65,099	—	—	—
Other income (expense)	5,914	(2,572)	(2,752)	(2,768)
Income tax expense (benefit)	4,972	5,625	9,601	20,831
Net income (loss)	(59,215)	16,052	20,072	12,014
Basic net income (loss) per share (1)	\$ (0.77)	\$ 0.21	\$ 0.26	\$ 0.16
Diluted net income (loss) per share (1)	\$ (0.77)	\$ 0.20	\$ 0.24	\$ 0.15
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)	3,184	849	(142)	(2,546)
Income tax expense (benefit)	6,315	7,783	5,587	(3,645)
Net income (loss)	16,386	22,783	27,106	(2,315)
Basic net income (loss) per share (1)	\$ 0.23	\$ 0.33	\$ 0.39	\$ (0.03)
Diluted net income (loss) per share (1)	\$ 0.22	\$ 0.29	\$ 0.34	\$ (0.03)

(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.

ViroPharma Incorporated

Notes to the Consolidated Financial Statements—(Continued)

- (2) Fourth quarter 2008 results include expenses for Cinryze, which was acquired in October in our acquisition of Lev
- (3) Fourth quarter 2009 and 2008 includes a impairment charges related to our previous Corporate headquarters.
- (4) We adopted the new accounting provisions for our convertible debt securities as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. The adoption is discussed further in Note 3 of the Consolidated Financial Statements.

SUBSIDIARIES OF THE COMPANY

<u>Entity</u>	<u>Name of State/Country of Incorporation</u>
ViroPharma Biologics, Inc.	Delaware
VCO Incorporated	Delaware
VPDE Incorporated	Delaware
VPINT, Inc.	Delaware
ViroPharma Limited	United Kingdom
ViroPharma SPRL	Belgium
ViroPharma SAS	France

Consent of Independent Registered Public Accounting Firm

The Board of Directors
ViroPharma Incorporated:

We consent to the incorporation by reference in the registration statements on Form S-8 (No. 333-160910, No. 333-152724, No. 333-136447, No. 333-34129, No. 333-38248, No. 333-60951, No. 333-38256, No. 333-109600 and No. 333-127188) registration statements on Form S-3 (No. 333-156422, No. 333-37960, No. 333-64482, No. 333-99533, No. 333-122315, No. 333-123994, and No. 333-141411) and registration statement on Form S-4 (No. 333-153088) of ViroPharma Incorporated of our reports dated February 24, 2010, with respect to the consolidated balance sheets of ViroPharma Incorporated as of December 31, 2009 and 2008, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2009 and the effectiveness of internal control over financial reporting as of December 31, 2009, which reports appear in the December 31, 2009 Annual Report on Form 10-K of ViroPharma Incorporated.

Our report on the consolidated financial statements refers to the Company's retrospective change in accounting for convertible debt instruments that may be settled in cash upon conversion due to the adoption of a new accounting standard issued by the FASB, as of January 1, 2009; to the Company's change in its method to measure the fair value of assets and liabilities as of January 1, 2008; and to the Company's change in method of recognizing and measuring the tax effects related to uncertain tax positions due to the adoption of a new accounting standard issued by the FASB, as of January 1, 2007.

/s/ KPMG LLP

Short Hills, NJ
February 24, 2010

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

I, Vincent J. Milano, President and Chief Executive 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/ VINCENT J. MILANO

Vincent J. Milano
President and Chief Executive Officer

February 24, 2010

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

I, Charles A. Rowland, Jr., 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.
Chief Financial Officer

February 24, 2010

**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, 2009 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 and Chief Executive Officer

February 24, 2010

/s/ CHARLES A. ROWLAND, JR.

Charles A. Rowland, Jr.
Chief Financial Officer

February 24, 2010

* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

STOCKHOLDERS' INFORMATION

CORPORATE HEADQUARTERS

730 Stockton Drive • Exton, PA 19341
Phone: (610) 458-7300 • **Fax:** (610) 458-7380
www.viopharma.com

CORPORATE COMMUNICATIONS

William Roberts
Vice President
Corporate Communications
Phone: (610) 321-6288
will.roberts@viopharma.com

INVESTOR RELATIONS

Robert Doody
Assistant Director
Investor Relations
Phone: (610) 321-6290
robert.doody@viopharma.com

PUBLIC RELATIONS

Kristina Broadbelt
Associate Director
Public Relations and Advocacy
Phone: (610) 321-2358
kristina.broadbelt@viopharma.com

BUSINESS DEVELOPMENT

R. Clayton Fletcher
Vice President
Business Development
Phone: (610) 321-6789
clayton.fletcher@viopharma.com

INDEPENDENT AUDITORS

KPMG LLP
150 John F. Kennedy Parkway • Short Hills, NJ 07078

ANNUAL SHAREHOLDERS' MEETING

The shareholder's meeting will be held on Monday, May 24, 2010 at 10:00 a.m. 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
Phone: (610) 649-7300
www.stocktrans.com



VIROPHARMA INCORPORATED
730 Stockton Drive • Exton, PA 19341
Phone: (610) 458-7300 • **Fax:** (610) 458-7380
www.viropharma.com