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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

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(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, 2012

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

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**VIROPHARMA INCORPORATED**

(Exact name of registrant as specified in its charter)


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**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** 

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

Title of each class:  
**Common Stock, par value \$0.002**

Name of each exchange on which registered:  
**The NASDAQ Stock Market LLC**

<https://www.sec.gov/Archives/edgar/data/946840/000104746913001835/a2213162z1...> 22.05.2017

**Securities registered pursuant to Section 12(g) of the Act:**  
**Title of each class: None**

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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 the definitions of "large accelerated filer", "accelerated filer", "non-accelerated filer" and "smaller reporting company" 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 \$1.3 billion as of June 30, 2012, 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 15, 2013 was 65,208,957 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 2013 Annual Meeting of Stockholders scheduled to be held on May 23, 2013 are incorporated by reference in Part III of this Annual Report on Form 10-K.

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**VIROPHARMA INCORPORATED**  
**FORM 10-K ANNUAL REPORT**  
**For Fiscal Year Ended December 31, 2012**  
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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.*

### FORWARD-LOOKING STATEMENTS

Statements contained or incorporated by reference in this document contain information that includes or is based on "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including expected future revenue growth drivers; clinical development timelines; expected future cost estimates; expected tax rates and expected sources and uses of liquidity, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. We have tried, whenever possible, to identify such statements by words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "projected," "forecast," "will," "may" or similar expressions. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Item 1A under the caption "Risk Factors" in this document, supplement, and as otherwise enumerated herein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained or incorporated by reference in this document.

We do not undertake any obligation to update our forward-looking statements after the date of this document for any reason, even if new information becomes available or other events occur in the future. You are advised to consult any further disclosures we make on related subjects in our reports filed with the Securities and Exchange Commission (SEC). Also note that, in Item 1A, we provide a cautionary discussion of the risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by Section 27A of the Securities Act and Section 21E of the Exchange Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this to be a complete discussion of all potential risks or uncertainties.

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**PART I****ITEM 1. BUSINESS****Overview**

ViroPharma Incorporated is an international biotechnology company dedicated to the development and commercialization of novel solutions for physician specialists to address unmet medical needs of patients living with diseases that have few if any clinical therapeutic options including therapeutics for rare and orphan diseases. We intend to grow through sales of our marketed products, through continued development of our product pipeline, through expansion of sales into additional territories outside the United States, through potential acquisition or licensing of products and product candidates and the acquisition of companies. We expect future growth to be driven by sales of Cinryze for hereditary angioedema (HAE), both domestically and internationally, sales of Plenadren for treatment of adrenal insufficiency (AI) and Buccolam in Europe for treatment of paediatric seizures, and by our development programs, including C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection, VP20621 for the prevention of recurrent *C. difficile*-associated diarrhea (CDAD) and VP20629 for the treatment of Friedreich's Ataxia (FA).

The following chart generally describes our approved products:

Product	Marketplace	Disease	Program Indication	Product Status
Cinryze—IV	US	HAE	Prophylaxis	Marketed
Cinryze—IV	EU	HAE	Prophylaxis, pre-procedural and acute	Marketed
Buccolam	EU	Pediatric Epilepsy	Treatment	Marketed
Plenadren	EU	AI	Treatment	Marketed
Vancocin	US	CDAD	Treatment	Marketed

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with 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. We acquired rights to Cinryze for the United States in October 2008 and in January 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 well as rights to develop future C1-INH derived products for additional indications and new formulations. In June 2011, the European Commission (EC) granted us Centralized Marketing Authorization for Cinryze® in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. We have begun to commercialize Cinryze in Europe and continue to evaluate our commercialization opportunities in countries where we have distribution rights.

We acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]) in May 2010. In September 2011, the EC granted a Centralized Paediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. With the grant of the PUMA, we began to commercialize Buccolam in Europe.

On November 15, 2011, we acquired worldwide rights to Plenadren® (hydrocortisone, modified release tablet) for treatment of AI. The acquisition of Plenadren further expanded our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren, an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We are in the process of launching Plenadren in various countries in Europe and a named patient program is available to

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patients in countries in which we have not launched Plenadren commercially. We are currently conducting an open label trial with Plenadren in Sweden and have initiated a registry study that was required as a condition of approval in Europe. We also are currently exploring commercialization opportunities in additional geographies including the United States.

We also sell branded and authorized generic Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is indicated for the treatment of CDAD. Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

Our product development portfolio is primarily focused on the following programs: C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection, VP20621 (prevention of recurrent CDAD) and VP20629 (treatment of Friedrich's Ataxia).

The following chart generally describes our investigational products:

Product	Marketplace	Disease	Proposed Indication	Product Status
C1 esterase inhibitor [human]—IV	ROW*	HAE	Prophylaxis, pre-procedural and acute	Filing/Pre-filing
C1 esterase inhibitor [human]—subcutaneous administration	Worldwide	HAE	Prophylaxis	Phase 2
C1 esterase inhibitor [human]—antibody-mediated rejection	Worldwide	AMR	Treatment	Phase 2
C1 esterase inhibitor [human]—IV	Worldwide		Additional indications under evaluation	Preclinical
maribavir	Worldwide (other than Japan)	CMV	Treatment	Phase 2
Non-toxigenic strain of <i>C. difficile</i> (VP20621)	Worldwide	CDAD	Prevention	Phase 2
VP20629	Worldwide	FA	Treatment	Phase 1

\* ROW is defined in the Business Development and Strategic Relationships section of this document.

We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. In May 2011, Halozyme Therapeutics Inc. (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology, in combination with a C1 esterase inhibitor which we intend to apply initially to develop a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In the first quarter of 2012, we completed a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 and announced the presentation of positive data. In December 2012, we initiated a Phase 2b double blind, multicenter, dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze® (C1 esterase inhibitor [human]) in combination with PH20 in adolescents and adults with HAE for prevention of HAE attacks. We will continue to evaluate the subcutaneous administration of Cinryze as a standalone therapy. We are also investigating a recombinant forms of C1-INH.

Additionally, we are working on developing our C1 esterase inhibitor in further therapeutic uses and potential additional indications in other C1 mediated diseases. We intend to support Investigator Initiated Studies (IIS) to identify further therapeutic uses for Cinryze. An IIS evaluating C1 INH as a

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treatment for Autoimmune Hemolytic Anemia (AIHA) and Neuromyelitis Optica (NMO) were initiated in 2012. We are also sponsoring a clinical trial in Antibody-Mediated Rejection (AMR) and are evaluating the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria and may conduct clinical and non-clinical studies to evaluate additional therapeutic uses in the future.

During the second quarter of 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV infections in transplant recipients. The program consists of two independent Phase 2 clinical studies that include subjects who have asymptomatic CMV, and those who have failed therapy with other anti-CMV agents (resistant/refractory study). During the third quarter of 2012 and first quarter of 2013, we presented interim data from the Phase 2 open label clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV. Results from this study, as well as data from a second Phase 2 open label study of maribavir as a treatment for patients with resistant or refractory cases of CMV, will periodically be evaluated.

We are also developing VP20621 for the prevention of recurrent CDAD. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP20621 for prevention of recurrence of CDAD in adults previously treated for CDAD. We presented interim data from this study during the third quarter of 2012. We closed enrollment of patients in December 2012 and anticipate having the complete dataset in 2013.

On September 30, 2011, we entered into a license agreement with Intellect Neurosciences, Inc. (INS) for the worldwide rights to its clinical stage drug candidate, VP20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. VP20629, or indole-3-propionic acid, is a naturally occurring, small molecule that has potent anti-oxidant properties that can protect against neurodegenerative disease. In a Phase 1 safety and tolerability study conducted in the Netherlands, VP20629 was demonstrated to be safe and well tolerated at all dose levels tested. We expect to initiate a single and repeat dose phase 1 study in patients in 2013 and expect to initiate a subsequent phase 2 study after completion of the phase 1 study. Following completion of the phase 2 study, a phase 3 study is planned. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

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 which we believe will provide both revenue and earnings growth over time.

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](http://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.

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**Marketed Products**

**Cinryze**

The FDA granted approval for Cinryze in October 2008 for routine prophylaxis against attacks in adolescent and adult patients with HAE. In June 2011, the EC granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. 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.

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.

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*Therapeutic Approaches 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. Additionally, in August 2011, the FDA approved a self-administered icatibant for treatment of acute attacks of HAE in adults 18 years of age and older. For swelling of the intestinal wall, which can cause debilitating pain, narcotics such as morphine and antiemetics for nausea are often given. In January 2012, the FDA approved a label expansion for the self administration of a competitor's C1-INH for facial and abdominal attacks and also indicates it to treat life-threatening laryngeal HAE attacks. 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 C1-INH 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 in October 2008 pursuant to the Orphan Drug Act.

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

**Buccolam**

In May 2010, we acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]). In September 2011, the European Commission granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from three months to less than 18 years of age. With the grant of the PUMA we began to commercialize Buccolam in Europe.

Seizures occur because of sudden and abnormal electrical activity in the brain. There are many causes of seizures affecting pediatric patients; many are the result of epilepsy, but other triggers can include medicines, head injuries, certain diseases, and high fevers (called 'febrile seizures'). Febrile seizures are the most common type of seizure in children; approximately one in every 25 children will have at least one febrile seizure, and more than one-third of these children will have additional febrile seizures before they outgrow the tendency to have them. Epilepsy is among the most common childhood neurological disorders in developed countries, affecting nearly one percent of the population. There are approximately six million people affected by epilepsy in Europe; nearly one million European children and adolescents have active epilepsy. Epilepsy commonly causes physical manifestations including neurological and muscle destruction and degradation of renal function, as well as numerous negative cognitive, behavioral and neurological effects. Seizures can last from a few seconds to several minutes or longer in some cases. If left untreated, seizures can lead to status epilepticus (SE) and patients may require hospitalization and intensive care.

Buccolam is oromucosal midazolam provided in an individual dose formulation for buccal delivery. It is provided as a convenient, portable, ready to use, pre-filled oral syringe containing an age-specific

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dose. Buccolam is approved throughout the European Union and the EEA for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from three months to less than 18 years of age. Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

### **Plenadren**

On November 15, 2011, we acquired the worldwide rights to Plenadren® (hydrocortisone, modified release tablet) for treatment of adrenal insufficiency (AI). The acquisition of Plenadren further expanded our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren, an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We are in the process of launching Plenadren in various countries in Europe and a named patient program is available to patients in countries in which we have not launched Plenadren commercially. We are currently conducting an open label trial with Plenadren in Sweden and have initiated a registry study as a condition of approval in Europe. We also are currently exploring commercialization opportunities in additional geographies including the United States.

Plenadren is a dual release hydrocortisone replacement therapy designed to better mimic the normal physiological cortisol profile in order to improve outcomes for patients suffering from adrenal insufficiency. Plenadren is given as an oral tablet once daily. It has an outer layer releasing hydrocortisone immediately and an inner core releasing the rest of the drug more slowly during the day.

AI is a disorder caused by dysfunction of the adrenal gland resulting in low levels of the hormone cortisol, which normally follows a circadian rhythm and regulates many critical body functions. To survive, AI patients need replacement therapy with glucocorticoids (usually hydrocortisone). Primary AI is referred to as Addison's disease, which affects up to 15 in every 100,000 people. Common symptoms of Addison's disease include fatigue, muscle weakness, fever, weight loss, difficulty in standing up, changes in personality, and gastrointestinal involvement. Severe adrenal insufficiency, which can manifest as shock (very low blood pressure with loss of consciousness), dehydration, and imbalance of sodium and potassium levels, can be life threatening. These cases of adrenal crisis (sometimes called 'Addisonian crisis') can occur after a significant stress such as infection or trauma, and can be fatal if not promptly diagnosed and treated with glucocorticoid therapy. To maintain a reasonable quality of life, these patients rely on cortisol replacement therapy. Because it is a chronic condition, these patients require this therapy throughout their entire lives.

### **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 indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin also is used for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Both are potentially serious infections of the gastrointestinal (GI) tract. *S. aureus* enterocolitis is rare; accordingly, CDAD is the indication that accounts for the significant majority of Vancocin's use.

CDAD 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 CDAD.

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Historically, metronidazole has been commonly used as first-line treatment for CDAD, while Vancocin has been reserved for those patients who have failed metronidazole, have recurrent disease, or who are suffering from severe CDAD. In May 2011, FDA approved Optimer Pharmaceuticals' product, Difcid® (fidaxomicin), for the treatment of CDAD. On April 9, 2012, the FDA denied the citizen petition we filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of generic versions of Vancocin (vancomycin hydrochloride, USP) capsules. The FDA also informed us in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin which was approved on December 14, 2011 would not qualify for three additional years of exclusivity, as the agency interpreted Section 505(v) of the FD&C Act to require a showing of a significant new use (such as a new indication) for an old antibiotic such as Vancocin in order for such old antibiotic to be eligible for a grant of exclusivity. FDA also indicated that it approved three ANDA's for generic vancomycin capsules and the companies holding these ANDA approvals indicated that they began shipping generic vancomycin hydrochloride, USP. In June 2012, the FDA approved a fourth ANDA for generic vancomycin capsules.

We granted a third party a license under our NDA for Vancocin to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. We are also obligated to pay Genzyme royalties of 10 percent, 10 percent and 16 percent of our net sales of Vancocin for the three year period following the approval of the sNDA as well as a lower royalty on sales of our authorized generic version of Vancocin in connection with our purchase of exclusive rights to two studies of Vancocin.

**Product Pipeline**

Our product development portfolio is primarily focused on four programs: Cinryze (C1 esterase inhibitor [human]) for management of hereditary angioedema, maribavir for cytomegalovirus (CMV) infection, VP 20621 for the management of CDAD and VP20629, which we expect to develop for the treatment of Friedreich's Ataxia. We are also working on developing alternative modes of administration for Cinryze and additional therapeutic uses for C1 esterase inhibitor in other complement-mediated diseases.

***HAE Program***

**Cinryze IV—Outside the United States and Europe**

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 continue to evaluate our commercialization plans in countries outside of the United States and Europe where we have distribution rights. We are currently in the process of identifying the steps necessary to launch in other territories where we have distribution rights and have made regulatory filings in several countries.

**Cinryze IV—Other formulations and other complement-mediated diseases**

We are currently evaluating the feasibility of other (non-IV) formulations and modes of administration for Cinryze. We have conducted a Phase 1 study utilizing subcutaneous administration of Cinryze, and results of this study supported the conduct of a Phase 2 study. In October 2010, we announced the completion of enrollment in this Phase 2 study which is designed to evaluate the safety, pharmacokinetics and pharmacodynamics of subcutaneous versus intravenous administration of Cinryze in adolescent and adult subjects with HAE.

In the first quarter of 2012, we completed a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 and announced the presentation of positive data. In December 2012, we initiated a Phase 2b double blind, multicenter, dose ranging study to evaluate the safety and efficacy of

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subcutaneous administration of Cinryze (C1 esterase inhibitor [human]) in combination with PH20 in adolescents and adults with HAE for prevention of HAE attacks. We will continue to evaluate a subcutaneous formulation of Cinryze as a standalone therapy. We are also investigating a recombinant form of C1-INH.

Additionally, we are working on developing our C1 esterase inhibitor in further therapeutic uses and potential additional indications in other C1 mediated diseases. We intend to support IISs to identify further therapeutic uses for Cinryze. An IIS evaluating C1 INH as a treatment for Autoimmune Hemolytic Anemia (AIHA) and Neuromyelitis Optica (NMO) were initiated in 2012. We are also sponsoring a clinical trial in Antibody-Mediated Rejection (AMR) and are evaluating the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH) and may conduct clinical and non-clinical studies to evaluate additional therapeutic uses in the future.

**CMV Program**

**Maribavir**

On June 4, 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV in transplant recipients. The program will consist of two independent Phase 2 clinical studies that will include subjects at different ends of the spectrum of CMV infection or disease, namely those who have asymptomatic CMV, and those who have failed therapy with other anti-CMV agents. The first study, a randomized, dose blinded multicenter Phase 2 study intended to enroll up to 160 subjects (recipients of either hematopoietic stem cell or solid organ transplant) who have demonstrated CMV viremia but do not have CMV organ disease. The study is being conducted at multiple transplant centers in countries in Europe.

The second study, a randomized, dose blinded multicenter Phase 2 study intended to enroll up to 120 subjects (recipients of either hematopoietic stem cell or solid organ transplant) who have demonstrated CMV viremia with or without CMV organ disease. All subjects will have failed to have an adequate virologic response to prior treatment with ganciclovir, valganciclovir, or foscarnet, and may have documented viral genetic resistance to any of these anti-CMV agents. The study is being conducted at multiple transplant centers in the United States.

Maribavir was granted U.S. Orphan Drug Designation in May 2011 for treatment of clinically significant cytomegalovirus viremia and disease in at-risk patients. Maribavir, a member of a new class of drugs called benzimidazole ribosides, is a potent and selective, orally bioavailable antiviral drug with a unique mechanism of action against cytomegalovirus and a favorable clinical safety profile. Unlike currently available anti-CMV agents that inhibit CMV DNA polymerase, maribavir inhibits viral DNA assembly and inhibits egress of viral capsids from the nucleus of infected cells. Maribavir is active *in vitro* against strains of CMV that are resistant to commonly used anti-CMV drugs. The previous focus of clinical development of maribavir as an anti-CMV agent was on the prevention of CMV disease in transplant patients. Results from Phase 3 studies indicated that maribavir at a dose of 100mg BID failed to meet its efficacy endpoints; however, maribavir has demonstrated a favorable safety and tolerability profile in all clinical studies to date. While Phase 3 studies of CMV prophylaxis at the 100mg BID dose did not show sufficient activity to prevent CMV disease, the overall safety profile of maribavir and limited data from cases in which open-label maribavir was used as CMV treatment suggest that higher doses may provide clinical activity.

CMV is a member of the herpes virus group, which includes the viruses that cause chicken pox, mononucleosis, herpes labialis (cold sores), and herpes genitalis (genital herpes). Like other herpes viruses, CMV has the ability to remain dormant in the body for long periods of time. Human CMV infection rates average between 50 percent and 85 percent of adults in the U.S. by 40 years of age, but in healthy adults causes little to no apparent illness. However, in immunocompromised individuals including cancer patients, HIV patients, and transplant patients, and in children born with primary

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CMV infection, CMV can lead to serious disease or death. Patients who are immunosuppressed following hematopoietic stem cell (bone marrow) or solid organ transplantation are at high risk of CMV infection. In these patients, CMV can lead to severe conditions such as pneumonitis or hepatitis, or to complications such as acute or chronic rejection of a transplanted organ. While currently available systemic anti-CMV agents are effective against the virus, their use is limited by toxicities, most notably bone marrow suppression and renal impairment.

**CDAD Program**

**VP20621**

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 a non-toxigenic strain of *C. difficile* (VP20621) for the treatment and prevention of CDAD. Under the license agreement, we are required to make royalty payments to Dr. Gerding based on a low single digit percentage of our net sales of the product. If certain milestones are achieved, we will be obligated to pay Dr. Gerding additional milestone payments, if and when, certain regulatory developments are achieved, in an aggregate amount equal to \$850,000 in total, with no single milestone payment exceeding \$250,000. The license agreement will remain in effect for ten years from the date any product is first commercialized, on a country-by-country basis, unless earlier terminated. The agreement contains a standard early termination provision which provides for early termination by either party in the event certain conditions have occurred, including, but not limited to, either party's breach of the agreement, either party's filing for bankruptcy or either party making an assignment for the benefit of its creditors.

We plan to initially focus our efforts on the opportunity to prevent recurrence of CDAD, using oral administration of VP20621 spores. According to published literature, approximately 20 to 30 percent of patients suffering from CDAD will have at least one episode of relapse of disease. The goal of this VP20621 program is to prevent such recurrence of disease using a novel non-antibiotic approach. 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 CDAD. The treated patient could potentially then be dosed with oral VP20621 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 September 2010, we announced results of a completed Phase 1 study which was designed to determine the safety and tolerability of VP20621 dosed orally as single and repeat escalating doses in healthy young (18 to 45 years of age) and older (60 years of age and older) adults. After VP20621 was shown to be generally well tolerated following single and repeat doses in younger and older healthy subjects, we also performed repeat dosing in older adults following exposure to oral antibiotic. Subjects above 60 years of age were pre-dosed with oral vancomycin to disrupt their gastrointestinal flora and render them potentially susceptible to *C. difficile* colonization; these subjects were subsequently given either placebo or VP20621 doses of 10(4), 10(6), or 10(8) spores once daily for 14 days. The study demonstrated that VP20621 was generally well tolerated at all dose levels; there were no serious or severe adverse events, and no discontinuations from study drug due to adverse events. All 27 volunteers (100%) who were given VP20621 had positive non-toxigenic *C. difficile* stool cultures by day 6, suggesting that VP20621 rapidly colonizes the susceptible GI tract. No subject dosed with VP20621 tested positive for toxin-producing strains of *C. difficile* during the 28-day study period. By comparison, 5 of 9 subjects (56%) who received placebo (i.e. did not receive VP20621) tested positive for either toxin-negative or toxin-positive *C. difficile* during the study period. Based on these results, during the second half of 2011, we started a Phase 2 clinical trial for the prevention of recurrence of CDAD in patients recently treated with an antibiotic for CDAD. We closed enrollment of patients in December 2012 and anticipate having the complete data set in 2013.

[Table of Contents](#)**FA Program****VP20629**

On September 30, 2011, we entered into a license agreement with Intellect Neurosciences, Inc. (INS) for the worldwide rights to its clinical stage drug candidate, VP20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA).

Friedreich's Ataxia is a rare hereditary disease caused by a mutation in a gene which encodes frataxin, a protein essential for proper functioning of mitochondria, the energy pumps of the cell. In the absence of frataxin, iron in the cytoplasm builds up and causes free radical damage. The disease causes progressive damage to the nervous system, resulting in symptoms ranging from gait disturbance to speech problems; it can also lead to heart disease and diabetes. Ataxia in general refers to the inability to coordinate voluntary muscular movements. The ataxia of Friedreich's Ataxia results from the degeneration of nerve tissue in the spinal cord, in particular sensory neurons essential for directing muscle movement of the arms and legs. The spinal cord becomes thinner and nerve cells lose some of their myelin sheath. The primary sites of pathology are the spinal cord and peripheral nerves. Symptoms typically begin sometime between the ages of 5 and 15 years, but may occur in patients between the ages of 20 to 30. The disease usually presents with progressive staggering or stumbling and frequent falling. The symptoms are slow and progressive with a median age of death at 35 years old. FA is the most common form of hereditary ataxia, and is thought to affect about 1 in every 50,000 people or approximately 6,000 patients in the United States. Currently there are no FDA approved drugs for FA.

VP20629, or indole-3-propionic acid, is a naturally occurring, small molecule that has potent anti-oxidant properties that can protect against neurodegenerative disease. In a recent Phase 1 safety and tolerability study conducted in the Netherlands, VP20629 was demonstrated to be safe and well tolerated at all dose levels tested. We expect to initiate a single and repeat dose phase 1 study in patients in 2013 and expect to initiate a subsequent phase 2 study after completion of the phase 1 study. Following completion of the phase 2 study, a phase 3 study is planned.

**Business Development and Strategic Relationships**

We intend to continue to evaluate in-licensing or other opportunities to acquire development stage or marketed products. 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. 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. 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 product's potential.

[Table of Contents](#)*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 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.

Also, 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 Ceter) 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, Ceter and Ceter 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"). 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.

On December 6, 2012, we entered into a first amendment to ROW Agreement. The first amendment to the ROW Agreement (the "First Amendment") expands our territory to worldwide, with the exception of all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel, which remain the subject of the Restated US Agreement. The First Amendment also grants Sanquin the license to commercialize Cinryze in certain countries in which Sanquin has pre-existing marketing arrangements, including Belgium, Luxembourg, The Netherlands, Finland, Turkey, Indonesia, and Egypt (the "Sanquin Licensed Territories"). In the event that the marketing arrangements in the Sanquin Licensed Territories expire or are terminated, VP SPRL has a right of first refusal to include such country in its territory and/or to exclude such country

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from the countries covered by its license to Sanquin. As a result of the First Amendment, we have worldwide rights to commercialize C1-INH products other than in the Sanquin Licensed Territories. In connection with the First Amendment, we made a payment of \$1.3 million to Sanquin.

Additionally, under the First Amendment, Sanquin agreed to withdraw its Cetor and Cebitor product from certain markets in which it is currently being sold in order to transition to Cinryze and its future forms and formulations. The transition will be on a country by country basis and on a schedule agreed by VP SPRL and Sanquin to avoid supply interruptions to patients using Sanquin's Cetor and/or Cebitor products. The First Amendment also provides that in the countries in which Sanquin is licensed to commercialize VP SPRL C1-INH product, Sanquin shall have the right to liaise with regulators to set the reimbursement price, unless regulators require VP SPRL to do so.

We and Sanquin also agreed to certain provisions restricting the sale of competitive products relating to C1-INH without the other's consent. We may not directly or indirectly commercially exploit competitive products in our territory without Sanquin's consent. On a country by country basis, following the applicable transition date in each country, Sanquin agrees not to directly or indirectly commercially exploit competitive products to any person anywhere in the world. The First Amendment provides Sanquin with the right to sell and supply Cetor and/or Cebitor before the transition date and VP SPRL's C1-INH product thereafter to a named manufacturer provided that the named manufacturer uses the products solely in connection with the manufacturer's manufacture of certain plasma products under its own marketing authorization and corporate brand.

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 \$1.3 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

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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 Ceter or Ceter 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.

*Cinryze and Halozyme*

In May 2011, Halozyme granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. Under the terms of the license agreement, we paid Halozyme an initial upfront payment of \$9 million. In the fourth quarter of 2011, we made a milestone payment of \$3 million related to the initiation of a Phase 2 study begun in September 2011 to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. Pending successful completion of an additional series of clinical and regulatory milestones, anticipated to begin during 2012, we may make further milestone payments to Halozyme, which could reach up to an additional \$41 million related to HAE and up to \$30 million of additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyme until specified events have occurred. Upon regulatory approval, Halozyme will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

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*Meritage*

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). OBS is a proprietary formulation that is viscous and is designed to coat the esophagus with budesonide where it acts topically. Budesonide is an anti-inflammatory corticosteroid that is the active pharmaceutical ingredient in several products approved by the FDA, including products for the treatment of pediatric asthma, allergic rhinitis and Crohn's disease. The FDA has granted Orphan Drug Status designation to OBS for the treatment of eosinophilic esophagitis. In addition, OBS has pending patent applications, which may result in patent protection to approximately 2028. EoE occurs when eosinophils, a type of white blood cell involved in allergic reactions, infiltrate the surface of the esophagus. Eosinophil infiltration leads to inflammation of the esophagus and is believed to cause tissue remodeling and fibrosis if left untreated. There are no approved products for the treatment of EoE. There are approximately 160,000 patients diagnosed with EoE in the U.S.

We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. As consideration for the option, we paid an initial \$7.5 million. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

During the second quarter of 2012, Meritage completed the delivery of all the documents and notifications needed to satisfy the conditions of the First Option Milestone, as defined in the agreement. As a result of achieving this milestone we made a \$5.0 million milestone payment in the third quarter of 2012. We retain the option to provide Meritage up to an additional \$7.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS.

*Plenadren*

On November 15, 2011, we acquired a 100% ownership interest in DuoCort, a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency, or Addison's Disease (AD). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$37 million to \$132 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$25 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$108 million of the contingent payments are related to commercial milestones based on the success of the product. As part of the closing of this transaction, we also paid approximately SEK 9.3 million or \$1.4 million to certain of DuoCort's creditors. We incurred approximately \$1.4 million of transaction cost as part of this acquisition.

On September 30, 2011, we entered into an exclusive license agreement with Intellect Neurosciences, Inc. and Intellect USA, Inc. (together, INS) whereby INS grants us an exclusive license and an exclusive sublicense of its rights pursuant to a license agreement with New York University and South Alabama Medical Science Foundation for the worldwide rights to its clinical stage drug candidate, indole-3-propionic acid, also known as VP20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP20629

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for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales.

*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 indicated for the treatment of *C. difficile*-associated diarrhea (CDAD). Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus 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 were obligated to pay additional purchase price consideration based on annual net sales of Vancocin through 2011. In June 30, 2011, we satisfied our obligations to Lilly to make additional purchase price consideration payments under the purchase agreement. In aggregate we paid \$51.1 million to Lilly in additional purchase price consideration.

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.

*Vancocin Capsules and Genzyme*

On June 12, 2009, we entered into an Exclusive Clinical Study and Data License Agreement with Genzyme Corporation (Genzyme). Under the agreement, we exclusively licensed certain clinical studies that Genzyme has performed and/or sponsored relating to its proprietary product, tolevamer, including the data generated from the clinical studies. In consideration for exclusive rights to the clinical studies and data generated from such clinical studies, we agreed to pay Genzyme royalties of 10%, 10% and 16% on the net sales of Vancocin (vancomycin hydrochloride capsules, USP) for the three year period following approval of a supplemental new drug application to update Vancocin's label based on the data licensed from Genzyme. We will pay lower royalties on sales of any authorized generic depending on the number of parties selling a generic vancomycin product. The agreement continues in effect unless terminated earlier pursuant to its terms. In addition to standard termination rights, we also may terminate the agreement at any time after the expiration of the royalty term. The royalty term commenced on December 15, 2011, the day following approval by FDA of the sNDA, and will continue until December 15, 2014, the third anniversary.

*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,

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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.

### **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.

We expect to continue to rely solely on third-party manufacturers to manufacture drug substance and final drug products for both clinical development and commercial sale. However, there are numerous factors that could cause interruptions in the supply of our products, including regulatory reviews; changes in our sources for manufacturing; disputes with a manufacturer; or financial instability of manufacturers, which could negatively impact our operation.

#### *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 \$9.9 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 \$6.6 million) loan facility provided by us. The €5,000,000 loan facility was satisfied during 2011 and we anticipate that Sanquin will repay the remaining loan amount during 2013 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.

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*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 of 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, the EMA 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 have an option 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 (DCI) 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 approximately \$37 million. Beginning in 2014, the annual purchase commitment will range between approximately \$33 million and \$37 million, subject to annual adjustments to the purchase price based on market conditions. 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 \$175 million.

The amended agreement expires December 31, 2017, 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.

In February 2010, we amended the agreement to fix the pricing of product for 2011. Beginning in 2012, the annual price adjustment shall depend on market conditions and increases or decreases shall

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be limited to the maximum percentage per year. In May 2012, we amended the agreement to extend the term to December 31, 2017 and to extend the payment terms. In October 2012 we amended the agreement to increase the base purchase price per liter of plasma, increase the minimum purchase requirements, adjust the base price in the event certain testing is performed by certain third parties, and modified the price adjustment terms for future periods. In addition, the October 2012 amendment allows DCI to use an additional testing laboratory.

*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.

In February 2012, we amended the Supply Agreement to terminate as of December 31, 2012, which represents a two year reduction in the term of the Supply Agreement. The amendment also set forth volume ranges and prices for the 2012 calendar year for the Intermediates. Prior to the amendment, we sold all excess output of the Intermediates to Biotest. In addition, the amendment terminated our right of first refusal, subject to certain exceptions, to repurchase certain byproducts derived from the Intermediates. We also agreed to swap certain quantities of plasma with Biotest during 2012.

*Strategic Supply Agreement with Biotest Pharmaceuticals Corporation*

In February 2010, we entered into a Strategic Supply Agreement (the "2010 Agreement") with Biotest Pharmaceuticals Corporation (BPC) pursuant to which we will purchase certain quantities of plasma. Our contractual purchase commitments are subject to annual percentage increases based on changes in the consumer price index and is subject to other market conditions. BPC has built three additional plasma centers (the "Initial Centers"). The Initial Centers are open and fully licensed by the FDA and the EMA. The 2010 Agreement was terminated in September 2012.

In September 2012, we entered into the 2012 Strategic Supply Agreement (the "2012 Agreement") with BPC pursuant to which we will purchase certain quantities of U.S. source plasma. In addition to the Initial Centers, BPC will construct and operate four additional plasma collection centers, instead of the two additional plasma collections centers set forth in the 2010 Agreement. The 2012 Agreement expires on December 31, 2017.

The purchase commitment for 2012 was approximately \$11 million, which includes purchases made during 2012 under the 2010 Agreement, and the purchase commitment for 2013 is approximately \$27 million, subject to purchase price discounts, annual adjustments to the purchase price based on market conditions and changes in the consumer price index. Beginning in 2014, the annual purchase commitment will range between approximately \$40 million and \$44 million, subject to purchase price discounts, annual adjustments to the purchase price based on market conditions and changes in the consumer price index. We estimate our remaining commitment under the 2012 Agreement to be

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approximately \$217 million. If we require plasma in addition to the plasma provided under the 2012 Agreement plus a specified amount, then BPC will have a right of first refusal to supply the additional plasma.

Over the course of the three years after the effective date of the 2012 Agreement, BPC has committed to open four additional new plasma collection centers in the United States (the "New Centers") and we will have the right to acquire the Initial Centers and the New Centers subject to the terms of the 2012 Agreement. We will provide BPC with funding, a portion of which is non-refundable, to develop and open the New Centers, pursuant to the terms of the 2012 Agreement.

*ROW Agreement with Sanquin*

As described above, we entered into the ROW Agreement with Sanquin on January 8, 2010. Under the terms of the ROW Agreement, 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.

*Vancocin*

In December 2005, we entered into a toll manufacturing agreement with Norwich Pharmaceuticals, Inc. (NPI) (formerly OSG Norwich Pharmaceuticals, Inc.) to produce finished Vancocin product. The qualification process required to transfer Vancocin manufacturing from Lilly to NPI 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. In April 2011, we amended the agreement to extend the term to August 31, 2016. The amendment fixed the pricing of product for the remainder of 2011 and the full year 2012.

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 from which we began to acquire API during 2010. In January 2011, we extended our agreement with Xellia Pharmaceuticals, Inc. (formerly Alpharma Inc.) through December 2015.

In November 2007, we entered into a Distribution and Supply Agreement with Prasco, LLC (Prasco) granting to Prasco a license under our New Drug Application (NDA) for Vancocin (vancomycin hydrochloride capsules, USP) to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. We delivered the commencement notice to Prasco on April 10, 2012. In consideration for the license to distribute vancomycin hydrochloride capsules as an authorized generic, Prasco will pay us (i) a supply price for each carton of vancomycin hydrochloride capsules and (ii) a specified percentage of the net distributable profits. The supply price and the percentage of the net distributable profits will vary depending on the number of additional generic versions of vancomycin hydrochloride capsules that are available. The agreement continues in effect for an initial term of five (5) years from the date of the commencement notice (or April 9, 2017) unless terminated earlier pursuant to its terms.

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 candidate

**Customers**

We have principally sold our products directly to wholesale drug distributors and specialty pharmacies/specialty distributors in the United States who then distribute the product to pharmacies,

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hospitals, patients, physicians and long-term care facilities, among others. In the fourth quarter of 2011, we began to sell product to drug distributors in Europe who then distribute the product to pharmacies, hospitals, and physicians.

Net product sales to customers who accounted for 10% or more of our net product sales during the years ended December 31, 2012, 2011 and 2010 are as follows:

	Percentage of total revenues		
	2012	2011	2010
Customer A	43%	27%	25%
Customer B	25%	24%	24%
Customer C	11%	20%	21%
Customer D	—	17%	16%
Customer E	—	—	10%
Total	79%	88%	96%

In 2012, three customers represented approximately 79% of our total net product sales. We do not believe that the loss of any one of these customers would have a material adverse effect on product sales because product sales would shift to other customers or alternative forms of distribution. However, the loss of a customer could increase our dependence on a reduced number of customers.

### Marketing and Sales

Our U.S. Cinryze sales force targets 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, gastroenterologists and home healthcare providers.

In 2010, we established a sales organization in Europe, initially focusing on Germany and the UK. The aim of this effort was to target key healthcare professionals in preparation for the launches of Cinryze and Buccolam. During 2011 and 2012 the sales teams expanded to cover both new European geographies, to meet the specific needs of Cinryze and Buccolam customers and to support the commercial launch of Plenadren. Today the primary focus of our sales teams is allergists, immunologists, neurology, pediatricians and endocrinologists. We also support a wider group of healthcare professional to deliver care at home and training support for patients, parents and care givers.

### Foreign Operations

We conduct business in several European countries as well as Australia, Bermuda and Canada 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 Australia, Belgium, Bermuda, Canada, France, Italy, Germany, Puerto Rico, Spain, Sweden, Switzerland and the United Kingdom. We have begun to expand our own commercial organizations in such territories in order to market and sell Cinryze, Buccolam and Plenadren through our own sales force in these territories. 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.

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**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. There are no core patents protecting Cinryze. There are no core patents protecting Buccolam. We own, through a subsidiary, 3 non-U.S. issued patents and 4 pending U.S. patent applications covering technology related to glucocorticoid therapy. We have three pending U.S. patent applications covering benzimidazole related technology. We also file international, regional and non-U.S. national patent applications as appropriate in order to pursue patent protection in major foreign countries. The last core patent protecting Vancocin expired in 1996. We own one issued U.S. patent covering vancomycin related technology.

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

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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.

#### **U.S. 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, and in the case of biological products the Public Health Service Act, each 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

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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, and in the case of a biological product also purity and potency, 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 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 with accompanying labeling 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 or commercially viable 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 for 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. Some studies also use a special committee often referred to as a data safety monitoring board to review data from the study as it progresses and determine whether it is appropriate for the study to continue.

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. 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, restrict the approved conditions of use in the product labeling, or impose other limitations or requirements such as in a Risk Evaluation and Mitigation Strategy (REMS) requirement. The limitations on approval can include restricted access to the product and potential registries in the US and to a greater extent in Europe. In addition, all new products are subject to requirements to assess pediatric safety and effectiveness, unless a waiver or deferral is obtained. The FDA 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 uses approved in the NDA or BLA.

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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, other reporting requirements and restrictions on advertising and promotional activities. In addition to continued compliance with standard regulatory requirements, the FDA also may require post-marketing testing and surveillance to monitor the safety and efficacy of the marketed product. Results of post-marketing studies may limit or expand the further marketing of the products. If we propose any modifications to a product, including changes in indication, formulation, 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 or limited if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product are discovered following approval.

An abbreviated approval process is currently available under the Federal Food, Drug and Cosmetic Act (FDCA) for generic versions of conventional chemical drug products, sometimes referred to as small molecule drugs. The applicant for a generic version of a small molecule drug must refer to an approved drug for which full clinical data demonstrating safety and effectiveness were submitted (the "reference drug"). Generally, the generic applicant must show that its product has the same active ingredient or ingredients, dosage form, strength, route of administration, and labeling as the reference drug, and is absorbed in the body at the same rate and to the same extent as the referenced drug. It is possible to obtain permission to deviate from some of these requirements. A generic applicant must seek approval for conditions of use for which FDA approved the reference drug, it must include certifications to patents listed with FDA for the reference drug, and it must wait for the expiry of any applicable non-patent exclusivity in order to receive final approval, unless the exclusivity is associated with a condition of use that the generic applicant is permitted to omit for its product. A generic applicant must also manufacture its product in accordance with current good manufacturing practices and other product quality standards. FDA also permits abbreviated applications that cite to reference drugs and propose new conditions of use or other changes that require clinical data. For these applications, FDA may require substantially less data and information than it requires for reference drugs. These abbreviated approval processes could have a material impact on our business as generic products that compete with our products may be significantly less costly to bring to market and may be priced significantly lower than our products.

An abbreviated approval process is also available under the Public Health Service Act (PHSA) for biosimilar versions of biologics licensed under full BLAs ("reference biologics"). A biosimilar applicant generally must submit analytical, animal, and clinical data showing that the proposed product is "highly similar" to the reference product and has no "clinically meaningful differences" from the reference product in terms of the safety, purity, and potency, although FDA may waive some or all of these requirements. The proposed product also must have the same route of administration, dosage form, strength, and mechanism(s) of action (if known) as the reference biologic, and the application must seek approval for a condition of use for which FDA already approved the reference biologic. FDA cannot license a biosimilar until 12 years after it first licensed the reference biologic. After expiry of the applicable exclusivity, our biologics may face direct competition from licensed biosimilar products. Biosimilar manufacturers may price these products at material discounts to our products. Therefore, this competition could have a negative effect on sales and gross profits for our product, and on our overall profitability and financial condition.

In addition to obtaining FDA approval for each indication for which we plan to market 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.

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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.

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) established outpatient prescription drug coverage to eligible Medicare beneficiaries under Medicare Part D. Medicare Part D coverage began in January 2006. The Part D prescription drug benefit is administered regionally through Medicare-approved insurance plans. The MMA also 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 of the MMA and/or amendments to the MMA could 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.

In March 2010, the Patient Protection and Affordable Care Act (PPACA) was signed into law and was subsequently amended by the Health Care and Education Reconciliation Act of 2010. The PPACA, as amended, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, will affect us. These include new restrictions on private insurance companies that prohibit coverage denials because of a pre-existing condition; prohibit the application of annual and lifetime benefits limits on health insurance policies; and prohibit coverage rescissions (except for fraud) and health-based insurance rating. In addition, the PPACA, as amended, funds an interim high risk pool

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that states can draw on. Following the expiration of this high risk pool funding, the PPACA provides for the creation of state-run "exchanges" that will allow people without employer-provided coverage, or who cannot afford their employer's plan, to buy health insurance. The PPACA will also provide federal subsidies to those who cannot afford premiums. Collectively, these factors may increase the availability of insurance reimbursement to patients seeking the products that ViroPharma commercializes. However, PPACA's amendments to the Social Security Act will likely increase certain of our costs. For example, PPACA increased the Medicaid rebate rate on branded prescription drugs from 15.1% to 23.1%, and manufacturers must now pay rebates on drugs dispensed to beneficiaries in Medicaid managed care organizations. The PPACA also imposed a manufacturer's fee based on the sale of branded Pharmaceuticals (excluding orphan drugs) to specified government programs, expanded the 340B drug discount program (excluding orphan drugs), and required manufacturers to fund a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "doughnut hole". The PPACA has and will continue to affect our business, and we will also continue to monitor the trends and changes that may be encouraged by the legislation that may potentially impact on our business over time.

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 under the Veterans Health Care Act ("VHCA"). 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), through a program also created by the VHCA. As a part of our VHCA obligations, we are required to enter into several agreements with the Government, including a Federal Supply Schedule contract with the VA which imposes certain compliance requirements of the Federal Acquisition Regulations ("FAR") and agency procurement regulations.

In connection with several of these government programs, we are required to report prices to various government agencies. Pricing calculations vary among programs. The calculations are complex and are often subject to interpretation by the reporting entities, government agencies and the courts. Our methodologies for calculating these prices could be challenged under false claims laws or other laws. We could make a mistake in calculating reported prices and required discounts, which could result in retroactive liability to government agencies. Government agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. If we make these mistakes or if governmental agencies make these changes, we could face, in addition to prosecution under federal and state false claims laws, substantial liability and civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines or imprisonment, or prosecutors may impose a Corporate Integrity Agreement, Deferred Prosecution Agreement, or similar arrangement.

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 willfully 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

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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 companies to adopt compliance programs; banning gifts to healthcare providers; and requiring companies to report of gifts, certain payments, and other value given to healthcare providers. Under the PPACA and forthcoming regulations, pharmaceutical manufacturers will be required to report payments or other transfers of value made to healthcare providers during the preceding calendar year. These reports will be available on a public database. Similarly, pharmaceutical manufacturers will be required to report samples of prescription drugs requested by and distributed to healthcare providers during the preceding calendar year. The PPACA does not state whether the sample reports will be made publicly available. 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.

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. 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.

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

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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.

### 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 regional and 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, and is required for certain categories of products including biological products. 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) for a new medicinal product in the EU, a company must obtain approval of a Paediatric Investigation Plan (PIP) from the EMA. 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 can be updated as new information is obtained. The incentives for completing the PIP include 6 months extension of the term of the supplementary protection certificate (the European patent term extension) and, for orphan medicinal products, an additional 2 years orphan exclusivity. In October 2009 a PIP was approved for Cinryze (C1 inhibitor deficiency). The PIP has not yet been completed.

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 European Commission. In addition, the Commission must reconfirm the orphan designation in connection with the approval of an MAA.

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

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direct or indirect controls on the profitability of the company placing the medicinal product on the market. After having received regulatory approval of Cinryze in the EU, we engaged 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 and *C. difficile*. 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.

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. Additionally, in August 2011, the FDA approved a self-administered icatibant for treatment of acute attacks of HAE in adults 18 years of age and older.

In the fourth quarter of 2009 the FDA 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. In January 2012, the FDA approved a label expansion for self-administration of Berinert. As part of the label expansion, Berinert is now also indicated to treat life-threatening laryngeal HAE attacks, as well as facial and abdominal attacks. In addition, CSL Behring has stated that they are developing a subcutaneous version of their C1 inhibitor for treatment of HAE attacks and that they plan to commence clinical efficacy trials in the second half of 2013.

In August 2011, the FDA granted Shire plc a marketing approval for FIRAZYR® (icatibant injection) for the self-administered treatment of acute attacks of HAE in adults 18 years of age and older.

In the fourth quarter of 2009, Dyax received FDA approval for their product candidate for the acute treatment of HAE.

In Europe, the EMA granted Cinryze MAA centralized approval in 2011 for prevention of HAE attacks, treatment of acute HAE attacks, pre-procedural prevention and self administration. Cinryze in Europe currently has no regulatory or patent exclusivity. In the EU, CSL Behring's product Berinert has been approved for nearly three decades as an acute treatment therapy for HAE through a decentralized route with Germany the reference member state. Also available on the EU market is

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Shire's Firazyr. Recently Pharming has achieved approval for their C1 INH recombinant product Rhucin.

## AI

In October 2011, we acquired the rights to Plenadren® (hydrocortisone, modified release tablet), an EU approved orphan drug for treatment of adrenal insufficiency (AI) in adults.

Plenadren is a dual release hydrocortisone replacement therapy designed to better mimic the normal physiological cortisol profile in order to improve outcomes for patients suffering from adrenal insufficiency. Plenadren is given as an oral tablet once daily. It has an outer layer releasing hydrocortisone immediately and an inner core releasing the rest of the drug more slowly during the day.

AI is an orphan disorder that is caused by a dysfunction of the adrenal gland resulting in low levels of the corticoid hormone cortisol, which follows a circadian rhythm and regulates many critical body functions. Primary AI is referred to as Addison's disease and affects up to 15 in every 100,000 people worldwide. The most common symptoms of Addison's disease include fatigue, lightheadedness, muscle weakness, fever, weight loss, difficulty standing, anxiety, GI involvement and personality changes. Addison's disease also can be deadly. The lack of cortisol carries an invariably fatal outcome if patients receive no replacement therapy. Mortality is precipitated by "traumatic events" such as infections, accidents, surgery, etc in what is called "adrenal crisis". Such crisis still occurs in 10% of the patients annually underlining the severity of the condition and the need for optimal cortisol replacement therapy. These crisis are medical emergencies and demand urgent supplementation of the cortisol replacement therapy, usually through an intramuscular injection of hydrocortisol. To maintain a reasonable quality of life, these patients rely on daily cortisol replacement therapy. Because it is a chronic condition, these patients require this therapy throughout their entire lives.

Glucocorticoid hormone replacement therapy for adrenal insufficiency has been available for decades. However, studies have recorded complications and comorbidities including premature death, impaired quality of life, increased risk of cardiovascular diseases, and decreased bone mineral density in treated patients, most likely because it is difficult to match the natural secretion pattern of cortisol. We also are aware of at least one other program sponsored by Diurnal Pharma, a company based on the UK, that reported early stage clinical testing of a modified release hydrocortisone formulation for the treatment of adrenal insufficiency

## Buccolam

Buccolam is oromucosal midazolam provided in an individual dose formulation for buccal delivery. It is provided as a convenient, portable, ready to use, pre-filled oral syringe containing an age-specific dose. Buccolam is approved throughout the European Union and the EEA for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from three months to less than 18 years of age. Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

The licensing and availability of Buccolam follows its recent central approval in the European Union through the Pediatric Use Marketing Authorization (PUMA) in 2011. Buccolam is the first product approved using a PUMA, which is a type of centralized marketing authorization procedure requested for medicines already authorized but no longer covered by intellectual property rights and exclusively developed for use in children.

In most European markets the key competitors for Buccolam are typically either available generically, such as intra rectal diazepam, or are used off label.

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There are a number of potential future competitors in the same or similar medical areas. Namely, the following are in Phase 3 trials in the U.S.: Intranasal midazolam (USL261 (ITI-111)) under development by Upsher-Smith Laboratories; intramuscular diazepam (Vanquix) being developed by Pfizer; and, intramuscular midazolam from the University of Michigan. Also, DZNS nasal spray midazolam being developed by Acorda is in Phase 2 in the U.S.

Additionally, there are other potential products in early stage clinical development such as NRL-01 nasal diazepam developed by Neurelis and a unit dosed nasal spray midazolam developed by Medir

*Clostridium Difficile*-Associated Diarrhea (CDAD)

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"), and that meet certain other conditions, 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.

On April 9, 2012, the FDA denied the citizen petition we filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of generic versions of Vancocin (vancomycin hydrochloride, USP) capsules. The FDA also informed us in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin which was approved on December 14, 2011 would not qualify for three additional years of exclusivity, as the agency interpreted Section 505(v) of the FD&C Act to require a showing of a significant new use (such as a new indication) for an old antibiotic such as Vancocin in order for such old antibiotic to be eligible for a grant of exclusivity. FDA also indicated that it approved three abbreviated new drug applications (ANDAs) for generic vancomycin capsules and the companies holding these ANDA approvals indicated that they began shipping generic vancomycin hydrochloride, USP. In June 2012, the FDA approved a fourth ANDA for generic vancomycin capsules.

We granted a third party a license under our NDA for Vancocin® (vancomycin hydrochloride capsules, USP) to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. As noted above, there are four other generic drug companies selling vancomycin hydrochloride capsules.

In May 2011, FDA approved Optimer Pharmaceuticals' product, Difcid® (fidaxomicin), for the treatment of CDAD. Additionally, several other companies, including, Merck & Co., Sanofi-Aventis 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.

Metronidazole, a generic product, is regularly prescribed to treat CDAD and products which are currently marketed for other indications by other companies may also be prescribed to treat this indication.

**Employees**

As of December 31, 2012, we had 410 employees, of which, 265 were employed in the United States, 139 were located in Europe and 6 were located in other countries. 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;

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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	49	President, Chief Executive Officer and Chairman of the Board of Directors
Charles A. Rowland, Jr.	54	Vice President, Chief Financial Officer
Colin Broom, M.D.	57	Vice President, Chief Scientific Officer
Thomas F. Doyle	52	Vice President, Strategic Initiatives
Daniel B. Soland	54	Vice President, Chief Operating Officer
Robert G. Pietrusko	64	Vice President, Regulatory Affairs and Quality
J. Peter Wolf	43	Vice President, General Counsel and Secretary
Robert C. Fletcher	50	Vice President, Business Development and Project Management
John J. Kirby	41	Vice President, 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 has served on the board of directors of Vanda Pharmaceuticals Inc. since April 2010 and 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

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

J. Peter Wolf has served as Vice President, General Counsel, and Secretary since January 2008. Mr. Wolf previously served as Associate General Counsel of ViroPharma since 2004. From 1995 to 2004 Mr. Wolf was a corporate attorney at 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.

Robert C. Fletcher has served as Vice President, Business Development and Project Management since January 2005. Mr. Fletcher joined ViroPharma in 2001 as a project leader, and has since held roles of increasing responsibility during his tenure in the areas of business development and project management. Prior to joining ViroPharma, Mr. Fletcher held multiple roles of escalating responsibility at SmithKline Beecham Pharmaceuticals/GlaxoSmithKline, Becton-Dickinson and Company, Zynaxis Inc./Intracell Corporation, and Centocor Corporation. He holds both a master of science degree and a bachelor of arts degree in biology from Wake Forest University.

John J. Kirby, CPA has served as Vice President and Chief Accounting Officer since joining the company in August 2012. From 2010 to 2012 Mr. Kirby held positions of increasing responsibility with AstraZeneca Pharmaceuticals, most recently as the Regional Audit Director—Americas. Prior to that, Mr. Kirby worked for KPMG LLP for fourteen years where he held positions of increasing responsibility, most recently as Senior Manager. Mr. Kirby received his bachelor of science degree in accounting from Villanova University and is a certified public accountant.

**Available Information**

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

[Table of Contents](#)**PART II—OTHER INFORMATION****ITEM 1A. Risk Factors**

**If we are unable to continue to successfully commercialize Cinryze in the United States, or are delayed in our efforts to commercialize Cinryze in Europe and additional territories, 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. In June 2011, the European Commission granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. 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;
- manufacturing or supply interruptions which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product;
- continued 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;
- acceptance and utilization of competitive products;
- patients' ability to obtain sufficient coverage or reimbursement by third-party payors in the United States and our ability to receive sufficient reimbursement and price approvals that are separately required in each country in Europe;
- sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze; and,
- our ability to receive regulatory approvals to market Cinryze in territories outside the United States and Europe in the timeframes we anticipate.

Sales of Cinryze represented approximately 46 and 77 percent of our revenue in 2011 and 2012 respectively, and we expect Cinryze will continue to account for an increasing percentage of our future revenues as Vancocin sales continue to decrease. If we are not able to continue to successfully commercialize Cinryze in the United States and Europe, or are significantly delayed or limited in doing so, we could fail to achieve our estimates for peak year sales for Cinryze, and our business, financial condition, results of operations and liquidity could be materially impacted.

**If our efforts to commercialize Buccolam or Plenadren in Europe are delayed or are not as successful as we anticipate, our business will be materially harmed.**

In September of 2011, the European Commission granted a centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. Additionally, in November 2011, we acquired rights to Plenadren, which had recently received European Marketing Authorization and was commercially launched in several European countries in late 2012. The

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commercial success of Buccolam and Plenadren in the EU will depend on several factors, including the following:

- the number of patients that may be treated with Buccolam and Plenadren;
- acceptance by physicians and patients of Buccolam and Plenadren as a safe and effective treatment;
- our ability to effectively market and distribute Buccolam and Plenadren in Europe;
- cost effectiveness of treatment of epilepsy or other prolonged, acute, convulsive seizures using Buccolam and adrenal insufficiency with Plenadren;
- relative convenience and ease of administration of Buccolam and Plenadren;
- potential advantages of Buccolam and Plenadren over alternative treatments;
- the timing of the approval of competitive products;
- the timing and levels of pricing approvals that are separately required in each country in Europe; and
- manufacturing or supply interruptions, including delays in the scale-up of the manufacturing process, which could impair our ability to acquire an adequate supply of Buccolam or Plenadren to meet demand for the products including, without limitation, sufficient supply and reasonable pricing of raw materials necessary to manufacture Buccolam or Plenadren.

If we are not able to continue to successfully commercialize Buccolam and Plenadren in Europe, or are significantly delayed or limited in doing so, we could fail to achieve our estimates for peak year sales for Buccolam and Plenadren and our financial condition, results of operations and liquidity could 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 United States while the Hereditary Angioedema Association estimates there are 6,500 patients in the United States. 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 United States, Europe or other countries may turn out to be lower than expected or such patients may not be amenable to treatment with Cinryze as not all HAE patients are appropriately treated through routine prophylaxis. 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.

**We do not have patent protection for the composition of Cinryze, Buccolam or Plenadren and we rely on regulatory exclusivity in Europe.**

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 in the United States 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

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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, in the first quarter of 2011, we withdrew our orphan designation in Europe and no longer maintain regulatory exclusivity for Cinryze in Europe. We currently do not have any issued patents for Plenadren in Europe or the United States but have received an orphan drug designation for Plenadren in the EU, Switzerland and the U.S. and have received orphan exclusivity in the EU. In order to receive orphan exclusivity in the United States the FDA has requested that we demonstrate that Plenadren provides a significant measure of safety over existing therapies.

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 United States 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 to us of the existing statute will remain in effect. We cannot predict when generic competition for Cinryze may arise, if at all, in Europe.

We have received a pediatric-use marketing authorization (PUMA) for Buccolam in Europe. The PUMA is a new type of marketing authorization which may be requested for a medicine which is already authorized, but no longer covered by intellectual property rights, and which will be exclusively developed for use in children. A PUMA provides 10 years of market protection as a reward for the development in children. As the PUMA for Buccolam was the first such approval to be granted, the EMA and EC may interpret the legislation in ways which restrict the duration or scope of the market exclusivity of a PUMA and, thus, we cannot be sure that the benefits to us of the existing statute will remain in effect.

**We do not know whether Cinryze will continue to be competitive in the markets which it serves.**

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 United States, CSL Behring, Shire and Dyax had products approved for the treatment of acute attacks of HAE, and steroid based products are currently used for prophylaxis of HAE. In addition, Pharming NV is currently developing products for the acute treatment of HAE. Approval of new products, or the expanded use of currently available products, to prophylax or treat HAE, could materially and adversely affect our sales of Cinryze in the United States. In addition, there are currently several products approved for the acute treatment of HAE in Europe, including CSL Behring's product Berinert which has been approved for nearly three decades as an acute treatment therapy for HAE. There can be no assurance that physicians in Europe will change their historic practice of treating patients having attacks of HAE to adopt prophylaxis against HAE. In the United States, competition from other C1-Esterase Inhibitors for prophylaxis may arise following the expiry of orphan drug market exclusivity in October 2015.

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

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

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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 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 markets their product in the United States. 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.

We also rely on a single supplier of the active pharmaceutical ingredient (API) of Vancocin, Buccolam and Plenadren and also rely on a single manufacturer of finished Vancocin capsules, Buccolam pre-filled syringes and Plenadren capsules. Our third party API suppliers and finished product suppliers are the only manufacturers qualified by the FDA to manufacture API and finished products for distribution and sale in the United States and Europe for each of these products. We are therefore dependent upon these suppliers and attempt to maintain inventory levels to meet our current projections, plus a reasonable stock in excess of those projections. In addition, we have loaned the manufacturer of finished Buccolam pre-filled syringes approximately \$10 million for the purchase of equipment and to support the scale up of their operations. In the event our commercial launch of Buccolam is not as successful as we expect, we may not recover the full amount of the loaned funds and we may also incur an impairment of our intangible assets.

There are numerous factors that could cause interruptions in the supply of our products, including regulatory reviews; changes in our sources for manufacturing; disputes with a manufacturer; or financial instability of manufacturers. 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. Supply interruptions may occur, and our inventory may not always be adequate. This in turn could cause a loss of our market share and negatively affect our revenues. Additionally, in the event one of our sole source suppliers of API were to cease operations the resulting reductions in forecasted revenue or operating results could result in an impairment charge of intangible assets related to the product involved. We maintain limited property insurance which would only protect us from physical damage to our assets caused by certain types of occurrences to the extent of the value of the property damaged and would not cover lost revenue.

**We currently depend, and will in the future continue to depend, on third parties to manufacture raw, intermediate and finished goods for Cinryze, Buccolam, Plenadren, Vancocin 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

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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 contractors must have additional technical skills and take multiple steps to attempt to control the manufacturing processes.

Problems with these manufacturing processes such as equipment malfunctions, maintenance requirements, facility contamination, labor shortages or other labor problems, raw material shortages, variability in batch yields, 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 which could result in our inability to supply product to patients, create opportunities for our competitors and reduce our revenues. In addition, the financial instability of any of our suppliers could result in their inability to meet their contractual obligations to us.

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, the EMA 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, suppliers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our products and product candidates may be delayed. For example, in addition to FDA, Sanquin is also subject to the requirements of the European health authorities which may impose on Sanquin obligations relating to facility maintenance and/or equipment modifications that could cause delays in Cinryze production.

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.

In connection with several inspections of two facilities maintained by Sanquin, our contract manufacturer for Cinryze, FDA issued notices of observations on FDA Form 483 for each site. Responses to the observations on 483 have been provided to the FDA, however, several of the responses remain the subject of continuing corrective and preventive action procedures. Biologics such as Cinryze require processing steps that are more complex than those required for most chemical pharmaceuticals and FDA may determine that we have not satisfied their requirements for these continuing corrective and preventive action procedures. 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, create opportunities for our competitors and reduce our revenues.

The number of patients enrolling into our treatment support service for patients with HAE and their healthcare providers, CinryzeSolutions, has periodically exceeded our expectations. For example, in 2010 we temporarily limited the rate at which additional patients were started on drug to ensure that those already receiving commercial product continue with a supply of Cinryze until capacity increases. During the fourth quarter of 2011 and first quarter of 2012, we reduced the amount of Cinryze inventory held by our distributors and by patients. If our manufacturing capacity expansion projects at Sanquin do not result in the capacity we anticipate, or if we experience batch failures, or variability in batch yields, or encounter facility shut downs as a results of maintenance or other causes, we may not

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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.

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, EMA or other applicable 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.

**Our subcutaneous Cinryze development program is dependent upon Halozyme's proprietary rHuPH20 enzyme which is an important component of our current development program, and any failure to supply rHuPH20 or regulatory concerns about rHuPH20 could delay the development and commercialization efforts for our subcutaneous Cinryze development program.**

Halozyme is responsible for providing its proprietary rHuPH20 enzyme which is an important component of our current development program for subcutaneous administration of Cinryze. If Halozyme, or any applicable third party service provider of Halozyme, encounters difficulties in the manufacture, storage, delivery, fill, finish or packaging of either components of rHuPH20, such difficulties could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of subcutaneous Cinryze; and/or (ii) delay or prevent the effective commercialization of subcutaneous Cinryze. Such delays could have a material adverse effect on our business and financial condition. Additionally, Halozyme has partnered rHuPH20 with other companies that are developing combination products for other indications. In the event the FDA or other foreign regulatory agencies refuse or delay approval of product candidates which include rHuPH20 for reasons related to the safety or efficacy of rHuPH20, we may be required to collect additional clinical or animal safety data or to conduct additional clinical or animal safety studies which may cause lengthy delays to, and increase costs for our subcutaneous Cinryze development program. For example, in August 2012 Baxter International Inc. announced that the Center for Biologics Evaluation and Research (CBER) of the FDA had issued a complete response letter for Baxter's HyQ Biologics License Application which includes rHuPH20 for subcutaneous administration in patients with primary immunodeficiency disease. The letter requested additional preclinical data to support the BLA as a result of potential safety concerns. Pending the provision of additional preclinical data sufficient to address the regulatory questions, CBER notified us that studies of the combination of Cinryze and rHuPH20 were being placed on temporary clinical hold. On September 21, 2012, we announced that the FDA provided guidance enabling us to resume clinical studies of the subcutaneous administration of Cinryze in combination with rHuPH20. The FDA has advised us to amend the study protocol, allowing for increased laboratory sampling to monitor rHuPH20 antibody levels, and keep the FDA informed of elevated antibody levels during the treatment phase of the study. There can be no assurance that the issues identified by CBER related to the use of rHuPH20 will not arise at a future time.

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**The distribution of our commercial products in the U.S. 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 and Cinryze from two warehouses located in the central United States and western United States. 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.

Additionally, we do not require collateral from our distribution partners 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 2012 we experienced from any one distribution partner was approximately \$39.7 million and we anticipate that this amount could increase if our net product 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 results of operations.

We have entered into agreements with two specialty distributors / specialty pharmacies that distribute Cinryze to physicians, hospitals, pharmacies, home health providers and patients.

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 in the United States 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.

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Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford. We 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 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 established the CinryzeSolutions™ program, a treatment support service for patients with HAE and their healthcare providers. CinryzeSolutions personnel provide education about HAE and Cinryze and help facilitate solutions for reimbursement, coverage and access. Although case managers assist patients and healthcare providers in locating and accessing Cinryze, we cannot guarantee a sufficient level of coverage, reimbursement or financial assistance.

**If we are unable to obtain reimbursement for our products from European government health administration authorities our products may be too costly for regular use and our ability to generate revenues would be harmed.**

In European countries where we sell or are seeking or may seek to commercialize Cinryze, Buccolam and Plenadren, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control. We may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. 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, and we cannot guarantee that we will have the capabilities or resources to successfully conclude the necessary processes and commercialize Cinryze, Buccolam and Plenadren in every or even most countries in which we seek to sell these products. Reimbursement sources are different in each country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. For example, countries in the European Union may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may from time to time approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the volume of product sold in that country or the profitability of the company placing the medicinal product on the market. Some countries have or may seek to impose limits on the aggregate reimbursement for Cinryze, Buccolam or Plenadren or for the use of Cinryze, Buccolam or Plenadren for certain indications. In such cases, our commercial operations in such countries and our results of operations and our business are and may be adversely affected. Our results of operations may suffer if we are unable to successfully and timely conclude reimbursement, price approval or funding processes and market Cinryze, Buccolam or Plenadren in such foreign countries or if coverage and reimbursement for Cinryze, Buccolam or Plenadren is limited or reduced. If we are not able to obtain coverage, pricing or reimbursement on terms acceptable to us or at all, or if such terms should change in any foreign countries, we may not be able to or we may determine not to sell Cinryze, Buccolam or Plenadren for one or more indications in such countries, or we could decide to sell Cinryze, Buccolam or Plenadren at a lower than anticipated price in such countries, and our revenues may be adversely affected as a result.

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**If supplies of human plasma are interrupted or if we are unable to acquire adequate supplies of 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 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 are responsible for obtaining an adequate supply of United States source plasma to meet demand for Cinryze in the United States. Pursuant to our manufacturing and distribution agreement, Sanquin is responsible for providing European plasma for Cinryze sold in the European market. We have a contract for the purchase and sale of plasma with DCI Management Group, LLC, pursuant to which we purchase specified quantities of United States source plasma. Under this agreement, DCI agreed to sell us specified annual quantities of United States source plasma in accordance with applicable good manufacturing practices. In addition to DCI, we entered into a Strategic Supply Agreement with Biotest Pharmaceuticals Corporation (BPC) pursuant to which we will purchase certain quantities of United States source plasma. Our contractual purchase commitments are subject to annual percentage increases based on change in the consumer price index and are subject to other market conditions. BPC has also built three additional plasma centers, and has committed to build another four additional plasma centers, to support our plasma requirements during the term of the agreement. We have an option to purchase these seven plasma centers. We have also made periodic spot purchases of United States source 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 addition, some plasma derived products are currently in clinical development for indications, including Alzheimer's disease, that, if approved, could cause a substantial increase in the demand for, and price of, plasma. 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. In addition, the EMA requires that all United States human plasma imported into Europe is sourced from plasma collection centers that are approved by a competent European authority, which limits the number of plasma collection centers available for sourcing of United States human plasma and potentially increases the costs.

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 or EMA. 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, prions and other pathogens are present in the plasma of infected individuals. If infected individuals donate plasma, the plasma would likely contain those agents. As a result, the sourcing of plasma, and the production of

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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.

**If patients using our commercial products suffer injuries, even if unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted and 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 market two commercial products in the United States and will market four products in the EU during 2013. As HAE and treatment of adrenal insufficiency are rare diseases, we tested Cinryze and Plenadren in only a small number of patients. As more patients use Cinryze and Plenadren, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant. Previously unknown risks and adverse effects of our products may also be discovered in connection with unapproved, or off-label, uses of our products. We conducted or are conducting required post approval studies in the United States and EU with Cinryze and Plenadren. Clinical evaluations of outcomes of these studies as well as in the post-marketing setting are required to be reported to appropriate regulatory agencies in accordance with relevant regulations.

In addition, we are studying and expect to continue to study Cinryze in diseases other than HAE in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks or adverse effects discovered as new patients are treated for approved indications and as Cinryze is studied in or used by patients for off-label indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials, make changes in labeling of Cinryze, reformulate Cinryze or make changes and obtain new approvals for our and our suppliers' manufacturing facilities.

The discovery of previously unknown risks and side effects of our products could result in a significant drop in the potential sales of our products, harm our reputation and the reputation of our products in the marketplace or become subject to lawsuits, including class actions. Any of these results

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could decrease or prevent any sales of our products or substantially increase the costs and expenses of commercializing and marketing our products.

We may be sued by people who use our products, whether as a prescribed therapy, during a clinical trial, during an investigator initiated study, or otherwise. Any informed consents or waivers obtained from people who enroll in our trials or use our products and product candidates may not protect us from liability or litigation. In addition, negative publicity relating to the use of our products or a product candidate, or to a product liability claim, may make it more difficult, or impossible, for us to market and sell our products. We currently maintain product liability insurance in connection with our clinical development programs and marketed products. 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. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

**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.

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**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 the feasibility of additional indications and/or other formulations for Cinryze. We plan to initially focus on C-1 mediated diseases affecting transplant patients, including AMR and DGF. We are also currently undertaking studies on the viability of subcutaneous administration of Cinryze. In the first quarter of 2012, we completed a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 and announced the presentation of positive data. In December 2012, we initiated a Phase 2b double blind, multicenter, dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze® (C1 esterase inhibitor [human]) in combination with PH20 in adolescents and adults with hereditary angioedema (HAE) for prevention of HAE attacks.

*Maribavir*

During the second quarter of 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV infections in transplant recipients. The program consists of two independent Phase 2 clinical studies that include subjects who have asymptomatic CMV, and those who have failed therapy with other anti-CMV agents. During the third quarter of 2012 and first quarter of 2013, we presented interim data from the Phase 2 open label clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV. Results from this study as well as data from a second Phase 2 open label study of maribavir as a treatment for patients with refractory cases of CMV will periodically be evaluated. Our prior evaluation of maribavir for prophylaxis in allogeneic stem cell, or bone marrow, transplant patients did not achieve its primary or key secondary endpoints and we also discontinued a study evaluating maribavir in liver transplant patients. While the current studies are in different patient populations and utilize different dosing levels, there can be no assurance that our clinical program with maribavir for the treatment of subjects with asymptomatic CMV as well as resistant/refractory CMV disease will yield positive results or support further development of maribavir for either indication. The preliminary results from a small number of NPP and emergency-use IND patients may not be predictive of the results of the studies being conducted.

*Non-toxigenic difficile*

In February 2006, we entered into a licensing agreement for the rights to develop non-toxigenic strains of *C. difficile*, or VP20621, for the treatment and prevention of CDAD. We plan to initially focus our efforts on the opportunity to prevent recurrence of CDAD following treatment with antibiotics such as Vancocin. On May 19, 2011 we announced that dosing had begun in the initiation of a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP20621 for prevention of recurrence of *Clostridium difficile* infection in adults previously treated for CDAD and closed enrollment in this study in December 2012. The Phase 2 clinical data from this study may not be conclusive requiring additional Phase 2 studies, or may not support continued clinical development of this product candidate.

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*VP20629, or indole-3-propionic acid*

In September 2011, we entered in to a licensing agreement for the worldwide rights to develop VP20629, or indole-3-propionic acid for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a single and repeat dose phase 1 study in patients in 2013 and expect to initiate a subsequent phase 2 study after completion of the phase 1 study. We may not be successful in completing the phase 1 or 2 studies in the time frame we anticipate. Following completion of the Phase 2 study, a Phase 3 study is planned although the results of the clinical trials may not support further clinical development.

*Plenadren*

We are evaluating the potential to file for regulatory approval of Plenadren in the United States. Our decision whether to pursue approval for Plenadren in the United States is dependent upon feedback from the FDA regarding whether the data filed in the European Union and approved by EMA is sufficient for US regulatory approval or whether additional clinical data would be required. There can be no assurance that FDA will approve Plenadren on the basis of the data that were submitted to and approved by the EMA. FDA may, instead, require additional clinical studies. In addition, there can be no assurance that we will receive orphan exclusivity. In order to receive orphan exclusivity in the United States the FDA has requested that we demonstrate that Plenadren provides a significant measure of safety over existing therapies.

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 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 Cinryze, Buccolam, Plenadren and Vancocin. 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.

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, EMA, 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

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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, or 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, VP20621, for the treatment and prevention of CDAD in clinical development. In addition, we are currently evaluating 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 2013 to assess at least one additional therapeutic use of Cinryze as well as continue to study the sub-cutaneous administration of Cinryze. We may also initiate clinical studies for other product candidates, including VP20629, or indole-3-propionic acid for the treatment of Friedreich's Ataxia. We must complete significant laboratory, animal and clinical testing on these product candidates before submitting marketing applications in the United States 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

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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 Marketing Authorization Application (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.

**Healthcare reform could adversely affect our revenue and financial results.**

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% became effective as of January 1, 2010, and the volume of rebated drugs was expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. The PPACA also includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "doughnut hole" and imposes an annual fee on pharmaceutical manufacturers based on the manufacturer's sale of branded pharmaceuticals and biologics (excluding orphan drugs). Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners. In addition, the new law establishes an abbreviated licensure pathway for products that are biosimilar to FDA-approved biological products, such as Cinryze, with provisions covering exclusivity periods and a specific reimbursement methodology for biosimilars.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact our business over time.

In addition, Federal, state, and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could impact our ability to market products and generate revenues in the United States and foreign countries.

**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.

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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 a 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 Europe and 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 (approximately \$33 million) million per year, net of the agreed upon discount.

In December 2011, we entered into a development and option agreement with Meritage Pharma, Inc. (Meritage) under which we agreed to make certain payments to Meritage to facilitate Meritage's development of the oral budesonide suspension for the treatment of eosinophilic esophagitis in exchange for an irrevocable option to acquire Meritage.

In September 2011, we entered into a license agreement with INS under which we acquired an exclusive worldwide license to develop, manufacture, distribute, market and sell products containing indole-3-propionic acid, or VP20629. We intend to develop a licensed product containing VP20629 for the treatment of Friedreich's Ataxia.

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 May 2011, Halozyme Therapeutics Inc.(Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology, in combination with a C1 esterase inhibitor which we intend to apply initially to develop a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. 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, INS, GSK and Halozyme, and will attempt to obtain in the future, licensed rights to certain

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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. Our agreement with Meritage requires us to rely upon their efforts to advance the clinical development of OBS. 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 are 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 INS 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 agreements with INS, Halozyme and GSK impose various obligations on us, including diligence obligations, milestone payment requirements and royalties. If we fail to comply with these obligations, Sanquin, INS, Halozyme 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

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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.

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.

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**Funding, especially on terms acceptable to us, may not be available to meet our future capital needs.**

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.

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.

**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 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 United States and in other countries. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to us and diversion of our efforts. We intend to file applications as appropriate for patents describing the composition of matter of our drug candidates, the proprietary processes for producing such compositions, and the uses of our drug candidates. We own three issued United States patents, one non- United States patents and have a number of pending United States patent applications, some of which we co-own with collaborators. We also have filed international, regional and non- United States national patent applications in order to pursue patent protection in major foreign countries.

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

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

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

**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, Halozyme and INS rights to patents and patent applications in a variety of countries throughout the world related to development candidates in our clinical development pipeline. We depend on GSK, Halozyme and INS to prosecute and maintain many of these patents and patent applications and protect such patent rights. Failure by GSK, Halozyme or INS to prosecute or maintain such patents or patent applications and protect such patent rights could lead to our loss of future revenue. Under certain circumstances, our ability to sublicense our rights under these license agreements is subject to the licensor's consent. If our license agreement with GSK, Halozyme or INS is 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 the United States, Europe and other markets. 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

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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 in the EU, we are required to conduct an observational (non-interventional) study conducted to characterize the safety and use of Cinryze in routine clinical practice in patients with HAE who receive Cinryze for prevention and/or treatment of angioedema attacks. We are also required to conduct a registry study for Plenadren in the EU. Collection and periodic reporting of CMC data also have been requested as a post-approval commitment for Cinryze in the United States. 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 presented efficacy claims for Cinryze but failed to reveal, and they minimized, material facts; they made unsubstantiated comparative claims; and they overstated 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 United States 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

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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 United States 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 United States 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, Connecticut, 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, file periodic reports with the state or make periodic public disclosures on sales, sampling, marketing, pricing, clinical trials, and other activities. Similar legislation was approved by the federal government in 2010 and will take effect upon the release of final regulations. 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.

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

There are products similar to Cinryze which are approved in the E.U. and other countries. There have been cases in which pharmaceutical products were sold at steeply discounted prices in markets outside the United States 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 United States. If this happens with Cinryze our revenues would be adversely affected.

In recent years, various legislative proposals have been offered in the United States Congress and in some state legislatures that would authorize re-importation of pharmaceutical products into the United States from other countries including Canada. We cannot predict the outcome of such initiatives, 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 have employees located in Europe and are engaged in marketing and distributing several products, conducting clinical trials and have established manufacturing relationships 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. We plan to expand our operations or enter into distribution arrangements with third parties to market our products and product candidates in countries outside of the United States and Europe. For example, we have employees located in Canada and Australia to help with the launch of our products in those markets. 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.

In Europe, we market two products that contain active ingredients that are controlled substances, and are therefore subject to additional regulation by European regulatory authorities relating to the procurement, manufacture, labeling, packaging, security controls, shipment, sale and use of these products. We continue to monitor economic conditions, including volatility associated with international economies, associated impacts on the financial markets and our business, and the sovereign debt crisis in Europe. The credit and economic conditions in Greece, Italy, Spain, France, Ireland and Portugal,

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among other members of the European Union have fluctuated throughout 2011 and 2012. These conditions have resulted in, and may continue to result in, an increase in the average length of time it takes to collect our outstanding accounts receivable in these countries. We currently do not have a material amount of receivables in Greece, Italy, Spain France or Portugal but anticipate that sales in one or more of these countries may increase during 2013. In addition, incidents of product misuse, product diversion or theft may occur with products containing controlled substances. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

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

In accordance with Statement of Financial Accounting Standard No. 141R, Business Combinations, the initial purchase price was allocated to DuoCort's net tangible assets or identifiable intangible assets based on their fair values as of the date of completion of the merger. We will incur additional amortization expense based on the identifiable amortizable intangible assets acquired pursuant to the merger agreement and their relative useful lives. We also recorded liabilities for potential future payments to the former shareholders of DuoCort. The fair value of these contingent consideration amounts must be re-measured through earnings each reporting period. These charges will have a material impact on our results of operations, and therefore could have an adverse impact on the market value of our common stock.

**We may be required to take a significant non-cash impairment charge related to Vancocin related intangible assets. If we are required to take an impairment charge related to these intangible assets, our financial position and results of operations would be adversely affected.**

The approval of generic copies of Vancocin has and will continue to adversely impact our revenues, operating results and cash flows in future periods. Following the approval of generic versions of oral vancomycin, we tested the Vancocin intangible assets for impairment as of March 31, 2012. There was no impairment of these intangible assets as of March 31, 2012. During the third quarter of 2012, we experienced larger than anticipated erosions in the sales volume, market share and pricing of both our branded and authorized generic vancomycin. This coupled with the entrance of a fourth generic competitor prompted us to perform step one of the impairment test as of September 30, 2012. We performed step one of the impairment test and there was no impairment of these intangible assets as of September 30, 2012. There were no events during the fourth quarter of 2012 that would have indicated the need to perform another step one of the impairment test for Vancocin. However, should future events occur that cause further reductions in revenue or operating results we would incur an impairment charge, which would be significant relative to the carrying value of the intangible assets of \$133.3 million as of December 31, 2012.

**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, 2012 is \$205.0 million. Additionally, we have unused availability under the three-year senior secured revolving credit facility of up to \$200.0 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;

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- 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.

In addition, we have a future liability in the form of contingent milestone payments to the former stockholders of DuoCort. Payments of up to 860 million SEK or approximately \$124 million would become payable upon the achievement of certain milestones related to Plenadren manufacturing, sales and territory expansion. We cannot predict if or when these payments may be payable or if they could materially adversely affect our business at the time of payment.

**Covenants in our Credit Facility will limit our ability to borrow which may restrict our business.**

The Credit Facility contains financial covenants that can limit our ability to borrow under the credit agreement. As of the date of this filing, we have not drawn any amounts under the Credit Facility and are in compliance with our covenants. As a result of the negative impact of the approval of generic vancomycin on our operating results, our ability to borrow the full \$200 million provided under Credit Facility during portions of 2013 and 2014 may be limited or prohibited. Limitations on our ability to borrow under the Credit Facility could impact our liquidity and limit our ability to fund general corporate requirements, such as research and development expenses, or to make acquisitions.

The Credit Facility also subjects us to various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase debt;
- make loans, investments and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

A breach of any of these covenants could result in a default under our Credit Facility.

**Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in a default under our outstanding indebtedness that could materially and adversely affect our results of operations and our financial condition.**

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and our lenders could terminate all commitments to extend further credit. The instruments governing our debt contain cross-default or cross-acceleration

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provisions that may cause all of the debt issued under such instruments to become immediately due and payable as a result of a default under an unrelated debt instrument. An event of default or an acceleration under one debt agreement could cause a cross-default or cross-acceleration of other debt agreements. We cannot assure you that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if the obligations thereunder are accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. We have pledged substantially all of our assets as collateral under our Credit Facility. If the lenders under our Credit Facility accelerate the repayment of borrowings, we may not have sufficient assets to repay the obligations outstanding under our Credit Facility and our other indebtedness, including the Senior Notes.

**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, 2012, the market price for our common stock fluctuated between \$19.02 and \$33.17 per share. The following factors, among others, could have a significant impact on the market for our common stock:

- period to period fluctuations in sales of our commercial products;
- our ability to successfully manufacture sufficient amounts of Cinryze to meet demand;
- results of clinical trials with respect to our product candidates in development or those of our competitors;
- developments with our collaborators;
- announcements of technological innovations or new products by our competitors;
- litigation or public concern 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, the EMA 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.

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**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 5,000,000 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.

**Conversion of the senior convertible senior notes will dilute the ownership interest of existing stockholders.**

To the extent we issue any shares of our common stock upon conversion of the senior convertible senior notes, the conversion of some or all of the senior convertible senior notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the senior convertible senior notes may encourage short selling by market participants because the conversion of the senior convertible senior notes could depress the price of our common stock.

**The convertible note hedge and warrant transactions may affect the value of our common stock and other securities, and expose us to counterparty risk.**

In connection with the issuance of the senior convertible senior notes, we have entered into privately-negotiated convertible note hedge transactions with two counterparties, which are expected to generally reduce the potential equity dilution of our common stock upon conversion of the senior convertible notes. To reduce the cost to us of the convertible note hedge transactions, we also entered into warrant transactions with these counterparties. To the extent that the price of our common stock exceeds the exercise price of the warrant transactions, the warrant transactions will be dilutive to us.

In connection with establishing their initial hedge of these transactions, the counterparties (and/or their affiliates) may have entered into various derivative transactions with respect to our common stock. The counterparties (and/or their affiliates) may modify their hedge positions 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 or other securities in secondary market transactions, which could adversely affect the value of our common stock or such securities, or could have the effect of

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increasing or preventing a decline in the value of our common stock or such securities. We are exposed to counterparty credit risk to the extent that the counterparties do not satisfy their obligations under the convertible note hedge transactions. We will be required to perform in full our obligations under the warrant transactions, regardless of whether the counterparties perform, in whole or in part, their obligations under the convertible note hedge transactions.

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

**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. On August 2012, we entered into an amended and restated lease to expand the headquarters building. The amended lease expires fifteen years from the commencement date, which will occur when the landlord has substantially completed the expansion, including any tenant improvements, which is expected to occur in the first half of 2014.

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. In February 2013, we amended the lease to include an additional 2,047 square feet of office space. The lease expires in February 2018.

We also lease office space for our operations in the following countries; Belgium, Canada, Germany, France, Italy, Spain, Sweden, and Puerto Rico and intend to lease additional office space in additional countries as we establish operations in those countries.

In January 2007, we purchased a 33,000 square foot 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**

On May 17, 2012, a class action complaint was filed in the United States District Court for the Eastern District of Pennsylvania naming as defendants ViroPharma Incorporated and Vincent J. Milano. The complaint alleges, among other things, possible securities laws violations by the defendants in connection with certain statements made by the defendants related to the Company's Vancocin

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product. On October 19, 2012, the complaint was amended to include additional officers of the Company as named defendants and allege additional information as the basis for the claim. The defendants believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of this lawsuit.

On April 13, 2012, we filed a complaint for declaratory and injunctive relief with the United States District Court for the District of Columbia against the Food and Drug Administration, Margaret A. Hamburg, M.D., in her official capacity as Commissioner of Food and Drug Administration, the United States Department of Health and Human Services, and Kathleen Sebelius, in her official capacity as Secretary of HHS. The complaint sought to set aside under the Administrative Procedure Act the FDA's denial of our petition for stay of action and the FDA's approval of three Abbreviated New Drug Applications for generic versions of Vancocin® (vancomycin hydrochloride) capsules. Concurrent with the filing of the complaint, we filed a motion for a temporary restraining order and/or a preliminary injunction, which the District Court denied on April 23, 2012. On January 9, 2013, the District Court dismissed all of our claims and we do not expect to appeal the decision.

On April 6, 2012, we received a notification that the Federal Trade Commission (FTC) is conducting an investigation into whether we engaged in unfair methods of competition with respect to Vancocin. On August 3, 2012, we received a Civil Investigative Demand from the FTC requesting additional information related to this matter. The existence of an investigation does not indicate that the FTC has concluded that we have violated the law, and we do not believe that we have engaged in unfair methods of competition with respect to Vancocin. We intend to continue to cooperate with the FTC investigation; however, at this time we cannot assess potential outcomes of this investigation.

From time to time we are a party to litigation in the ordinary course of our business and may become a party to additional litigation in the future as several law firms have issued press releases indicating that they are commencing investigations concerning whether the Company and certain of its officers and directors have violated laws. 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. MINE SAFETY DISCLOSURES**

Not applicable.

[Table of Contents](#)**PART II****ITEM 5. MARKET FOR 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 2011 and 2012 and through February 15, 2013.

	<u>High</u>	<u>Low</u>
Year ended December 31, 2011		
First Quarter	\$ 20.28	\$ 15.80
Second Quarter	\$ 22.16	\$ 17.21
Third Quarter	\$ 20.34	\$ 14.62
Fourth Quarter	\$ 28.34	\$ 17.25
Year ended December 31, 2012		
First Quarter	\$ 33.17	\$ 27.41
Second Quarter	\$ 31.13	\$ 19.02
Third Quarter	\$ 31.36	\$ 19.58
Fourth Quarter	\$ 30.60	\$ 22.12
First Quarter 2013 (through February 15, 2013)	\$ 27.28	\$ 23.37

**Holders and Dividends**

There were approximately 519 record holders of our common stock as of February 15, 2013. 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 27, 2013, 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.

**Issuer Purchases of Equity Securities**

Below is a summary of stock repurchases for the three months ended December 31, 2012:

<u>Month</u>	<u>Total Number of Shares Purchased(1)</u>	<u>Average Price Paid per Share(2)</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Approximate Dollar Value of Shares that May Yet Be Purchased under the Plans or Programs (in thousands)(1)</u>
October 1—October 31	220,000	\$ 25.40	220,000	\$ 222,857
November 1—November 30	904,221	\$ 25.28	904,221	\$ 200,000
December 1—December 31	—	\$ —	—	\$ 200,000
Total	<u>1,124,221</u>	<u>\$ 25.30</u>	<u>1,124,221</u>	

- (1) In March 2011, our Board of Directors authorized the use of up to \$150 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. In September 2011, our Board of Directors authorized up to \$200.0 million for repurchases of ViroPharma Incorporated's outstanding shares of common stock or 2% senior convertible notes due 2017. On September 7, 2012, our Board of Directors authorized the use of up to an additional \$200 million

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to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. The authorizations authorize management to repurchase shares in the open market, in block transactions, in private transactions or other techniques from time to time, depending on market conditions.

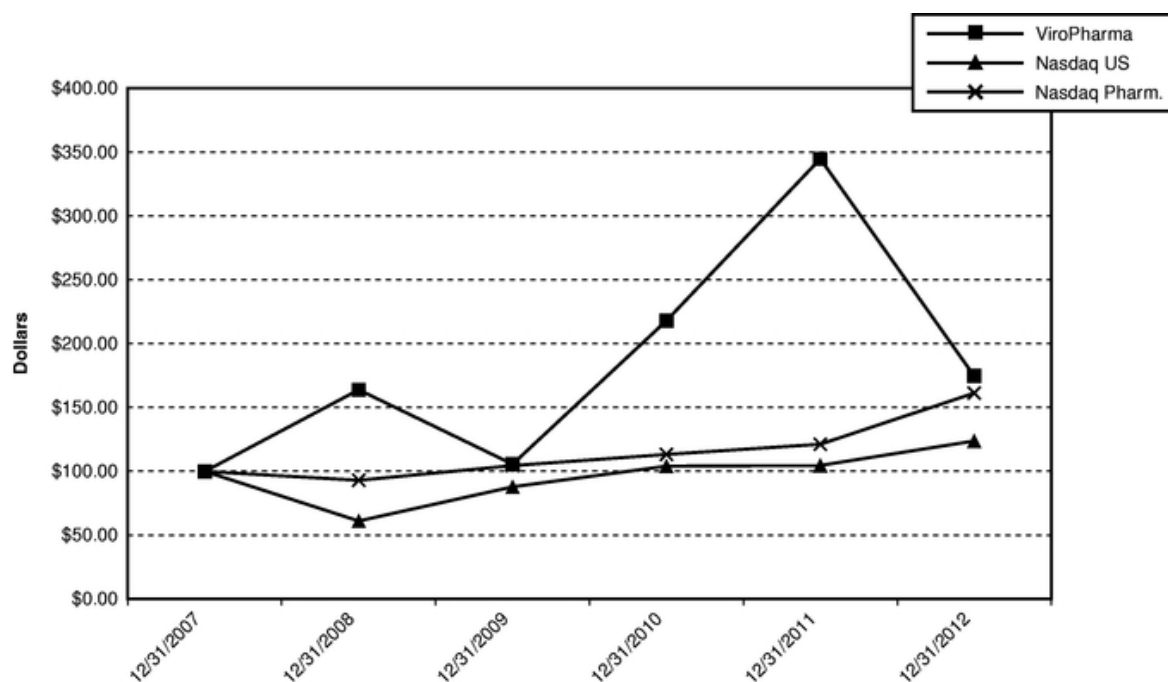
During 2012, through open market purchases, we reacquired approximately 6.9 million shares at a cost of approximately \$180.3 million or an average price of \$26.20 per share.

- (2) The Average Price Paid per Share is based on the price paid per share in the open market. The average price was determined based on the volume weighted-average-price of our stock during the day the repurchases had occurred.

During the period covered by this report, we did not sell any of our equity shares that were not registered under the Securities Act of 1933, as amended.

### Performance Graph

The following graph compares the cumulative five-year total return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index. An investment of \$100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2007 and its relative performance is tracked through December 31, 2012.



	As of December 31,					
	2007	2008	2009	2010	2011	2012
ViroPharma Incorporated	100.00	163.98	105.67	218.14	344.96	174.81
NASDAQ Composite Index	100.00	61.17	87.92	104.13	104.69	123.85
NASDAQ Pharmaceutical Index	100.00	93.04	104.55	113.33	121.31	161.38

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

[Table of Contents](#)**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, 2012, 2011, 2010, 2009, and 2008 and under the caption "Consolidated Balance Sheet Data" as of December 31, 2012, 2011, 2010, 2009, and 2008 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 October 2008, we acquired Lev Pharmaceuticals, Inc., in May 2010 we acquired Auralis Limited and in November 2011 we acquired DuoCort Pharma AB.

(in thousands, except per share amounts)	Year Ended December 31,				
	2012	2011	2010	2009	2008
<b>Consolidated Statement of Operations Data:</b>					
Net product sales	\$ 427,933	\$ 544,374	\$ 439,012	\$ 310,449	\$ 232,307
Operating expenses:					
Cost of sales (excluding amortization of product rights)	108,547	79,976	61,288	40,214	8,874
Research and development	67,709	66,477	39,613	52,083	64,434
Selling, general and administrative	174,315	127,775	95,664	89,316	67,270
Intangible amortization	35,301	31,035	29,357	28,183	10,809
Goodwill impairment	—	—	—	65,099	—
Impairment loss	—	8,495	—	3,424	2,265
Other operating expenses	8,718	8,488	1,390	—	—
Total operating expenses	394,590	322,246	227,312	278,319	153,652
Operating income	33,343	222,128	211,700	32,130	78,655
Interest income	594	655	372	352	14,296
Interest expense	(14,093)	(12,640)	(11,616)	(11,609)	(12,951)
Other (expense) income, net	(823)	(2,136)	430	—	—
Gain on long-term debt repurchase	—	—	—	9,079	—
Income tax expense	13,410	67,348	75,278	41,029	16,040
Net income (loss)	<u>\$ 5,611</u>	<u>\$ 140,659</u>	<u>\$ 125,608</u>	<u>\$ (11,077)</u>	<u>\$ 63,960</u>
Net income (loss) per share:					
Basic	\$ 0.08	\$ 1.89	\$ 1.61	\$ (0.14)	\$ 0.90
Diluted	\$ 0.08	\$ 1.68	\$ 1.47	\$ (0.14)	\$ 0.84
Shares used in computing net income (loss) per share:					
Basic	68,214	74,517	77,820	77,423	71,391
Diluted	71,764	88,076	90,081	77,423	85,712

	As of December 31,				
	2012	2011	2010	2009	2008
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 246,856	\$ 459,830	\$ 505,171	\$ 331,672	\$ 275,839
Working capital	339,390	537,280	561,019	406,375	317,413
Total assets	1,219,952	1,336,797	1,287,574	1,084,451	1,086,129
Long-term debt	161,793	153,453	145,743	138,614	161,003
Total stockholders' equity	757,039	891,124	891,135	750,387	749,334

We have never paid dividends on our common stock.



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

**Background**

ViroPharma Incorporated is an international biotechnology company dedicated to the development and commercialization of novel solutions for physician specialists to address unmet medical needs of patients living with serious diseases that have few if any clinical therapeutic options, including therapeutics for rare and orphan diseases. We intend to grow through sales of our marketed products, through continued development of our product pipeline, through expansion of sales into additional territories outside the United States, through potential acquisition or licensing of products and product candidates and the acquisition of companies. We expect future growth to be driven by sales of Cinryze for hereditary angioedema (HAE), both domestically and internationally, sales of Plenadren for treatment of adrenal insufficiency (AI) and Buccolam in Europe for treatment of paediatric seizures, and by our development programs, including C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection, VP20621 for the prevention of recurrent *C. difficile*-associated diarrhea (CDAD) and VP20629 for the treatment of Friedreich's Ataxia (FA).

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with 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. We acquired rights to Cinryze for the United States in October 2008 and in January 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 well as rights to develop future C1-INH derived products for additional indications. In June 2011, the European Commission (EC) granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. We have begun to commercialize Cinryze in Europe and continue to evaluate our commercialization opportunities in countries where we have distribution rights.

On August 6, 2012, FDA approved our supplement to the Cinryze Biologics License Application (BLA) for industrial scale manufacturing which increases our manufacturing capacity of Cinryze.

We acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]) in May 2010. In September 2011, the EC granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. We have begun to commercialize Buccolam in Europe.

On November 15, 2011, we acquired rights to Plenadren® (hydrocortisone, modified release tablet) for treatment of AI. The acquisition of Plenadren further expands our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren, an orphan drug for treatment of AI in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We are in the process of launching Plenadren in the various countries in Europe and a named patient program is available to patients in countries in which we have not launched Plenadren commercially. We are currently conducting an open label trial with Plenadren in Sweden and have initiated a registry study as a condition of approval in Europe. We also are currently exploring commercialization opportunities in additional geographies including the United States.

We also sell branded and authorized generic Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is indicated for the treatment of

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*C. difficile*-associated diarrhea (CDAD). Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On April 9, 2012, the FDA denied the citizen petition we filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of generic versions of Vancocin (vancomycin hydrochloride, USP) capsules. The FDA also informed us in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin which was approved on December 14, 2011 would not qualify for three additional years of exclusivity, as the agency interpreted Section 505(v) of the FD&C Act to require a showing of a significant new use (such as a new indication) for an old antibiotic such as Vancocin in order for such old antibiotic to be eligible for a grant of exclusivity. FDA also indicated that it approved three abbreviated new drug applications (ANDAs) for generic vancomycin capsules and the companies holding these ANDA approvals indicated that they began shipping generic vancomycin hydrochloride, USP. In June 2012, the FDA approved a fourth ANDA for generic vancomycin capsules.

We granted a third party a license under our NDA for Vancocin® (vancomycin hydrochloride capsules, USP) to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. We are also obligated to pay Genzyme royalties of 10 percent, 10 percent and 16 percent of our net sales of Vancocin for the three year period following the approval of the sNDA as well as a lower royalty on sales of our authorized generic version of Vancocin in connection with our purchase of exclusive rights to two studies of Vancocin.

Our product development portfolio is primarily focused on the following programs: C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection, VP20621 (prevention of CDAD) and VP20629 (treatment of Friedreich's Ataxia).

We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. In May 2011, Halozyne Therapeutics Inc. (Halozyne) granted us an exclusive worldwide license to use Halozyne's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyne's recombinant human hyaluronidase enzyme (rHuPH20) technology, in combination with a C1 esterase inhibitor which we intend to apply initially to develop a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In the first quarter of 2012, we completed a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 and announced the presentation of positive data. In December 2012, we initiated a Phase 2b double blind, multicenter, dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze® (C1 esterase inhibitor [human]) in combination with PH20 in adolescents and adults with HAE for prevention of HAE attacks. We will continue to evaluate the subcutaneous administration of Cinryze as a standalone therapy. We are also investigating a recombinant forms of C1-INH.

Additionally, we are working on developing our C1 esterase inhibitor in further therapeutic uses and potential additional indications in other C1 mediated diseases. We intend to support IISs to identify further therapeutic uses for Cinryze. An IIS evaluating C1 INH as a treatment for Autoimmune Hemolytic Anemia (AIHA) and Neuromyelitis Optica (NMO) were initiated in 2012. We are also sponsoring a clinical trial in Antibody-Mediated Rejection (AMR) and are evaluating, the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH) and may conduct clinical and non-clinical studies to evaluate additional therapeutic uses in the future.

During the second quarter of 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV infections in transplant recipients. The program consists of two independent Phase 2 clinical studies that include subjects who have asymptomatic CMV, and those who have failed therapy with other anti-CMV agents. During the third quarter of 2012 and first quarter of 2013, we presented interim data from the Phase 2 open label clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV. Results from this

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study as well as data from a second Phase 2 open label study of maribavir as a treatment for patients with refractory cases of CMV will periodically be evaluated.

We are also developing VP20621 for the prevention of CDAD. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP20621 for prevention of recurrence of CDAD in adults previously treated for CDAD. We presented interim data from this study during the third quarter of 2012. We completed enrollment of patients in December 2012 and anticipate having the complete data set in 2013.

In September 2011, we entered in to a licensing agreement for the worldwide rights to develop VP20629, or indole-3-propionic acid for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a single and repeat dose phase 1 study in patients in 2013 and expect to initiate a subsequent phase 2 study after completion of the phase 1 study. We may not be successful in completing the phase 1 or 2 studies in the time frame we anticipate. Following completion of the phase 2 study, a phase 3 study is planned. although the results of the clinical trials may not support further clinical development. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

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 which we believe will provide both revenue and earnings growth over time.

## Executive Summary

Since December 31, 2011, we experienced the following:

### *Recent Business Activities*

Cinryze:

- Shipped approximately 80,000 doses of Cinryze to specialty pharmacy/specialty distributors (SP/SDs) in the U.S. and approximately 4,100 doses to wholesalers and pharmacies in the EU and launched Cinryze commercially in 7 countries in Europe;
- Announced the presentation of positive data from our initial Phase 2 subcutaneous trial of C1 esterase inhibitor [human] in combination with Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology and, in December 2012, initiated a Phase 2b dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze in combination with (rHuPH20);
- In August 2012, FDA approved our Prior Approval Supplement for industrial scale manufacturing of Cinryze; and,
- Announced data from an open-label study to assess the safety, tolerability, and treatment effect of escalating doses of C1-INH in patients with HAE who were not adequately controlled with

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1000 U every 3 or 4 days. The data provide evidence for the safety profile of Cinryze at doses up to 2500 units in patients with hereditary angioedema;

CMV:

- Announced the initiation of two Phase 2 programs to evaluate maribavir for the treatment of CMV infections in transplant recipients; and,
- Presented interim data from the Phase 2 clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV;

Plenadren:

- Launched Plenadren commercially in 5 countries in Europe;

Buccolam:

- Launched Buccolam commercially in 3 countries in Europe;

*C. difficile* infection (CDAD):

- Presented interim data from a global Phase 2 clinical study evaluating VP20621 as a prevention against recurrent *C. difficile* infections;
- Completed enrollment of the Phase 2 study and expect data in 2013; and,
- Announced that FDA denied the citizen petition we filed on March 17, 2006, determined the sNDA for Vancocin approved December 14, 2011 would not qualify for three years of exclusivity and approved several ANDA's for generic vancomycin capsules;

*Financial Results*

- Net sales of Cinryze increased to \$327.1 million for the year ended December 31, 2012 from \$251.2 million for the year ended December 31, 2011;
- Net sales of Vancocin decreased to \$90.8 million for the year ended December 31, 2012 from \$288.9 million for the year ended December 31, 2011;
- Generated net sales of approximately \$16.6 million in Europe; and,
- Reported net income of \$5.6 million for the year ended December 31, 2012;

*Liquidity*

- Generated net cash from operations of \$43.0 million;
- Ended 2012 with working capital of \$339.4 million which includes cash and cash equivalents and short-term investments of \$246.9 million;
- Repurchased approximately 6.9 million shares of our common stock at a cost of approximately \$180.3 million, or an average price of \$26.20 per share; and,
- Paid approximately \$92.3 million related to the Lev acquisition CVR.

During 2013 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 sales will meet or exceed the historical rate of sales for the

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product, for reasons that include, but are not limited to, competition and/or changes in prescribing habits or disease incidence. The commercial success of Cinryze, Plenadren and Buccolam in Europe will depend on a number of factors, including the number of patients that may be treated with each product, physician and patient acceptance of each of the products, cost effectiveness of each product, the timing and level of pricing approvals for each product in each country in the EU, and our ability to manufacture sufficient quantities of product to meet patient needs.

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. In Europe, the EC has granted us Centralized Marketing Authorization for Cinryze in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients.

The commercial success of Cinryze depends on several factors, including: the number of patients with HAE that may be treated with 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; our ability to maintain manufacturing capabilities in the capacities and timeframes currently anticipated; 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; variations in dosing arising from physician preferences and patient compliance; and sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze. In addition, our ability to develop and commence clinical studies for additional indications and pursuing regulatory approvals in additional indications or territories will impact our ability to generate future revenues from Cinryze.

Since the first quarter of 2012, Cinryze inventory in the channel has been below normal levels. However, on August 6, 2012, FDA approved our supplement to the Cinryze Biologics License Application (BLA) for industrial scale manufacturing, which increases our manufacturing capacity of Cinryze. We intend to rebuild channel inventory during the first half of 2013 and also build a quantity of safety stock during the year in anticipation of a planned shutdown of our manufacturing partners' production facility.

The acquisition of Plenadren further expands our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren, an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We are in the process of launching Plenadren in various countries in Europe and a named patient program is available to patients in countries in which we have yet to launch Plenadren commercially. We are currently conducting an open label trial with Plenadren in Sweden and have initiated a registry study as a condition of approval in Europe. We also are currently exploring commercialization opportunities in additional geographies including the United States.

The licensing and availability of Buccolam follows its central approval in the European Union through the PUMA in the fourth quarter of 2011. Buccolam is the first product approved using a PUMA, which is a type of centralized marketing authorization procedure requested for medicines already authorized but no longer covered by intellectual property rights and exclusively developed for use in children. In most European markets, the key competitors for Buccolam are typically either available generically or are used off label. There are a number of potential future competitors in the same or similar medical areas.

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The approval of generic copies of Vancocin has and will continue to adversely impact our revenues, operating results and cash flows in future periods. Following the approval of generic versions of oral vancomycin, we tested the Vancocin intangible assets for impairment as of March 31, 2012. There was no impairment of these intangible assets as of March 31, 2012. Vancocin will continue to be utilized and sold as a branded drug product and we are selling an authorized generic version of Vancocin in competition with generics of other companies that have entered the market.

During the third quarter of 2012, we experienced larger than anticipated erosion in the sales volume, market share and pricing of both our branded and authorized generic vancomycin. This coupled with the entrance of a fourth generic competitor prompted us to perform step one of the impairment test as of September 30, 2012. We performed step one of the impairment test and determined that there was no impairment of these intangible assets as of September 30, 2012. There have been no events during the quarter ended December 31, 2012 that would indicate we must re-test these assets for impairment. However, should future events occur that cause further reductions in revenue or operating results, we would incur an impairment charge, which would be significant relative to the carrying value of the intangible assets as of December 31, 2012.

On May 17, 2012, a class action complaint was filed in the United States District Court for the Eastern District of Pennsylvania naming as defendants ViroPharma Incorporated and Vincent J. Milano. The complaint alleges, among other things, possible securities laws violations by the defendants in connection with certain statements made by the defendants related to the Company's Vancocin product. On October 19, 2012, the complaint was amended to include additional officers of the Company as named defendants and allege additional information as the basis for the claim. The defendants believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of this lawsuit.

In addition, we have received a notification that the Federal Trade Commission (FTC) is conducting an investigation into whether we engaged in unfair methods of competition with respect to Vancocin. The existence of an investigation does not indicate that the FTC has concluded that we have violated the law and we do not believe that we have engaged in unfair methods of competition with respect to Vancocin. We intend to continue to cooperate with the FTC investigation; however, at this time we cannot assess potential outcomes of this investigation.

In the fourth quarter of 2012, we became aware that certain Vancocin sales made to Government agencies under the Federal Supply Schedule contract between ViroPharma and the Veterans Administration (VA) were not compliant with the Trade Agreements Act. Absent a waiver, the Trade Agreements Act prohibits the sale to the government of products manufactured in non-designated countries, such as China. We have self-reported the discovery to the VA and will work with the VA to address this matter moving forward. The timing and outcome of these discussions are not certain. As such, we are not in a position to determine whether we have any liability or the extent of any such liability. Accordingly, we have not made any provisions for potential fines or penalties related to these potential violations in our consolidated financial statements as of December 31, 2012.

We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. Studies using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with Cinryze are subject to laboratory sampling to monitor rHuPH20 antibody levels as a result of potential safety signals detected in the clinical development program of another company's product being studied in combination with rHuPH20. The FDA may impose future clinical holds in the event studies conducted by us or other companies with rHuPH20 identify elevated antibody levels.

During the second quarter of 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV infections in transplant recipients. The program consists of two independent Phase 2 clinical studies that include subjects who have asymptomatic CMV, and those who

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have failed therapy with other anti-CMV agents. During the third quarter of 2012 and first quarter of 2013, we presented interim data from the Phase 2 open label clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV. Results from this study, as well as data from a second Phase 2 open label study of maribavir as a treatment for patients with refractory cases of CMV, will periodically be evaluated.

We are developing VP20621 for the treatment and prevention of CDAD, and in May 2011 we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP20621 for prevention of recurrence of CDAD in adults previously treated for CDAD. We presented interim data from this study during the third quarter of 2012. Based on the interim data, we stopped enrolling patients in December 2012 and anticipate having the complete data set in 2013.

We are also developing VP20629 for the treatment of Friedreich's Ataxia. In a Phase 1 safety and tolerability study conducted in the Netherlands, VP20629 was demonstrated to be safe and well tolerated at all dose levels tested. We expect to initiate a study in patients by the second half of 2013. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data.

The outcome of our clinical development programs is subject to considerable uncertainties. There can be no assurance that our clinical programs with Cinryze, maribavir, VP20621 or VP20629 will yield positive results or support further development. There can also be no assurance that the OBS development efforts at Meritage will yield positive results or support further development.

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 obtaining regulatory approval of any of our product candidates in the timeframes that we expect, or at all.

We cannot assure you that our current cash and cash equivalents and investments or cash flows from product 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.

We will face intense competition in acquiring additional products to further expand our product portfolio. Many of the companies and institutions that we will compete with in acquiring additional products to further expand 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. Upon completion of business development transactions, we will face risks related to the integration of the acquired asset or business which could result in delays in development timelines, increased expenses or assumption of undisclosed liabilities, and disruption from the transaction making it more difficult to maintain relationships with manufacturers, employees or other suppliers.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which was amended by the Health Care and Education Reconciliation Act of 2010. PPACA, as amended, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the new law, which have varying effective dates, will affect us. We continue to evaluate PPACA to determine not only the immediate effects on our business, but also the trends and changes that may be encouraged by the legislation that may potentially impact our business over time.

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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, 2012 are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Please also see our discussion of the "Risk Factors" in Item 1A, which describe other important matters relating our business.

## Results of Operations

### *Years ended December 31, 2012 and 2011*

(in thousands, except per share data)	For the years ended December 31,	
	2012	2011
Net product sales	\$ 427,933	\$ 544,374
Cost of sales (excluding amortization of product rights)	\$ 108,547	\$ 79,976
Operating income	\$ 33,343	\$ 222,128
Net income	\$ 5,611	\$ 140,659
Net income per share:		
Basic	\$ 0.08	\$ 1.89
Diluted	\$ 0.08	\$ 1.68

The \$33.3 million in operating income for the year ended December 31, 2012 decreased \$188.8 million compared to the same period in 2011. The primary drivers of this decrease were lower net sales of \$116.4 million due to lower Vancocin revenues; increased cost of sales of \$28.6 million due to increased Cinryze sales volume; and increased selling, general and administrative expenses of \$46.5 million due to our European commercialization efforts and the growth of our global organization. Research and development expenses increased slightly by \$1.2 million, during the year ended December 31, 2012 as compared to the prior year. Increased spending related to our Phase 2 study of subcutaneous administration of Cinryze in combination with rHuPH20 and increased spending in our CMV program during 2012 was offset by a \$9.0 million upfront fee related to our license arrangement with Halozyme, a \$3.0 million charge related to the achievement of a development milestone under our license arrangement with Halozyme and a \$6.5 million upfront fee related to our license agreement with INS incurred in 2011. Other operating expenses in both periods include the expense associated with change in the fair value of the contingent consideration related to our acquisitions. These charges were approximately \$4.5 million during the year ended December 31, 2012 and approximately \$4.7 million during the year ended December 31, 2011. Also included in other operating expenses during 2012 is approximately \$2.8 million related to non-refundable start up costs with no alternative future use paid to suppliers and approximately \$0.9 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin, while 2011 reflects approximately \$3.4 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin and an \$8.5 million impairment charge related to certain assets acquired from Auralis.

We sell Diamorphine in the UK, primarily to hospitals, through approved wholesalers. The revenues and operating income from these sales are not material to our consolidated revenues for 2012 or 2011.

We began commercial sales of Cinryze and Buccolam in Europe during the fourth quarter of 2011 and Plenadren during the third quarter of 2012.

[Table of Contents](#)*Revenues*

Revenues consisted of the following:

(in thousands)	For the years ended December 31,	
	2012	2011
Net product sales		
Cinryze	\$ 327,113	\$ 251,201
Vancocin	90,778	288,893
Other	10,042	4,280
Total revenues	<u>\$ 427,933</u>	<u>\$ 544,374</u>

*Net product sales*

In the US, we sell Cinryze to specialty pharmacy/specialty distributors (SP/SD's) who then distribute to physicians, hospitals and patients, among others. In Europe, we sell Cinryze to wholesalers who then distribute the product principally to pharmacies and hospitals. We continue to work to expand our manufacturing capacity to ensure the availability of Cinryze to meet growing patient needs and believe our efforts will allow us to continue to meet this growing patient demand for the foreseeable future. On August 6, 2012, FDA approved our Prior Approval Supplement (PAS) to the Cinryze Biologics License Application (BLA) for industrial scale manufacturing which increases our manufacturing capacity of Cinryze. Since the first quarter of 2012, Cinryze inventory in the channel has been below normal levels. However, the approval of our supplement to the BLA for industrial scale manufacturing increased our manufacturing capacity of Cinryze and enabled us to begin rebuilding our channel inventory in the fourth quarter of 2012 and we intend to complete the rebuilding of channel inventory during the first half of 2013.

Our net sales of Cinryze during the year ended December 31, 2012 increased \$75.9 million compared to the same period in 2011 primarily due to increased volume driven by patient growth and consistent dosing rates as well as the U.S. channel rebuild. Europe contributed approximately \$6.6 million of the Cinryze revenue during 2012 compared to approximately \$1.0 million during 2011.

Net sales of Vancocin decreased \$198.1 million during the year ended December 31, 2012 compared to the same period in 2011 due to the introduction of generic vancomycin. On April 9, 2012, we announced the FDA denied the citizen petition we filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of generic versions of Vancocin (vancomycin hydrochloride, USP) capsules. FDA also approved three ANDA's for generic vancomycin capsules. In June 2012, FDA approved a fourth ANDA.

Pursuant to the terms of a previously entered distribution agreement, we granted a third party a license under our NDA for Vancocin® (vancomycin hydrochloride capsules, USP) to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. We also continue to sell branded Vancocin. We are also obligated to pay Genzyme royalties of 10 percent, 10 percent and 16 percent of net sales of Vancocin for the three year period following the approval of the sNDA as well as a lower royalty on sales of our authorized generic version of Vancocin in connection with our purchase of exclusive rights to two studies of Vancocin.

The approval of generic copies of Vancocin has and will continue to adversely impact our sales of our Vancocin brand prescription products and have a negative impact on our financial condition and results of operations, including causing a significant decrease in our revenues, operating income and cash flows compared to historical levels.

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*Cost of sales (excluding amortization of product rights)*

Cost of sales increased for the year ended December 31, 2012 by \$28.6 million as compared to the same period in 2011. This increase is primarily due to the effect of the shift in product mix from decreased sales of higher margin Vancocin to increased sales of lower margin Cinryze, and the royalty due to Genzyme for Vancocin sales which was not incurred in 2011. We anticipate that our cost of sales, on a relative basis, will remain higher than historical levels due to the introduction of generic vancomycin and the reduction of our sales of Vancocin relative to our Cinryze sales along with the royalty due to Genzyme.

Cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights.

*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 clinical and development costs. Indirect expenses include personnel, facility, stock compensation and other overhead costs.

Due to our study of subcutaneous administration of Cinryze in combination with rHuPH20, support for research exploring the use of Cinryze in additional indications, our study of maribavir for the treatment of CMV infections in transplant recipients, and our VP20621 clinical program we expect costs in these programs to increase in the future.

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

(in thousands)	For the years ended	
	December 31,	
	2012	2011
<b>Direct</b>		
Cinryze & C1 esterase inhibitor	\$ 18,172	\$ 23,383
CMV	5,735	1,028
Non-toxicogenic strains of <i>C. difficile</i> (VP20621)	9,243	7,653
VP20629	1,298	6,500
Plenadren	1,327	—
New Initiatives	3,548	2,773
Other assets	701	813
<b>Indirect</b>		
Development	27,685	24,327
<b>Total</b>	<u>\$ 67,709</u>	<u>\$ 66,477</u>

*Direct Expenses*

Our costs associated with our Cinryze program decreased during 2012 compared to 2011. The decrease in 2012 compared to 2011 is due to two payments totaling \$12 million to Halozyme in 2011 pursuant to the terms of a license agreement that was partly offset by an increase in development spending during the 2012 period associated with our Phase 2 study of subcutaneous administration of Cinryze in combination with rHuPH20 and the continuation of our support for research exploring the use of Cinryze in additional indications. On August 1, 2012, we were notified by the CBER division of the FDA that studies of the combination of Cinryze and rHuPH20 were being placed on temporary clinical hold. We resumed our studies of subcutaneous administration of Cinryze in combination with

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rHuPH20 during the fourth quarter of 2012, and we will continue to conduct activities related to subcutaneous administration of Cinryze as a standalone therapy. As such, we anticipate that costs associated with our Cinryze program to increase in future periods.

Our direct expenses related to our CMV program increased during 2012 compared to 2011 as we initiated two Phase 2 clinical studies during the first and third quarters of 2012 to evaluate maribavir for the treatment of CMV infections in transplant recipients.

The costs of VP20621 program for the year ended December 31, 2012 increased compared to the same period in 2011 due to the costs incurred during 2012 from our Phase 2 clinical trial compared to the cost incurred in 2011 related to our Phase 1 study.

Our direct expenses related to our VP20629, being developed for the treatment of Friedreich's Ataxia (FA), decreased in 2012 compared to 2011 as we paid a \$6.5 million up-front licensing fee during the third quarter of 2011 and conducted preclinical activities during 2012.

The Plenadren costs incurred during 2012 is related to our open label trial and our registry study.

Our costs related to New Initiatives represent expenses associated with our evaluation of a recombinant C1-INH technology and spending under our collaboration agreement with Sanquin supporting their early stage research programs.

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.

*Selling, general and administrative expenses (SG&A)*

During the year ended 2012 compared to 2011, SG&A increased \$46.5 million. This increase was primarily driven by higher compensation expense and employee cost of \$25.0 million, increased marketing expenses of \$10.3 million, increased corporate and other costs of \$13.3 million, partly offset by lower medical education costs of \$4.1 million.

Our European commercialization efforts and the growth of our global organization represented approximately \$26 million of the increase during 2012, primarily due to higher compensation cost and the higher spending in the areas of medical affairs and marketing efforts as we launch our products. We anticipate that our SG&A spending will continue to increase in future periods as we continue our commercialization and expansion efforts outside the United States.

*Intangible amortization*

Intangible amortization for the year ended December 31, 2012 was \$35.3 million, as compared to \$31.0 million in 2011. The increase is due to the higher amortization of our Buccolam and Plenadren assets during 2012 as we did not begin to amortize Buccolam until it was approved in the third quarter of 2011 and Plenadren was acquired in the fourth quarter of 2011.

*Impairment losses*

We did not record impairment charges during 2012. However, during 2011 due to the approval and launch of Buccolam, coupled with the launch of Cinryze in Europe, we decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision

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resulted in the impairment of the IPR&D asset and the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during 2011.

*Other operating expenses*

Other operating expenses included charges to income resulting from the re-measurement of the fair values of the contingent consideration liabilities incurred as part of our acquisitions. These charges were approximately \$4.5 million during 2012 and approximately \$4.7 million during 2011. Additionally, included in the year ended December 31, 2012 is approximately \$2.8 million related to non-refundable start up costs with no alternative future use paid to suppliers and approximately \$0.9 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin, while the year ended December 31, 2011 includes approximately \$3.4 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin.

*Other Income (Expense)*

*Interest Income*

Interest income for year ended December 31, 2012 was \$0.6 million and \$0.7 million in 2011.

*Interest Expense*

(in thousands)	For the years ended December 31,	
	2012	2011
Interest expense	\$ 4,816	\$ 4,372
Amortization of debt discount	8,340	7,711
Amortization of finance costs	937	557
Total interest expense	<u>\$ 14,093</u>	<u>\$ 12,640</u>

Interest expense during 2012 principally reflects interest on our senior convertible notes and commitment fees on the unused credit facility while 2011 consists of only interest on our senior convertible notes. The amortization of debt discount relates solely to the senior convertible notes and the increase in the amortization of finance costs is due to the amortization of the costs related to the \$200 million credit facility entered into during the third quarter of 2011.

*Other income (expense), net*

Our other income, net includes net foreign exchange gains and losses. Additionally, the year ended December 31, 2012 includes approximately \$3.8 million of amortization expense of the deferred asset related to the Meritage transaction.

*Income Tax Expense*

Our income tax expense was \$13.4 million and \$67.3 million for 2012 and 2011, respectively. Our income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences.

Our effective tax rates for 2012 and 2011 were 70.5% and 32.4%, respectively.

The effective tax rates for the years ended December 31, 2012 and 2011 were negatively impacted by state income taxes and items that are not deductible for income tax purposes, such as certain share-based compensation and increases in the fair value of contingent consideration. In addition, the

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effective tax rate for the year ended December 31, 2012 is negatively impacted by foreign losses on which no tax benefit is provided or on which the tax benefit is less than the U.S. statutory tax rate and non-deductible amortization expense. The effective of these increases to the effective tax rate are partially offset in both years by tax benefits related to orphan drug credits, manufacturing deductions and charitable contributions. In addition, in 2011 a valuation allowance related to state net operating losses was reduced resulting in a reduction in the effective tax rate for that period. In 2012, a valuation allowance related to state net operating losses was increased resulting in an increase in the effective tax rate.

Our effective tax rate in future years will depend on a number of factors but will depend heavily on foreign operating results. In 2013, we expect our effective tax rate to be lower than the 2012 tax rate, although still higher than the US statutory rate, based on improving foreign operating results. Our effective tax rate if future years should continue to improve if our product launches outside the U.S. are successful in generating profits.

## Results of Operations

### Years ended December 31, 2011 and 2010

(in thousands, except per share data)	For the years ended December 31,	
	2011	2010
Net product sales	\$ 544,374	\$ 439,012
Cost of sales (excluding amortization of product rights)	\$ 79,976	\$ 61,288
Operating income	\$ 222,128	\$ 211,700
Net income	\$ 140,659	\$ 125,608
Net income per share:		
Basic	\$ 1.89	\$ 1.61
Diluted	\$ 1.68	\$ 1.47

The \$222.1 million in operating income for the twelve months ended December 31, 2011 increased \$10.4 million compared to the same period in 2010. The primary driver of this increase is increased net sales of \$105.4 million. Partly offsetting the increased sales are: (1) an increase of \$18.7 million in cost of sales due to increased Cinryze volume; (2) an increase in research and development expense of \$ 26.9 million due to: a \$9.0 million upfront fee and an additional \$3.0 million payment related to the achievement of a development milestone under our license arrangement with Halozyme; a \$6.5 million upfront fee related to our license agreement with Intellect Neurosciences, Inc. (INS); and, (3) an increase of \$32.1 million in selling, general and administrative expenses primarily related to our European expansion efforts and our Cinryze marketing programs. Additionally, we recorded the following in other operating expenses: (1) an impairment charge of approximately \$8.5 million related to certain assets acquired from Auralis; (2) a charge of approximately \$4.6 million related to the changes in the fair value of the Auralis contingent consideration liability; and, (3) a charge of approximately \$3.4 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin.

We sell Diamorphine in the UK, primarily to hospitals, through approved wholesalers. We began commercial sales of Cinryze and Buccolam in Europe during the fourth quarter of 2011. The revenues and operating income from these sales are not material to our consolidated revenues and operating income for 2011 or 2010.

[Table of Contents](#)*Revenues*

Revenues consisted of the following:

(in thousands)	For the years ended December 31,	
	2011	2010
Net product sales		
Vancocin	\$ 288,893	\$ 259,567
Cinryze	251,201	176,815
Other	4,280	2,630
Total Revenues	<u>\$ 544,374</u>	<u>\$ 439,012</u>

*Net product sales*

In the US, we sell Cinryze to specialty pharmacy/specialty distributors (SP/SD's) who then distribute to physicians, hospitals and patients, among others. In Europe, we sell Cinryze to wholesalers who then distribute the product principally to pharmacies and hospitals.

During the year ended December 31, 2011, net sales of Vancocin increased 11.3% compared to 2010. The increase is primarily due to net realized price growth period over period. The net increase in Vancocin sales includes the negative impact on sales during 2011 of approximately \$5.4 million in sales deductions related to the Medicare Part D coverage gap discount enacted under PPACA which did not impact net sales in 2010. Based upon data reported by IMS Health Incorporated, prescriptions during the year ended December 31, 2011 decreased from the same period in 2010 by 5.6%, which we believe is due to a decrease in the incidence of severe disease, improved aseptic technique and an increase in compounding, both in the hospital and long-term care marketplace. Our net sales of Cinryze during the year ended December 31, 2011 increased \$74.4 million compared to the same period in 2010 due to an increase in the number of patients receiving Cinryze. Approximately \$73.4 million of the Cinryze revenue increase was generated in the US.

Cinryze product sales are influenced by prescriptions and the rate at which new patients are placed on Cinryze, as well as fluctuations in trade and patient inventory levels.

*Cost of sales (excluding amortization of product rights)*

Cost of sales increased for the year ended December 31, 2011 by \$18.7 million as compared to the same period in 2010 primarily due to increased Cinryze volume.

Vancocin and Cinryze cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights.

*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 clinical and development costs. Indirect expenses include personnel, facility, stock compensation and other overhead costs. Due to our support for research exploring the use of Cinryze in additional indications, the acquisition of DuoCort and the Meritage development agreement, as well as cost associated with our efforts to advance additional initiatives intended to increase our Cinryze capacity, advancements in our VP20621 clinical program, and the cost to develop VP-20629 and other compounds, we expect future costs in these programs to increase from historical levels.

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

(in thousands)	For the years ended December 31,	
	2011	2010
<b>Direct</b>		
Cinryze & C1 esterase inhibitor	\$ 23,383	\$ 7,113
CMV	1,028	866
Non-toxicogenic strains of <i>C. difficile</i> (VP20621)	7,653	7,643
VP20629	6,500	—
New Initiatives	2,773	2,279
Other assets	813	2,755
<b>Indirect</b>		
Development	24,327	18,957
<b>Total</b>	<u>\$ 66,477</u>	<u>\$ 39,613</u>

#### *Direct Expenses*

The increase in costs of VP20621 for the year ended December 31, 2011 compared to the same period in 2010 relates to timing of costs associated with our Phase 1 clinical trial and the initiation of our Phase 2 clinical trial during the second quarter of 2011.

Our costs associated with our Cinryze program increased during 2011 compared to 2010 as we incurred costs related to the continuation of our Phase 4 clinical trial and support for research exploring the use of Cinryze in additional indications, and initiation of a Phase 2 study of subcutaneous administration of Cinryze in combination with rHuPH20. In the same period in the prior year, we incurred costs related to the preparation of our Phase 4 clinical trial. During 2011, we made a \$9.0 million upfront payment related to our entering into a license with Halozyme for the development of a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE, and we made a \$3 million payment related to the achievement of a development milestone under our this license arrangement.

Our direct expenses related to our CMV program decreased in 2011 compared to 2010 as we wound down our stem cell and liver transplant studies during 2010.

The increase in costs of VP20621 for the year ended December 31, 2011 compared to the same period in 2010 relates to timing of costs associated with our Phase 1 clinical trial and the initiation of our Phase 2 clinical trial during the second quarter of 2011.

Also during 2011, we incurred a \$6.5 million upfront fee related to our license agreement with INS for the clinical stage drug candidate, VP20629, which is being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease.

Our costs related to New Initiatives represent expenses associated with our evaluation of a recombinant C1-INH technology and spending under our collaboration agreement with Sanquin supporting their Early Stage Research Programs.

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

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*Indirect Expenses*

These costs primarily relate to the compensation of and overhead attributable to our development team.

*Selling, general and administrative expenses (SG&A)*

In 2011 compared to 2010, SG&A increased by \$32.1 million. This increase was primarily driven by higher compensation expense and employee cost of \$14.5 million, increased marketing expenses of \$9.4 million and increased corporate cost of \$3.6 million.

Our European infrastructure and commercialization efforts and new Cinryze marketing programs in the US are predominant reasons for the overall increase in SG&A in both periods. We anticipate that our SG&A spending will continue to increase in future periods as we continue our commercialization and expansion efforts outside the United States.

*Intangible amortization*

Intangible amortization for the year ended December 31, 2011 was \$31.0 million, as compared to \$29.4 million in 2010. The year over year increases are primarily due to the amortization of the Auralis intangible assets acquired in May of 2010.

*Impairment losses*

Due to the approval and launch of Buccolam, coupled with the launch of Cinryze in Europe, we have decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision resulted in the impairment of the IPR&D asset and the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during 2011.

*Other operating expenses*

The re-measurement of the fair value of the contingent consideration given for the acquisition of Auralis resulted in a charge to income of approximately \$4.6 million during 2011. We incurred expense of approximately \$1.4 million for the re-measurement of the fair value of the contingent consideration during 2010. Also included in other operating expenses for 2011 is approximately \$3.4 million of costs associated with the funding of Cinryze manufacturing enhancements at Sanquin.

*Other Income (Expense)**Interest Income*

Interest income for year ended December 31, 2011 was \$0.7 million and \$0.4 million in 2010.

*Interest Expense*

(in thousands)	For the years ended December 31,	
	2011	2010
Interest expense on senior convertible notes	\$ 4,372	\$ 4,100
Amortization of debt discount	7,711	7,129
Amortization of finance costs	557	387
Total interest expense	<u>\$ 12,640</u>	<u>\$ 11,616</u>

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Interest expense and amortization of debt discount and finance costs in 2011 and 2010 relates primarily to the senior convertible notes issued on March 26, 2007. Also include in the 2011 amounts is the amortization of the debt issue cost associated with the \$200 million credit facility entered into during the third quarter of 2011 as well as commitment fees on the unused facility.

*Other income, net*

Our other income, net includes net foreign exchange gains and losses.

*Income Tax Expense*

Our income tax expense was \$67.3 million and \$75.3 million for 2011 and 2010, respectively. Our income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences.

Our effective tax rates for 2011 and 2010 were 32.4% and 37.5%, respectively. Our effective tax rate in 2011 is lower than the statutory U.S. tax rate due to domestic manufacturing tax deductions and a reduction in the valuation allowance for state net operating losses partly offset by state income taxes, and by certain share-based compensation and an increase in the fair value of contingent consideration, neither of which is deductible for tax purposes. Our effective tax rate in 2010 was higher than the statutory U.S. tax rate primarily due to state income taxes and certain share-based compensation that is not tax deductible.

The examination of our 2008 U.S. income tax return concluded during the quarter ended March 31, 2011 with no material adjustments. We are currently under examination in a foreign jurisdiction and by various states. At this time, we do not believe that the results of these examinations will have a material impact on our financial statements.

**Liquidity**

In the near term, we expect that our sources of revenue will continue to arise from Cinryze product sales. However, there are no assurances that demand for Cinryze will continue to grow or that we will be able to maintain adequate supply of product.

We began the commercial sales of Buccolam and Cinryze in Europe during the fourth quarter of 2011 and commercial sales of Plenadren in Europe in the third quarter 2012. The revenues and operating income from these European sales are not material to our consolidated revenues and operating income for years ended December 31, 2011 or 2012. There are no assurances that there will be growing demand for products in Europe or we will be successful in our commercialization efforts in Europe or any other territories we have the rights to sell these drug products.

On April 9, 2012, the FDA denied the citizen petition we filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of generic versions of Vancocin capsules. The FDA also informed us in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin which was approved on December 14, 2011 would not qualify for three additional years of exclusivity, as the agency interpreted Section 505(v) of the FD&C Act to require a showing of a significant new use (such as a new indication) for an old antibiotic such as Vancocin in order for such old antibiotic to be eligible for a grant of exclusivity. FDA also indicated that it approved three abbreviated new drug applications (ANDAs) for generic vancomycin capsules and the companies holding these ANDA approvals indicated that they began shipping generic vancomycin hydrochloride, USP. In June 2012, the FDA approved a fourth ANDA for generic vancomycin capsules.

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The approval of generic copies of Vancocin has and will continue to adversely impact sales of our Vancocin brand prescription products and have a negative impact on our consolidated financial condition and results of operations, including causing a significant decrease in our revenues, operating income and cash flows compared to historical levels. The number of generic competitors ultimately approved by the FDA will impact future sales of Vancocin.

Our ability to generate positive cash flow is also impacted by the timing of anticipated events in our Cinryze, VP20621, maribavir, VP20629, Plenadren and other development programs, including the timing of our expansions into other territories and the costs of our anticipated commercial activities, the scope of the clinical trials required by regulatory authorities, results from clinical trials, the results of our product development efforts, including the OBS development efforts at Meritage 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 commercial efforts, business development activities, general and administrative expenses, debt service, 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 and/or EMA regulatory approval is a time consuming and expensive process. Because we have product candidates that 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, our future costs may exceed current costs as we anticipate we will continue to invest in our pipeline, including our initiative to develop VP20621 (non-toxicogenic strains of *C. difficile*), maribavir, VP20629, any additional studies to identify additional therapeutic uses and expand the labeled indication for Cinryze to potentially include other C1 mediated diseases as well as new modes of administration for Cinryze. Also, we will incur additional costs as we intend to seek to commercialize Cinryze, Buccolam and Plenadren in Europe in countries where we have distribution rights and certain other countries as well as conduct studies to identify additional C1 mediated diseases, such as AMR, and may conduct clinical studies in additional indications in the future, which may be of interest for further clinical development.

During the second quarter of 2012, we recognized cumulative sales of Cinryze in excess of the \$600 million threshold; accordingly, we recorded the liability in the second quarter of 2012 with a corresponding increase to goodwill. We made this CVR payment along with certain other contingent acquisition related payments totaling approximately \$92.3 million in the third and fourth quarters of 2012. These payments, net of related tax benefits, are reflected as an increase to goodwill of approximately \$86.3 million.

On March 14, 2008, we entered into a lease for our corporate office building. The lease agreement had a term of 7.5 years from the commencement date. On August 29, 2012, we entered into an amended and restated lease (the Amended Lease) to expand the corporate headquarters. The Amended Lease expires fifteen years from the "commencement date", which will occur when the landlord has substantially completed the expansion, including any tenant improvements. We currently expect the commencement date to occur during the fourth quarter of 2013. We will continue to make the scheduled lease payments for the existing building through commencement date. At December 31, 2012, our minimum lease payments under the Amended Lease total approximately \$41.0 million. Upon the commencement date the lease payments will escalate annually based upon a consumer price index specified in the lease.

We have the option to renew the lease for two consecutive terms for up to a total of ten years at fair market value, subject to a minimum price per square foot. The first renewal term may be for between three and seven years, at our option, and the second renewal term may be for ten years less the length of the first renewal term .

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Under the terms of the Amended Lease, the landlord is responsible for the cost of construction of the core and shell of the expansion, as defined in the lease, which it will "deliver" to us when complete. We will be responsible for the "fit out" of the core and shell necessary for us to occupy the expanded building.

ASC 840, Leases, is the authoritative literature related to accounting for leases. Based on the results of the lease classification tests we have concluded that the Amended Lease qualifies as an operating lease. However, the lease arrangement involves the construction of expanded office space where we are involved in the design and construction of the expanded space and have the obligation to fund the tenant improvements to the expanded structure and to lease the entire building following completion of construction. This arrangement is referred to as a build-to suit lease. We have concluded that under the guidance of ASC 840-55-15, we are considered the owner of the construction project for accounting purposes and must record a construction in progress asset (CIP) and a corresponding financing obligation for the construction costs funded by the landlord. We anticipate to begin recording the CIP asset and a corresponding financing obligation during the first quarter of 2013 when construction is anticipated to start. Once the construction is complete we will depreciate the core and shell asset over 30 years. A portion of the lease payments will be reflected as principal and interest payments on the financing obligation.

The most significant of our near-term operating development cash outflows are as described under "**Development Programs**" as set forth below.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). The PPACA, as amended, will likely increase certain of our costs as well. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. The PPACA also imposes a manufacturer's fee on the sale of branded Pharmaceuticals (excluding orphan drugs) to specified government programs, expands the 340B drug discount program (excluding orphan drugs), and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "donut hole". The manufacturing fee was immaterial relative to our 2011 and 2012 consolidated operating income and cash flow and we anticipate it to be immaterial to our 2013 operating income and cash flow. The cost associated with the Medicare Part D coverage gap for the year ended December 31, 2012 was immaterial relative to our consolidated operating income and cash flow and we anticipate it to be immaterial to our 2013 consolidated operating income and cash flow due to the impact of generic vancomycin. For the year ended December 31, 2011, the cost of this program, before the introduction of generic vancomycin, was approximately \$5.5 million. We continue to evaluate PPACA to determine not only the immediate effects on our business, but also the trends and changes that may be encouraged by the legislation that may potentially impact our business over time.

In the fourth quarter of 2012, we became aware that certain Vancocin sales made to Government agencies under the Federal Supply Schedule contract between ViroPharma and the Veterans Administration (VA) were not compliant with the Trade Agreements Act. Absent a waiver, the Trade Agreements Act prohibits the sale to the government of products manufactured in non-designated countries, such as China. We have self-reported the discovery to the VA and will work with the VA to address this matter moving forward. The timing and outcome of these discussions are not certain. As such, we are not in a position to determine whether we have any liability or the extent of any such liability. Accordingly, we have not made any provisions for potential fines or penalties related to these potential violations in our consolidated financial statements as of December 31, 2012.

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*Capital Resources*

While we anticipate that cash flows from Cinryze, our current cash, cash equivalents and short-term investments (collectively referred to as our cash) and revolving credit facility should allow us to fund our ongoing development and operating costs, as well as our interest payments and future milestone payments or acquisition costs, we may need additional financing in order to expand our product portfolio. At December 31, 2012, we had cash, cash equivalents and short-term investments of \$246.9 million. Short-term investments consist of high quality fixed income securities with remaining maturities of greater than three months at the date of purchase and high quality debt securities or obligations of departments or agencies of the United States. At December 31, 2012, the annualized weighted average nominal interest rate on our short-term investments was 0.32% and the weighted average length to maturity was 10.7 months. At December 31, 2012, we also had \$200 million available under our revolving credit agreement. As of the date of this filing, we have not drawn any amounts under the Credit Facility and are in compliance with our covenants. However, because of the negative impact of approval of generic vancomycin on our operating results we may not be in compliance with our covenants at times in the near term which may limit the availability under the facility.

At December 31, 2012, approximately \$110.0 million of our cash and availability under the credit agreement is subject to the minimum liquidity covenant, as defined in our credit agreement.

*Financing*

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.

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, 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.

From time to time, we may 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.

***Overall Cash Flows***

During the year ended ended December 31, 2012, we generated \$43.0 million of net cash from operating activities, primarily from our net income adjusted for non-cash items, offset by the increase in prepaid income taxes and the Meritage payment reflected in other assets. Cash used in investing activities of \$38.0 million resulted primarily from the payment of the contingent consideration related to the Lev acquisition and purchase of investments offset by maturities of short-term investments. Our net cash used in financing activities for the year ended December 31, 2012 was \$161.3 million which relates to the common stock repurchases under our share repurchase program net of proceeds and excess tax benefits from stock option exercises.

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We anticipate net cash from operating activities to be adversely affected during 2013 as we build Cinryze inventory to replenish the channel and build safety stock in anticipation of a planned shutdown in 2014 of our manufacturing partners production facility.

During the year ended December 31, 2011, we generated \$170.7 million of net cash from operating activities, primarily from our net income after adjustments for non-cash items, including the charge for the intangible assets impairment, partly offset by our net increase in working capital and our payment of the Auralis contingent consideration. The decrease from 2010 is primarily related to higher cash payments for taxes during 2011. We used \$101.0 million of cash from investing activities mainly in the purchase of short-term investments, net of investment maturities and the acquisition of DuoCort. Our net cash used in financing activities for the year ended December 31, 2011 was \$163.2 million and is primarily attributable to the repurchases of our common stock and our payment of the Auralis contingent consideration.

***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.

*Cinryze*—We acquired Cinryze in October 2008 and through December 31, 2012 have spent approximately \$42.8 million in direct research and development costs related to Cinryze since acquisition. During 2012, we continue to expect research and development costs related to Cinryze to increase as we complete our Phase 4 commitment and evaluate additional indications, formulations and territories including our efforts on the C1 esterase inhibitor/rHuPH20 combination sub-subcutaneous formulation and AMR. We are solely responsible for the costs of Cinryze development. In the first quarter of 2012, we completed a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 and announced the presentation of positive data. We initiated additional Phase 2 studies of subcutaneous administration of Cinryze in combination with rHuPH20 in late 2012 and we will continue to evaluate the subcutaneous administration of Cinryze as a standalone therapy. We are also investigating recombinant forms of C1-INH, which may be included in future clinical studies. As such we anticipate that costs associated with our Cinryze program to increase in future periods.

*CMV program*—We acquired the rights to maribavir in September 2003 and through December 31, 2012 have spent approximately \$100.4 million in direct research and development costs. We expect our research and development activities related to maribavir to increase. During the second quarter of 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV infections in transplant recipients. The program consists of two independent Phase 2 clinical studies that will include subjects who have asymptomatic CMV, and those who have failed therapy with other anti-CMV agents. During the third quarter of 2012, we presented interim data from the Phase 2 open label clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV. Results from this study as well as data from a second Phase 2 open label study of maribavir as a treatment for patients with refractory cases of CMV will periodically be evaluated.

*VP20621*—We acquired VP20621 in February 2006 and through December 31, 2012 have spent approximately \$31.5 million in direct research and development costs. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD. We presented interim data from this study during the third quarter of 2012. Based on the interim data, we completed enrollment

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of patients in December 2012 and anticipate having the complete data in 2013. We are solely responsible for the costs of VP20621 development. In the event the data is supportive of continued clinical development, we expect our research and development expenses related to VP20621 to increase in future periods.

*VP20629*—On September 30, 2011, we entered into a license agreement with Intellect Neurosciences, Inc. (INS) for the worldwide rights to its clinical stage drug candidate, VP20629, which we expect to develop for the treatment of Friedrich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a single and repeat dose phase 1 study in patients in 2013 and expect to initiate a subsequent phase 2 study after completion of the phase 1 study. Following completion of the phase 2 study, a phase 3 study is planned. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP20629 for the treatment, management or prevention of any disease or condition covered by Intellect's patents. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales. We are solely responsible for the costs of VP20629 development.

*Plenadren*—We acquired Plenadren in November 2011. The cost incurred to date relate to our relate to our open label trial and registry study.

*Vancocin*—We acquired Vancocin in November 2004. As a result of the FDA approval of generic versions of oral vancomycin, we do not anticipate any future research and development expenses related to Vancocin.

We may make additional investments in assets or programs in the future. These investments will be dependent on our assessment of the potential future commercial success of or benefits from the asset. We will continue to incur costs under our collaboration agreement with Sanquin supporting their early stage research programs.

***Business Development Activities***

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. As consideration for the option, we paid an initial \$7.5 million.

During the second quarter of 2012, Meritage completed the delivery of all the documents and notifications needed to satisfy the conditions of the First Option Milestone, as defined in the agreement. As a result of achieving this milestone we made a \$5.0 million milestone payment in the third quarter of 2012 and increased the carrying value of our cost method investment. We retain the option to provide Meritage up to an additional \$7.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. If we exercise our option to acquire Meritage, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency (AI). We paid approximately 213 million

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Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$37 million to \$132 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$25 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$108 million of the contingent payments are related to commercial milestones based on the success of the product.

On September 30, 2011, we entered into a license agreement for the worldwide rights of Intellect Neurosciences, Inc. (INS) to its clinical stage drug candidate, VP20629, being developed for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We paid INS a \$6.5 million up-front licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales. We are solely responsible for the costs of VP20629 development.

In May 2011, Halozyme Therapeutics, Inc. (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop a novel subcutaneous formulation of Cinryze for routine prophylaxis against attacks. Under the terms of the license agreement, we paid Halozyme an initial upfront payment of \$9 million. In the fourth quarter of 2011, we made a milestone payment of \$3 million related to the initiation of a Phase 2 study begun in September 2011 to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. Pending successful completion of an additional series of clinical and regulatory milestones, which began during 2012, we may make further milestone payments to Halozyme which could reach up to an additional \$41 million related to HAE and up to \$30 million of additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyme until specified events have occurred. Upon regulatory approval, Halozyme will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

We intend to continue 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.

***Share Repurchase Program***

On March 9, 2011, our Board of Directors authorized the use of up to \$150 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. On September 14, 2011, our Board of Directors authorized the use of up to an additional \$200 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. On September 7, 2012, our Board of Directors authorized the use of up to an additional \$200 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. Purchases may be made by means of open market transactions, block transactions, privately negotiated purchase transactions or other techniques from time to time.

During 2012, through open market purchases, we reacquired approximately 6.9 million shares at a cost of approximately \$180.3 million or an average price of \$26.20 per share and during 2011, we reacquired approximately 9.2 million shares at a cost of approximately \$169.7 million or an average

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price of \$18.52 per share. At December 31, 2012, we had \$200 million available under the Board authorizations to repurchase shares of our common stock and/or our 2% Senior Convertible Notes.

From time to time, we may 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.

***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.

The debt and equity components of our senior 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 is 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. Accordingly, the senior convertible debt securities will recognize interest expense at effective rate of 8.0% as they are accreted to par value.

As of December 31, 2012, senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$161.8 million and a fair value of approximately \$284.6 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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

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 cost of the transactions was \$23.3 million.

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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 our common stock on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options (\$18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants.

Initially, the purchased call options and warrants sold with the terms described above were based upon the \$250.0 million offering, and the number of shares we would purchase under the call option and the number of shares we would sell under the warrants was 13.25 million, to correlate to the \$250.0 million principal amount. 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. 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 a result of the above negotiated sale and purchase transactions, we are now entitled to receive approximately 10.87 million shares of our 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, which correlates to \$205 million of convertible notes outstanding.

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.

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As long as the instruments are classified in stockholders' equity they are not subject to the mark to market provisions.

The senior convertible notes were convertible into shares of our common stock during the second quarter and fourth quarters of 2012 at the election of the holders as the last reported sale price of our common stock for the 20 or more trading days in the 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeded 130% of the conversion price, \$18.87 per share. No notes were converted

***Credit Facility***

In September 2011, we entered into a \$200 million, three-year senior secured revolving credit facility (the "Credit Facility"), the terms of which are set forth in a Credit Agreement dated as of September 9, 2011 (the "Credit Agreement") with JPMorgan Chase Bank, N.A., as administrative agent, BMO Harris Financing Inc., TD Bank, N.A. and Morgan Stanley Bank, NA as co-syndication agents and certain other lenders.

The Credit Facility is available for working capital and general corporate purposes, including acquisitions which comply with the terms of the Credit Agreement. The Credit Agreement provides separate sub-limits for letters of credit up to \$20 million and swing line loans up to \$10 million.

The Credit Agreement requires us to maintain (i) a maximum senior secured leverage ratio of less than 2.00 to 1.00, (ii) a maximum total leverage ratio of less than 3.50 to 1.00, (iii) a minimum interest coverage ratio of greater than 3.50 to 1.00 and (iv) minimum liquidity equal to or greater than the sum of \$100 million plus the aggregate amount of certain contingent consideration payments resulting from business acquisitions payable by us within a specified time period. The Credit Agreement also contains certain other usual and customary affirmative and negative covenants, including but not limited to, limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with affiliates.

Our obligations under the Credit Facility are guaranteed by certain of our domestic subsidiaries (the "Subsidiary Guarantors") and are secured by substantially all of our assets and the assets of the Subsidiary Guarantors. Borrowings under the Credit Facility will bear interest at an amount equal to a rate calculated based on the type of borrowing and our senior secured leverage ratio (as defined in the Credit Agreement) from time to time. For loans (other than swing line loans), we may elect to pay interest based on adjusted LIBOR plus between 2.25% and 2.75% or an Alternate Base Rate (as defined in the Credit Agreement) plus between 1.25% and 1.75%. We will also pay a commitment fee of between 35 to 45 basis points, payable quarterly, on the average daily unused amount of the Credit Facility based on our senior secured leverage ratio from time to time.

As of the date of this filing, we have not drawn any amounts under the Credit Facility and are in compliance with our covenants. However, as a result of the negative impact of approval of generic vancomycin on our consolidated operating results, our ability to borrow the full \$200 million provided under Credit Facility during portions of 2013 and 2014 may be limited or prohibited. Limitations on our ability to borrow under the Credit Facility could impact our liquidity and limit our ability to fund general corporate requirements, such as research and development expenses, or to make acquisitions.

At December 31, 2012, approximately \$110.0 million of our cash and availability under the credit agreement is subject to the minimum liquidity covenant (iv), described above.

[Table of Contents](#)**Contractual Obligations**

Future contractual obligations and commercial commitments at December 31, 2012 are as follows:

(in thousands) Contractual Obligations(1)(2)	Total	1 year or less	2-3 years	4-5 years	More than 5 years
Operating leases(3)	\$ 46,561	\$ 1,935	\$ 5,947	\$ 6,246	\$ 32,433
Senior convertible notes(4)	223,450	4,100	8,200	211,150	—
Collaboration agreements(5)	2,644	1,322	1,322	—	—
Purchase obligations(6)	477,767	97,487	221,007	159,273	—
Total	<u>\$ 750,422</u>	<u>\$ 104,844</u>	<u>\$ 236,476</u>	<u>\$ 376,669</u>	<u>\$ 32,433</u>

- (1) This table does not include any contingent consideration related to our business combinations. We account for this contingent consideration as a liability and recognize changes in its fair value in operating income. We will continue to recognize such fair value changes in income until the ultimate disposition or settlement of this liability. Nor does this table include any milestone payments under our licensing arrangements. We have several license agreements where we may pay up to \$191 million in milestone payments based on the occurrence of defined events. In connection with the development and option agreement with Meritage we retain the option to provide Meritage up to an additional \$7.5 million for the development of OBS. We have an exclusive option to acquire Meritage, at our sole discretion. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage.
- (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.
- (3) Operating leases represent building and equipment leases. Operating lease payments reflect estimates minimum lease payment per the terms of our amended and restated lease to expand the corporate headquarters. The amended lease expires fifteen years from the commencement date, which will occur when the landlord has substantially completed the expansion, including any tenant improvements. We currently expect the commencement date to occur during the fourth quarter of 2013. Upon the commencement date the lease payments will escalate annually based upon a consumer price index specified in the lease.
- (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 \$1.3 million) per year for a period of five years.
- (6) We have committed to purchase up to 395,000 liters of plasma in 2013 and up to 450,000 liters of plasma per year in 2014 through 2017 from our suppliers. 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.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of December 31, 2012.

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**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 accounting 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, 2012. 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 Cinryze, Buccolam, Plenadren, Vancocin branded and authorized generic product, and Diamorphine, 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, returns 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 defer recognition of revenue on a 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. Our external resources include written and verbal information obtained from our three distribution partners 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

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and interpretations. We analyze the accrual at least quarterly and adjust the balance as needed. These analyses have been adjusted to reflect the U.S. healthcare reform acts and their affect on governmental contractual prices and rebates. We believe that a 10% change in our estimate of the actual rate of sales subject to governmental rebates would affect our consolidated operating income and accruals by approximately \$2.0 million in the period of adjustment.

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.

Under the PPACA we are required to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients starting on January 1, 2011. For Vancocin sales subject to this discount we recognize this cost using an effective rebate percentage for all sales to Medicare patients throughout the year. For applicable Cinryze sales we recognize this cost at the time of sale for product expected to be purchased by a Medicare Part D insured patient when we estimate they are within the coverage gap.

Product return accruals are estimated based our products history of damage and product expiration returns and are recorded in the period in which we record the sale of revenue. There is a no returns policy with sales of generic Vancocin to our distributor and Cinryze has a no returns policy. Returns of product for our European sales depends on the country of sale in Europe. Where returns are not mandated by laws or regulations we generally have a no returns policy. Where returns are required to be taken back we defer revenue recognition until we receive information from our distribution partners that the drug has been consumed.

In April 2012, we began selling an authorized generic version of our prescription Vancocin capsules under a supply agreement with a distributor. The distributor has agreed to purchase all of its authorized generic product requirements from us and pay a specified invoice supply price for such products. We are also entitled to receive a percentage of the gross margin on net sales of the authorized generic products sold by the distributor. We recognize revenue from shipments to the distributor at the invoice supply price along with our percentage of the gross margin on net sales of the authorized generic products sold by the distributor when the distributor reports to us its gross margin on net sales of the products and our portion thereof. Any adjustments to the net sales previously reported to us related to the distributor's estimated sales discounts and other deductions are recognized in the period the distributor reports the adjustments to us.

- Impairment of Long-lived Assets—We test our long-lived fixed and intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

ASC 360-10-35 provides guidance with respect to the measurement of impairment. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment are subjective and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods.

On an ongoing periodic basis, we evaluate the useful life of our long-lived assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives.

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ASC 350-30-35 provides guidance on determining the finite useful life of a recognized intangible asset wherein it defines the useful life of an intangible asset is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of an entity.

It also states that the estimate of the useful life of an intangible asset to an entity shall be based on an analysis of all pertinent factors, in particular, all of the following factors with no one factor being more presumptive than the other:

- a. The expected use of the asset by the entity.
- b. The expected useful life of another asset or a group of assets to which the useful life of the intangible asset may relate.
- c. Any legal, regulatory, or contractual provisions that may limit the useful life. The cash flows and useful lives of intangible assets that are based on legal rights are constrained by the duration of those legal rights. Thus, the useful lives of such intangible assets cannot extend beyond the length of their legal rights and may be shorter.
- d. The entity's own historical experience in renewing or extending similar arrangements, consistent with the intended use of the asset by the entity, regardless of whether those arrangements have explicit renewal or extension provisions. In the absence of that experience, the entity shall consider the assumptions that market participants would use about renewal or extension consistent with the highest and best use of the asset by market participants, adjusted for entity-specific factors in this paragraph.
- e. The effects of obsolescence, demand, competition, and other economic factors (such as the stability of the industry, known technological advances, legislative action that results in an uncertain or changing regulatory environment, and expected changes in distribution channels).
- f. The level of maintenance expenditures required to obtain the expected future cash flows from the asset (for example, a material level of required maintenance in relation to the carrying amount of the asset may suggest a very limited useful life). As in determining the useful life of depreciable tangible assets, regular maintenance may be assumed but enhancements may not.

Further, if an income approach is used to measure the fair value of an intangible asset, in determining the useful life of the intangible asset for amortization purposes, an entity shall consider the period of expected cash flows used to measure the fair value of the intangible asset adjusted as appropriate for the entity-specific factors noted.

Our most significant long-lived assets are our acquired intangible assets (see Note 6 to the consolidated financial statements), the largest of which are our Cinryze and Vancocin intangible assets.

#### **Cinryze**

In October 2008, Cinryze was approved by the FDA for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE. Because the treatment indication is directed at a small population in the United States, orphan drug status was awarded by the FDA and orphan drug exclusivity was granted on the date of approval. Orphan drug exclusivity awards market exclusivity for seven years. These seven years of exclusivity prevent the FDA from approving another product with the same active ingredient for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE through October 2015. In addition, a biosimilar version of Cinryze could not be approved before 2020 as a result of data protection provisions contained in the relevant biosimilar regulations.

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As of December 31, 2012, the carrying amount of this intangible asset is approximately \$433.6 million. We are amortizing this asset over its estimated 25 year useful life, through October 2033, or 18 years beyond the orphan exclusivity period and 13 years beyond the data protection period for biosimilar versions.

Our estimate of the useful life of Cinryze was based primarily on the following four considerations: 1) the exclusivity period granted to Cinryze as a result of marketing approval by the FDA with orphan drug status; 2) the landscape subsequent to the exclusivity period and the ability of follow-on biologics (FOB) entrants to compete with Cinryze; 3) the financial projections of Cinryze for both the periods of exclusivity and periods following exclusivity; and 4) barrier to entry for potentially competitive products.

When determining the post exclusivity landscape for Cinryze we concluded that barriers to entry for competitors to Cinryze are greater than other traditional biologics. They include, but are not limited to the following. Cinryze treats a known population base of approximately 4,600 patients. HAE is generally thought to afflict approximately 10,000 people in the United States, but many of whom have not yet been diagnosed. Therefore the market upside for potential competitors is limited. The capital investment for a potential competitor to construct a manufacturing facility is prohibitive and would limit the number of participants willing to enter the prophylactic HAE market. In order to qualify for the abbreviated approval process for biosimilar versions of biologics licensed under full BLAs ("reference biologics") a biosimilar applicant generally must submit analytical, animal, and clinical data showing that the proposed product is "highly similar" to the reference product and has no "clinically meaningful differences" from the reference product in terms of the safety, purity, and potency, although FDA may waive some or all of these requirements. FDA cannot license a biosimilar until 12 years after it first licensed the reference biologic. It is therefore likely that a biosimilar would have to conduct clinical trials to show that a FOB is highly similar to Cinryze and has no clinically meaningful differences. To conduct these trials, one must produce enough drug to sustain a trial and attract the required number of HAE patients to prove safety and efficacy comparable to Cinryze. Patients on Cinryze are those HAE patients who experience life threatening laryngeal attacks, or frequent attacks that inhibit their quality of life and/or ability to work. To obtain patients for a clinical trial, the FOB company will have to convince patients to stop taking this life saving drug and test a new unproven product. We believe that this would be met with great resistance from both patients and doctors and would limit the ability of a FOB company to perform clinical trials.

At present, one C1 inhibitor has received approval from FDA for the acute indication with de minimus impact on the prophylactic market, primarily due to the payor environment. Though we might see competition at some point in the future, we believe it would be limited.

Based on the expected cash flows and value generated in the years following both the end of exclusivity and the potential entry of FOB competition, we concluded that estimated useful life of 25 years for the Cinryze product rights was appropriate.

#### **Vancocin**

We acquired Vancocin from Lilly in November of 2004 and determined that the identifiable intangible assets acquired had a 25 year useful life based consideration of the various factors in ASC 350-30-35 described above. Additionally, an income approach was used by an outside independent valuation expert to determine the fair value of these assets and a 25 year period of expected cash flows was used in this asset valuation process. As of December 31, 2012, the carrying amount of the assets is approximately \$113.3 million with a remaining estimated useful life of approximately 17 years.

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In April 2012, FDA denied the citizen petition filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of generic versions of Vancocin Capsules. In the FDA's response to the citizen petition, the agency denied our citizen petition. The FDA also informed us in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin approved December 14, 2011 would not qualify for three additional years of exclusivity based on the agency's assertion that in order for an sNDA for an old antibiotic such as Vancocin to be eligible for a grant of exclusivity, it must be a significant new use or indication. To date, FDA has approved four abbreviated new drug applications (ANDAs) for generic vancomycin capsules

We, along with the approved generic drug makers, began shipping generic vancomycin hydrochloride, USP, in addition to continuing the sales of Vancocin.

As a result of the actions of FDA, we performed step one of the impairment test in the first quarter of 2012 based on our current forecast (base case) of the impact of generics on our Vancocin and vancomycin cash flows. The sum of the undiscounted cash flows exceeded the carrying amount as of March 31, 2012 by approximately \$210 million. During the third quarter of 2012, we experienced larger than anticipated erosion in the sales volume and net realizable price in the Vancocin Branded Market and the entrance of a fourth generic competitor which prompted us to determine it appropriate to perform the step one of the impairment test again as of September 30, 2012. The sum of the undiscounted cash flows exceeded the carrying amount as of September 30, 2012 by approximately \$34 million.

As part of this analysis, we concluded that the erosion in vancomycin revenue in the third quarter of 2012 was due to customers working down their inventory and steeper generic competition. We believe that once the channel inventory is normalized to the new levels, our sales will begin to reflect the ongoing underlying prescription activity. Additionally, we will benefit from the expiration of the Genzyme royalty beginning in 2015. There were no events during the fourth quarter of 2012 that would have indicated the need to perform another step one of the impairment test for Vancocin. However, should future events occur that cause further reductions in revenue or operating results we would incur an impairment charge, which would be significant relative to the carrying value of the intangible assets as of December 31, 2012.

- **Impairment of Goodwill and Indefinite-lived Intangible Assets**—We review the carrying value of goodwill and indefinite-lived intangible assets, to determine whether impairment may exist. In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-08, Testing Goodwill for Impairment (the Update). The objective of this Update is to simplify how entities test goodwill for impairment. The amendments in the Update provide the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The two step goodwill impairment test consists of the following steps. The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an

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amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments which would then require an assessment in the period which a triggering event occurred.

- **Share-Based Payments**—We record the estimated grant date fair value of awards granted as stock-based compensation expense in our consolidated statements of operations over the requisite service period, which is generally the vesting period.
- **Income Taxes**—Our annual effective tax rate is based on pre-tax earnings, enacted tax laws and statutory tax rates, determination of manufacturing income and related deduction limits, 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 effective tax rate.

On a periodic basis, we evaluate the realizability of our deferred tax assets and adjust such amounts in light of changing facts and circumstances, including but not limited to projections of future 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. As part of this evaluation, we consider whether it is more likely than not that all or some portion of the deferred tax asset will not be realized. The ultimate realization of a deferred tax asset is dependent upon the generation of future taxable income during the period in which the related temporary difference becomes deductible or the NOL and credit carryforwards can be utilized. With respect to the reversal of valuation allowances, we consider the level of past and future taxable income, the existence and nature of reversing deferred tax liabilities, the utilization of 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.

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 tax expense in the year of resolution.

- **Acquisition Accounting**—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.

The total purchase price of businesses acquired will be allocated to the net tangible assets and identifiable intangible assets based on their fair values as of the date of the acquisition and the fair value of any contingent consideration. Changes in the fair value of contingent consideration will be expensed in the period in which the change in fair value occurs. 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

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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 judgements.

#### **Recently Issued Accounting Pronouncements**

In February, 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (Topic 220)*. The standard requires that public and non-public companies present information about reclassification adjustments from accumulated other comprehensive income in their annual financial statements in a single note or on the face of the financial statements. Public companies will also have to provide this information in their interim financial statements. The standard requires that companies present either in a single note or parenthetically on the face of the financial statements, the effect of significant amounts reclassified from each component of accumulated other comprehensive income based on its source and the income statement line items affected by the reclassification. If a component is not required to be reclassified to net income in its entirety, companies must instead cross reference to the related footnote for additional information. The standard allows companies to present the information either in the notes or parenthetically on the face of the financial statements provided that all of the required information is presented in a single location. The new disclosure requirements are effective for fiscal years, and interim periods within those years, beginning after December 15, 2012. The adoption of the provisions of this guidance will not have a material impact on our consolidated results of operations, cash flows, and financial position.

In July 2012, the FASB issued ASU 2012-02, *Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* (the revised standard). The objective of this ASU is to simplify how entities test indefinite-lived intangible assets other than goodwill for impairment. The amendments in the ASU provide the option to first assess qualitative factors to determine whether, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) the asset is impaired and it is necessary to calculate the fair value of the asset in order to compare that amount to the carrying value to determine the amount of the impairment, if any. If an entity believes, as a result of its qualitative assessment, that it is not more-likely-than-not (a likelihood of more than 50%) that the fair value of a asset is less than its carrying amount, no further testing is required. The revised standard includes examples of events and circumstances that might indicate that the indefinite-lived intangible asset is impaired. The approach in the ASU is similar to the guidance for testing goodwill for impairment contained in ASU 2011-08, *Intangibles—Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. The revised standard, which may be adopted early, is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and does not change existing guidance on when to test indefinite-lived intangible assets for impairment. The adoption of the provisions of this guidance is not expected to have a material impact on our consolidated results of operations, cash flows, and financial position.

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In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, and the IASB issued IFRS 13, *Fair Value Measurement*. The new guidance results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between U.S. GAAP and IFRS. The ASU is effective for interim and annual periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance changes certain fair value measurement principles and disclosure requirements. We adopted this ASU January 1, 2012. The adoption of the provisions of this guidance did not have a material impact on our consolidated results of operations, cash flows, and financial position.

In June 2011, the FASB issued ASU 2011-05, *Presentation of Comprehensive Income* (Topic 220). This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to enhance comparability between entities that report under US GAAP and those that report under IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. Under the ASU, an entity can elect to present items of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts, net income and other comprehensive income, would need to be displayed under either alternative. The statement(s) would need to be presented with equal prominence as the other primary financial statements. This ASU does not change items that constitute net income and other comprehensive income, when an item of other comprehensive income must be reclassified to net income or the earnings-per-share computation (which will continue to be based on net income). The new US GAAP requirements are effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. We adopted this ASU January 1, 2012. The adoption of the provisions of this guidance did not have a material impact on our consolidated results of operations, cash flows, and financial position.

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

Our holdings of financial instruments are primarily comprised of money market funds holding only U.S. government securities and fixed income securities, including a mix of corporate debt and 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. We generally invest in financial instruments with maturities of less than one year. The carrying amount, which approximates fair value based on the level 1 valuation hierarchy of the fair value measurement standard, and the annualized weighted average nominal interest rate of our investment portfolio at December 31, 2012, was approximately \$71.3 million and 0.32%, respectively. The weighted average length to maturity was 10.7 months. A one percent change in the interest rate would have resulted in an approximately \$0.7 million impact to interest income for the year ended December 31, 2012.

At December 31, 2012, 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

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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, 2012, the fair value of the principal of the \$205.0 million convertible senior notes outstanding was approximately \$284.6 million, based on the level 2 valuation hierarchy of the fair value measurements standard. The carrying value of the debt at December 31, 2012 is \$161.8 million.

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.

The senior convertible notes were convertible into shares of our common stock during the second quarter and fourth quarters of 2012 at the election of the holders as the last reported sale price of our common stock for the 20 or more trading days in the 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeded 130% of the conversion price, \$18.87 per share. No notes were converted

Additionally, if we were to utilize amounts under our revolving credit facility, we could be exposed to interest rate risk.

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

Our financial statements required by this item are attached to this Report beginning on page 116.

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

Not Applicable.

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## 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, 2012. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2012 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, 2012, 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 are 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

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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, 2012. 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, 2012, 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 which appears on the next page.

[Table of Contents](#)**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, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). ViroPharma Incorporated'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 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, ViroPharma Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, 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 ViroPharma Incorporated and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2012, and our report dated February 27, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
February 27, 2013

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**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](http://www.viropharma.com) under the investing—corporate governance section. In addition, hard copies can be obtained free of charge through our investor relations department. Any amendments to, or waivers from, a provision of our code of ethics that applies to our principal executive officer, principal financial officer, controller, or persons performing similar functions and that relate to any element of the code of ethics enumerated in paragraph (b) of Item 406 of Regulation S-K shall be disclosed by posting such information on our website.

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

**ITEM 11. EXECUTIVE COMPENSATION**

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

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

**Equity Compensation Plans**

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

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The following table gives information about equity awards under our 1995 Plan, 2001 Plan, 2005 Plan and ESPP as of December 31, 2012:

<u>Plan Category</u>	<u>(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>(b) Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>(c) Number of remaining securities available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by securities holders (the 1995 Plan, 2005 Plan and the ESPP)	9,122,578 <sup>(1)</sup>	15.31 <sup>(2)</sup>	5,063,901
Equity compensation plans not approved by security holders (the 2001 Plan)	80,742	\$ 9.88	—
Total	<u>9,203,320</u>	<u>\$ 15.26</u>	<u>5,063,901</u>

- (1) Does not include rights granted under the ESPP for which rights were granted in connection with the 4-month offering period that commenced in January 2013. The next scheduled purchase date under the Employee Stock Purchase Plan is April 30, 2013.
- (2) The weighted-average exercise price includes only the price for 8,734,089 options outstanding under the plans at December 31, 2012.

### 2001 Equity Incentive Plan

In November 2001, our board of directors adopted the 2001 Plan, which has not been submitted to or approved by stockholders. The 2001 Plan reserved for issuance up to 500,000 shares of our common stock, of which a maximum of 10% may have been awarded and sold or granted as restricted shares and the remainder may have been issued pursuant to the exercise of options granted under the plan. The number of shares available for previously granted but unexercised options are subject to adjustment for any future stock dividends, splits, mergers, combinations, or other changes in capitalization as described in the 2001 Plan. No shares remain available for future grant under this plan, however previously granted but unexercised options remain outstanding.

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

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

Options granted to employees may become exercisable based on the attainment of certain vesting conditions as may be set forth in the award agreement (as determined by the board or committee)—for example, an option may become exercisable if the optionee remains employed by us until a specified

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date, or if specified performance goals have been met. If a participant's employment terminates for any reason, the vested portion of an option remains exercisable for a fixed period of three months from the date of the participant's termination, and all of the restricted shares then subject to restrictions will be forfeited. If restricted shares are forfeited, we will refund to the participant the amounts paid for the restricted shares.

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

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

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

The remainder of 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.

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<u>Exhibit No.</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Company.(19) (Exhibit 3.1)
3.2	Amended and Restated By-Laws of the Company.(1) (Exhibit 3.1)
4.1	Form of Indenture dated March 19, 2007 between the Company and Wilmington Trust Company, as Trustee.(5) (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.(14) (Exhibit 4.1)
10.1††	Form of Employment Agreement.(9) (Exhibit 10.1)
10.2	Form of Indemnification Agreement.(9) (Exhibit 10.2)
10.3	Investment Agreement among ViroPharma Incorporated and Perseus-Soros Biopharmaceutical Fund, L.P. dated May 5, 1999.(4) (Exhibit 10.21)
10.4††	2001 Equity Incentive Plan.(6) (Exhibit 10.33)
10.5†	License Agreement dated August 8, 2003 by and between GlaxoSmithKline and ViroPharma Incorporated.(3) (Exhibit 10.35)
10.6†	Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated October 18, 2004.(7) (Exhibit 2.1)
10.7†	Amendment No. 1 to the Assignment, Transfer and Assumption Agreement between ViroPharma Incorporated and Eli Lilly and Company dated November 8, 2004.(7) (Exhibit 2.2)
10.8††	ViroPharma Severance Plan.(9) (Exhibit 10.37)
10.9††	ViroPharma Cash Bonus Plan.(15) (Exhibit 10.2)
10.10††	ViroPharma Board Compensation Policy.(27) (Exhibit 10.10)
10.11††	Amended and Restated 1995 ViroPharma Stock Option and Restricted Share Plan.(8) (Annex A)
10.12††	ViroPharma Incorporated Amended and Restated 2005 Equity Incentive Plan.(13) (Exhibit 10.3)
10.13††	Form Of Non-Qualified Stock Option Agreement For Members Of The Board Of Directors.(10) (Exhibit 10.2)
10.14††	Form Of Non-Qualified Stock Option Agreement.(10) (Exhibit 10.3)
10.15††	Form of Incentive Stock Option Agreement.(10) (Exhibit 10.4)
10.16†	Master Agreement by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated effective as of December 1, 2005.(11) (Exhibit 10.41)
10.17†	Project Agreement No. 1 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated.(11) (Exhibit 10.42)
10.18†	Project Agreement No. 2 by and between OSG Norwich Pharmaceuticals, Inc. and ViroPharma Incorporated dated May 15, 2006.(12) (Exhibit 10.2)



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<u>Exhibit No.</u>	<u>Description</u>
10.19	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.(14) (Exhibit 10.1)
10.20	Confirmation of Convertible Bond Hedge Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association.(14) (Exhibit 10.2)
10.21	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.(14) (Exhibit 10.3)
10.22	Confirmation of Issuer Warrant Transaction, dated as of March 20, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association.(14) (Exhibit 10.4)
10.23	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.(14) (Exhibit 10.5)
10.24	Amendment to Confirmation of Issuer Warrant Transaction, dated as of March 22, 2007, by and between ViroPharma Incorporated and Wells Fargo Bank, National Association.(14) (Exhibit 10.6)
10.25	Agreement and Plan of Merger, dated as of July 15, 2008, by and among ViroPharma Incorporated, HAE Acquisition Corp., and Lev Pharmaceuticals, Inc.(2) (Exhibit 2.1)
10.26	Form of Contingent Value Rights Agreement, by and among ViroPharma Incorporated, Lev Pharmaceuticals, Inc. and StockTrans, Inc.(2) (Exhibit 10.1)
10.27†	Agreement for the Purchase and Sale of Blood Plasma with DCI Management Group, LLC dated July 12, 2007(17) (Exhibit 10.1)
10.28	Form of Partial Unwind Agreement with respect to the Note Hedge Transaction Confirmation between ViroPharma Incorporated and Credit Suisse International(20) (Exhibit 10.1)
10.29	Form of Partial Unwind Agreement with respect to the Warrant Confirmation between ViroPharma Incorporated and Credit Suisse International(20) (Exhibit 10.2)
10.30	Form of Partial Unwind Agreement with respect to the Note Hedge Transaction Confirmation between ViroPharma Incorporated and Wells Fargo Bank, National Association(20) (Exhibit 10.3)
10.31	Form of Partial Unwind Agreement with respect to the Warrant Confirmation, dated July 11, 2007 between ViroPharma Incorporated and Wells Fargo Bank, National Association(20) (Exhibit 10.4)
10.32††*	Amended and Restated ViroPharma Incorporated 2000 Employee Stock Purchase Plan.
10.33††	Form of Amended and Restated Change of Control Agreement with the Executive Officers.(24) (Exhibit 10.1)
10.34†	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.(21) (Exhibit 10.4)

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<u>Exhibit No.</u>	<u>Description</u>
10.35†	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.(22) (Exhibit 10.1)
10.36†	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) (19) (Exhibit 10.63)
10.37†	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)(19) (Exhibit 10.64)
10.38†	Exclusive License Agreement dated as of February 20, 2006 by and between ViroPharma Incorporated and Dale N. Gerding, M.D.(19) (Exhibit 10.65)
10.39†	Amendment Number 2 to the Agreement for the Purchase and Sale of Blood Plasma dated as of February 5, 2010, by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated and DCI Management Group LLC.(23) (Exhibit 10.2)
10.40†	Second Amended and Restated Bulk Material Supply Agreement, effective January 1, 2011, by and between ViroPharma Incorporated and Xellia Pharmaceuticals, Inc.(27) (Exhibit 10.50)
10.41†	Amended and Restated Bulk Material Supply Letter Agreement dated December 14, 2010 by and between ViroPharma Incorporated and Xellia Pharmaceuticals, Inc.(27) (Exhibit 10.51)
10.42††	Form of Restricted Share Unit Award Agreement.(27) (Exhibit 10.52)
10.43††	Form of Performance Share Unit Award Agreement.(24) (Exhibit 10.53)
10.44†	Collaboration and License Agreement between ViroPharma SPRL and Halozyme Inc., dated May 10, 2011.(25) (Exhibit 10.1)
10.45†	Second Amendment to Project Agreement No. 2 between ViroPharma Incorporated and Norwich Pharmaceuticals, Inc., dated May 25, 2011.(25) (Exhibit 10.2)
10.46	Credit Agreement, dated as of September 9, 2011, among the Company, the lenders named therein, JPMorgan Chase Bank, N.A., as administrative agent, and BMO Harris Financing Inc., TD Bank, N.A. and Morgan Stanley Bank, NA as co-syndication agents.(26) (Exhibit 10.1)
10.47†	Exclusive License Agreement by and among ViroPharma Incorporated, Intellect Neurosciences, Inc. And Intellect USA, Inc. dated September 29, 2011.(26) (Exhibit 10.2)
10.48†	Exclusive Clinical Study and Data License Agreement, dated June 12, 2009, by and between ViroPharma Incorporated and Genzyme Corporation.(28) (Exhibit 10.58)
10.49	Amendment No. 1 to Exclusive Clinical Study and Data License Agreement, by and between Genzyme Corporation and ViroPharma Incorporated, effective as of October 22, 2009.(28) (Exhibit 10.59)
10.50†	Amendment No. 2 to Exclusive Clinical Study and Data License Agreement, by and between Genzyme Corporation and ViroPharma Incorporated, effective as of April 5, 2010.(28) (Exhibit 10.60)

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<u>Exhibit No.</u>	<u>Description</u>
10.51†	Share Purchase Agreement, dated October 26, 2011, by and between DuoCort AB and Goldcup 6975 AB.(28) (Exhibit 10.61)
10.52†	Development and Option Agreement, dated December 22, 2011, by and between ViroPharma Incorporated and Meritage Pharma, Inc.(29) (Exhibit 10.62)
10.53†	Amendment to Intermediate Supply Agreement by and between the Company and Biotest AG dated February 28, 2012.(30) (Exhibit 10.1)
10.54	Third Amendment to the Agreement for the Purchase and Sale of Blood Plasma dated as of May 22, 2012, by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated, and DCI Management Group LLC.(18) (Exhibit 10.1)
10.55†	Distribution and Supply Agreement between ViroPharma Incorporated and Prasco, LLC dated November 30, 2007.(18) (Exhibit 10.2)
10.56	Amendment No. 1 to Distribution and Supply Agreement between ViroPharma Incorporated and Prasco, LLC dated June 10, 2008.(18) (Exhibit 10.3)
10.57†	Amendment No. 2 Distribution and Supply Agreement between ViroPharma Incorporated and Prasco, LLC dated August 18, 2009.(18) (Exhibit 10.4)
10.58	Amendment No. 3 Distribution and Supply Agreement between ViroPharma Incorporated and Prasco, LLC dated November 30, 2010.(18) (Exhibit 10.5)
10.59†	Amendment No. 4 Distribution and Supply Agreement between ViroPharma Incorporated and Prasco, LLC dated November 30, 2011.(18) (Exhibit 10.6)
10.60	Amended and Restated Lease, dated August 29, 2012, by and between ViroPharma Incorporated, 730 Stockton Drive Associates, LP and The Hankin Group.(13) (Exhibit 10.1)
10.61†	Strategic Supply Agreement dated as of September 24, 2012, by and between ViroPharma Biologics, Inc., a wholly-owned subsidiary of ViroPharma Incorporated, and Biotest Pharmaceuticals Corporation.(13) (Exhibit 10.2)
10.62†*	Amendment Number 4 to the Agreement for the Purchase and Sale of Blood Plasma dated as of October 1, 2012, by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated and DCI Management Group LLC.
10.63†*	First Amendment to the Manufacturing and Distribution Agreement between ViroPharma SPRL and Stichting Sanquin Bloedvoorziening, dated December 6, 2012.
14	Code of Conduct and Ethics.(16) (Exhibit 14.1)
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.

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Exhibit No.	Description
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*†	Filed herewith.
†	Portions of this exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.
††	Compensation plans and arrangements for executives and others.
(1)	Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on November 14, 2008.
(2)	Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on July 18, 2008.
(3)	Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on November 12, 2003.
(4)	Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on May 14, 1999.
(5)	Filed as an Exhibit to the Company's Registration Statement on Form S-3 filed with the Commission on March 19, 2007.
(6)	Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 filed with the Commission on February 28, 2002.
(7)	Filed as an Exhibit to the Company's Current Report on Form 8-K/A filed with the Commission on November 24, 2004.
(8)	Filed as an Annex to the Company's Proxy Statement filed with the Commission on April 8, 2002.
(9)	Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004 filed with the Commission on March 15, 2005.
(10)	Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on August 4, 2005.
(11)	Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 filed with the Commission on March 2, 2006.
(12)	Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on August 2, 2006.
(13)	Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on October 25, 2012.
(14)	Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 26, 2007.
(15)	Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on January 14, 2009.
(16)	Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on February 24, 2010.

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- (17) Filed as an Exhibit to the Current Report Form 8-K filed by Lev Pharmaceuticals, Inc. on July 25, 2007.
- (18) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on August 9, 2012.
- (19) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 filed with the Commission on February 25, 2010.
- (20) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on March 24, 2009.
- (21) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2009.
- (22) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on October 28, 2009.
- (23) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on April 28, 2010.
- (24) Filed as an Exhibit to the Company's Current Report on Form 8-K filed with the Commission on January 5, 2011.
- (25) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on July 28, 2011.
- (26) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on October 27, 2011.
- (27) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the Commission on February 24, 2011.
- (28) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the Commission on February 28, 2012.
- (29) Filed as an Exhibit to the Company's Amendment No. 1 to Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the Commission on August 2, 2012.
- (30) Filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed with the Commission on May 1, 2012.
- 101 The following financial information from this Annual Report on Form 10-K for the fiscal year ended December 31, 2012, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Income (iv) the Consolidated Statements of Stockholders' Equity; (v) the Consolidated Statements of Cash Flows; and, (vi) the Notes to the Consolidated Financial Statements.

**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.**

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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> <b>Vincent J. Milano</b>	President, Chief Executive Officer (Principal Executive Officer)	February 27, 2013
<u>/s/ CHARLES A. ROWLAND, JR.</u> <b>Charles A. Rowland, Jr.</b>	Chief Financial Officer (Principal Financial Officer)	February 27, 2013
<u>/s/ JOHN J. KIRBY</u> <b>John J. Kirby</b>	Vice President, Chief Accounting Officer (Principal Accounting Officer)	February 27, 2013
<u>/s/ VINCENT J. MILANO</u> <b>Vincent J. Milano</b>	Chairman of the Board	February 27, 2013
<u>/s/ PAUL A. BROOKE</u> <b>Paul A. Brooke</b>	Director	February 27, 2013
<u>/s/ WILLIAM CLAYPOOL, M.D.</u> <b>William Claypool, M.D.</b>	Director	February 27, 2013
<u>/s/ MICHAEL R. DOUGHERTY</u> <b>Michael R. Dougherty</b>	Director	February 27, 2013

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<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ ROBERT J. GLASER</u> <u><b>Robert J. Glaser</b></u>	Director	February 27, 2013
<u>/s/ JOHN R. LEONE</u> <u><b>John R. Leone</b></u>	Director	February 27, 2013
<u>/s/ JULIE H. MCHUGH</u> <u><b>Julie H. McHugh</b></u>	Director	February 27, 2013
<u>/s/ HOWARD H. PIEN</u> <u><b>Howard H. Pien</b></u>	Director	February 27, 2013

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**VIROPHARMA INCORPORATED**  
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The Board of Directors and Stockholders  
ViroPharma Incorporated:

We have audited the accompanying consolidated balance sheets of ViroPharma Incorporated and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2012. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ViroPharma Incorporated and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ViroPharma Incorporated's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2013 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
February 27, 2013

[Table of Contents](#)**ViroPharma Incorporated****Consolidated Balance Sheets**

(in thousands, except share and per share data)	December 31, 2012	December 31, 2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 175,518	\$ 331,352
Short-term investments	71,338	128,478
Accounts receivable	74,396	78,534
Inventory	64,384	60,316
Prepaid expenses and other current assets	25,361	15,059
Prepaid income taxes	29,097	12,137
Deferred income taxes, net	13,324	10,055
Total current assets	453,418	635,931
Intangible assets, net	617,539	648,659
Property, equipment and building improvements, net	10,848	11,983
Goodwill	96,759	13,184
Debt issuance costs, net	2,551	3,488
Deferred income taxes	17,988	11,786
Other assets	20,849	11,766
Total assets	<u>\$ 1,219,952</u>	<u>\$ 1,336,797</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 21,254	\$ 11,339
Contingent consideration	8,367	7,293
Accrued expenses and other current liabilities	83,503	75,983
Income taxes payable	904	4,036
Total current liabilities	114,028	98,651
Other non-current liabilities	1,898	1,967
Contingent consideration	17,710	12,896
Deferred tax liability	167,484	178,706
Long-term debt	161,793	153,453
Total liabilities	462,913	445,673
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; outstanding 65,113,880 shares at December 31, 2012 and 70,568,501 shares at December 31, 2011	163	159
Treasury shares, at cost. 16,042,202 shares at December 31, 2012 and 9,159,083 shares at December 31, 2011	(350,000)	(169,661)
Additional paid-in capital	789,719	749,519
Accumulated other comprehensive loss	(2,975)	(3,414)
Retained earnings	320,132	314,521
Total stockholders' equity	757,039	891,124
Total liabilities and stockholders' equity	<u>\$ 1,219,952</u>	<u>\$ 1,336,797</u>

See accompanying notes to consolidated financial statements.

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**ViroPharma Incorporated**  
**Consolidated Statements of Operations**

(in thousands, except per share data)	Years ended December 31,		
	2012	2011	2010
<b>Revenues:</b>			
Net product sales	\$ 427,933	\$ 544,374	\$ 439,012
<b>Costs and Expenses:</b>			
Cost of sales (excluding amortization of product rights)	108,547	79,976	61,288
Research and development	67,709	66,477	39,613
Selling, general and administrative	174,315	127,775	95,664
Intangible amortization	35,301	31,035	29,357
Impairment loss	—	8,495	—
Other operating expenses	8,718	8,488	1,390
Total costs and expenses	394,590	322,246	227,312
Operating income	33,343	222,128	211,700
<b>Other Income (Expense):</b>			
Interest income	594	655	372
Interest expense	(14,093)	(12,640)	(11,616)
Other (expense) income, net	(823)	(2,136)	430
Income before income tax expense	19,021	208,007	200,886
Income tax expense	13,410	67,348	75,278
Net income	\$ 5,611	\$ 140,659	\$ 125,608
<b>Net income per share:</b>			
Basic	\$ 0.08	\$ 1.89	\$ 1.61
Diluted	\$ 0.08	\$ 1.68	\$ 1.47
Shares used in computing net income per share:			
Basic	68,214	74,517	77,820
Diluted	71,764	88,076	90,081

See accompanying notes to consolidated financial statements.

**ViroPharma Incorporated**  
**Consolidated Statements of Comprehensive Income**

(in thousands)	Years ended December 31,		
	2012	2011	2010
Net income	\$ 5,611	\$ 140,659	\$ 125,608
Other comprehensive income (loss), before tax:			
Foreign currency translations adjustments	427	(3,145)	(1,172)
Unrealized gain (loss) on available for sale securities			
Unrealized holding gain (loss) arising during period	23	(16)	—
Less: Reclassification adjustment for gains included in net income, net of tax expense	3	—	—
Income tax expense (benefit)	8	(5)	—
Unrealized gain (loss) on available for sale securities, net of tax	12	(11)	—
Other comprehensive income (loss), net of tax	439	(3,156)	(1,172)
Comprehensive income	<u>\$ 6,050</u>	<u>\$ 137,503</u>	<u>\$ 124,436</u>

See accompanying notes to consolidated financial statements

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

(in thousands)	Preferred Stock		Common Stock		Treasury Shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained Earnings	Total stockholders' equity
	Number of shares	Amount	Number of shares	Amount	Number of shares	Amount				
Balance, December 31, 2009	—	\$ —	77,443	\$ 156	—	\$ —	701,063	\$ 914	\$ 48,254	\$ 750,387
Exercise of common stock options	—	—	633	—	—	—	3,342	—	—	3,342
Employee stock purchase plan	—	—	65	—	—	—	202	—	—	202
Share-based compensation	—	—	—	—	—	—	11,172	—	—	11,172
Stock option tax benefits	—	—	—	—	—	—	1,596	—	—	1,596
Cumulative translation adjustment, net	—	—	—	—	—	—	—	(1,172)	—	(1,172)
Net income	—	—	—	—	—	—	—	—	125,608	125,608
Balance, December 31, 2010	—	—	78,141	156	—	—	717,375	(258)	173,862	891,135
Exercise of common stock options	—	—	1,548	3	—	—	14,239	—	—	14,242
Employee stock purchase plan	—	—	38	—	—	—	452	—	—	452
Share-based compensation	—	—	—	—	—	—	14,242	—	—	14,242
Unrealized losses on available for sale securities, net	—	—	—	—	—	—	—	(11)	—	(11)
Cumulative translation adjustment, net	—	—	—	—	—	—	—	(3,145)	—	(3,145)
Repurchase of shares	—	—	(9,159)	—	9,159	(169,661)	—	—	—	(169,661)
Stock option tax benefits	—	—	—	—	—	—	3,211	—	—	3,211
Net income	—	—	—	—	—	—	—	—	140,659	140,659
Balance, December 31, 2011	—	—	70,568	159	9,159	(169,661)	749,519	(3,414)	314,521	891,124
Exercise of common stock options	—	—	1,375	4	—	—	11,446	—	—	11,450
Restricted stock vested	—	—	27	—	—	—	—	—	—	—
Employee stock purchase plan	—	—	27	—	—	—	505	—	—	505
Share-based compensation	—	—	—	—	—	—	21,132	—	—	21,132
Other comprehensive income	—	—	—	—	—	—	—	439	—	439
Repurchase of shares	—	—	(6,883)	—	6,883	(180,339)	—	—	—	(180,339)
Stock option tax benefits	—	—	—	—	—	—	7,117	—	—	7,117
Net income	—	—	—	—	—	—	—	—	5,611	5,611
Balance, December 31, 2012	—	\$ —	65,114	\$ 163	16,042	\$(350,000)	\$ 789,719	\$(2,975)	\$ 320,132	\$ 757,039

See accompanying notes to consolidated financial statements.

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**ViroPharma Incorporated**  
**Consolidated Statements of Cash Flows**

(in thousands)	Years ended December 31,		
	2012	2011	2010
<b>Cash flows from operating activities:</b>			
Net income	\$ 5,611	\$ 140,659	\$ 125,608
Adjustments to reconcile net income to net cash provided by operating activities:			
Non-cash share-based compensation expense	21,132	14,242	11,176
Non-cash asset impairments	—	8,495	—
Non-cash interest expense	9,277	8,268	7,517
Non-cash charge for contingent consideration	4,477	4,664	1,390
Non-cash charge for option amortization	3,825	—	—
Deferred tax provision	(20,707)	(19,440)	19,211
Depreciation and amortization expense	37,818	33,467	31,206
Other, net	(3,568)	5,514	(370)
Changes in assets and liabilities, net of businesses acquired:			
Accounts receivable	4,214	(34,864)	(2,099)
Inventory	(3,248)	(6,939)	(12,320)
Prepaid expenses and other current assets	(5,241)	(1,801)	(4,277)
Prepaid income taxes and income taxes payable	(14,197)	(8,034)	1,451
Other assets	(12,657)	6,616	(4,061)
Accounts payable	9,297	(159)	4,014
Accrued expenses and other current liabilities	4,139	26,554	15,565
Payment of contingent consideration	—	(6,019)	—
Other non-current liabilities	2,843	(497)	(494)
Net cash provided by operating activities	43,015	170,726	193,517
<b>Cash flows from investing activities:</b>			
Purchase of Lev Pharmaceuticals, Inc.	(92,274)	—	—
Purchase of DuoCort Pharma AB, net of cash acquired	—	(32,041)	—
Purchase of Auralis, net of cash acquired	—	—	(13,152)
Payment for option purchase right	—	(7,500)	—
Purchase of Vancocin assets	—	(7,000)	(7,000)
Purchase of property, equipment and building improvements	(1,332)	(3,007)	(2,807)
Purchase of short-term investments	(107,177)	(152,557)	(86,975)
Maturities and sales of short-term investments	162,734	101,058	8,000
Net cash used in investing activities	(38,049)	(101,047)	(101,934)
<b>Cash flows from financing activities:</b>			
Payment for treasury shares acquired	(180,339)	(169,661)	—
Repayment of debt	—	(292)	(1,575)
Payment of financing costs	—	(1,357)	—
Payment of contingent consideration	—	(9,809)	—
Net proceeds from issuance of common stock	11,955	14,694	3,544
Excess tax benefits from share-based payment arrangements	7,117	3,211	1,596
Net cash (used in) provided by financing activities	(161,267)	(163,214)	3,565
Effect of exchange rate changes on cash	467	(1,845)	(88)
Net (decrease) increase in cash and cash equivalents	(155,834)	(95,380)	95,060
Cash and cash equivalents at beginning of year	331,352	426,732	331,672
Cash and cash equivalents at end of year	<u>\$ 175,518</u>	<u>\$ 331,352</u>	<u>\$ 426,732</u>

See accompanying notes to consolidated financial statements.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements****Note 1. Organization and Business Activities**

ViroPharma Incorporated is an international biotechnology company dedicated to the development and commercialization of novel solutions for physician specialists to address unmet medical needs of patients living with diseases that have few if any clinical therapeutic options including therapeutics for rare and orphan diseases. We intend to grow through sales of our marketed products, through continued development of our product pipeline, through expansion of sales into additional territories outside the United States, through potential acquisition or licensing of products and product candidates and the acquisition of companies. We expect future growth to be driven by sales of Cinryze for hereditary angioedema (HAE), both domestically and internationally, sales of Plenadren for treatment of adrenal insufficiency (AI) and Buccolam in Europe for treatment of paediatric seizures, and by our development programs, including C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection, VP20621 for the prevention of recurrent *C. difficile*-associated diarrhea (CDAD) and VP20629 for the treatment of Friedreich's Ataxia (FA).

We market and sell Cinryze in the United States for routine prophylaxis against angioedema attacks in adolescent and adult patients with 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. We acquired rights to Cinryze for the United States in October 2008 and in January 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 well as rights to develop future C1-INH derived products for additional indications. In June 2011, the European Commission (EC) granted us Centralized Marketing Authorization for Cinryze® in adults and adolescents with HAE for routine prevention, pre-procedure prevention and acute treatment of angioedema attacks. The approval also includes a self administration option for appropriately trained patients. We have begun to commercialize Cinryze in Europe and continue to evaluate our commercialization opportunities in countries where we have distribution rights.

On August 6, 2012, FDA approved our supplement to the Cinryze Biologics License Application (BLA) for industrial scale manufacturing which increases our manufacturing capacity of Cinryze.

We acquired Buccolam® (Oromucosal Solution, Midazolam [as hydrochloride]) in May 2010. In September 2011, the EC granted a Centralized Pediatric Use Marketing Authorization (PUMA) for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. We have begun to commercialize Buccolam in Europe.

On November 15, 2011, we acquired a 100% ownership interest in DuoCort Pharma AB (DuoCort), a private company based in Helsingborg, Sweden focused on developing Plenadren® (hydrocortisone, modified release tablet) for treatment of AI. The acquisition of Plenadren further expands our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren, an orphan drug for treatment of AI in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We are in the process of launching Plenadren in various countries in Europe and a named patient program is available to patients in countries in which we have not launched Plenadren commercially. We are currently conducting an open label trial with Plenadren in Sweden and have initiated a registry study as a condition of approval in Europe. We also are currently exploring commercialization opportunities in additional geographies including the United States.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 1. Organization and Business Activities (Continued)**

We also sell branded and authorized generic Vancocin HCl capsules, the oral capsule formulation of vancomycin hydrochloride, in the U.S. and its territories. Vancocin is indicated for the treatment of CDAD. Vancocin capsules are also used for the treatment of enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains.

On April 9, 2012, the FDA denied the citizen petition we filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of abbreviated new drug applications (ANDAs) referencing Vancocin (vancomycin hydrochloride, USP) capsules. The FDA also informed us in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin which was approved on December 14, 2011 would not qualify for three additional years of exclusivity, as the agency interpreted Section 505(v) of the FD&C Act to require a showing of a significant new use (such as a new indication) for an old antibiotic such as Vancocin in order for such old antibiotic to be eligible for a grant of exclusivity. FDA also indicated that it approved three ANDA's for generic vancomycin capsules and the companies holding these ANDA approvals indicated that they began shipping generic vancomycin hydrochloride, USP. In June 2012, the FDA approved a fourth ANDA for generic vancomycin capsules.

Pursuant to the terms of a previously entered distribution agreement, we granted a third party a license under our NDA for Vancocin® (vancomycin hydrochloride capsules, USP) to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. We are also obligated to pay Genzyme royalties of 10 percent, 10 percent and 16 percent of our net sales of Vancocin for the three year period following the approval of the sNDA as well as a lower royalty on sales of our authorized generic version of Vancocin in connection with our purchase of exclusive rights to two studies of Vancocin.

Our product development portfolio is primarily focused on the following programs: C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection, VP20621 (prevention of CDAD) and VP20629 (treatment of Friedreich's Ataxia).

We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. In May 2011, Halozyme Therapeutics Inc. (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology, in combination with a C1 esterase inhibitor which we intend to apply initially to develop a subcutaneous formulation of Cinryze for routine prophylaxis against attacks of HAE. In the first quarter of 2012, we completed a Phase 2 study to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 and announced the presentation of positive data. In December 2012, we initiated a Phase 2b double blind, multicenter, dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze® (C1 esterase inhibitor [human]) in combination with PH20 in adolescents and adults with HAE for prevention of HAE attacks. We will continue to evaluate the subcutaneous administration of Cinryze as a standalone therapy. We are also investigating recombinant forms of C1-INH.

Additionally, we are working on developing our C1 esterase inhibitor in further therapeutic uses and potential additional indications in other C1 mediated diseases. We intend to support Investigator Initiated Studies (IIS) to identify further therapeutic uses for Cinryze. An IIS evaluating C1-INH as a treatment for Autoimmune Hemolytic Anemia (AIHA) and Neuromyelitis Optica (NMO) were initiated in 2012. We are also sponsoring a clinical trial in Antibody-Mediated Rejection (AMR) and

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 1. Organization and Business Activities (Continued)**

are evaluating, the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH) and may conduct clinical and non-clinical studies to evaluate additional therapeutic uses in the future.

During the second quarter of 2012, we announced the initiation of a Phase 2 program to evaluate maribavir for the treatment of CMV infections in transplant recipients. The program consists of two independent Phase 2 clinical studies that include subjects who have asymptomatic CMV, and those who have failed therapy with other anti-CMV agents. During the third quarter of 2012 and first quarter of 2013, we presented interim data from the Phase 2 open label clinical study being conducted in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV. Results from this study as well as data from a second Phase 2 open label study of maribavir as a treatment for patients with refractory cases of CMV will periodically be evaluated.

We are also developing VP20621 for the prevention of CDAD. In May 2011, we initiated a Phase 2 dose-ranging clinical study to evaluate the safety, tolerability, and efficacy of VP 20621 for prevention of recurrence of CDAD in adults previously treated for CDAD. We presented interim data from this study during the third quarter of 2012. We completed enrollment of patients in December 2012 and anticipate having the complete data set in 2013.

On September 30, 2011, we entered into a license agreement with Intellect Neurosciences, Inc. (INS) for the worldwide rights to its clinical stage drug candidate, VP20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a single and repeat dose Phase 1 study in patients in 2013 and expect to initiate a subsequent Phase 2 study after completion of the phase 1 study. Following completion of the Phase 2 study, a phase 3 study is planned. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data.

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

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 which we believe will provide both revenue and earnings growth over time.

**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.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)***Cash and cash equivalents*

We consider all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

*Concentration of credit risk*

We invest our 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 our credit risk.

We have an exposure to credit risk in trade accounts receivable from sales of product. In the U.S., Vancocin is distributed through wholesalers that sell the product to pharmacies and hospitals. We also granted a third party a license under our NDA for Vancocin® (vancomycin hydrochloride capsules, USP) to distribute and sell vancomycin hydrochloride capsules as an authorized generic product. In the US, we sell Cinryze to specialty pharmacy/specialty distributors (SP/SD's) who then distribute to physicians, hospitals and patients, among others.

We sell Diamorphine in the UK, primarily to hospitals, through approved wholesalers. We began commercial sales of Cinryze and Buccolam in Europe during the fourth quarter of 2011, primarily through approved wholesalers, and launched Plenadren commercially through approved wholesalers and named patient program in Europe during the third quarter of 2012. The revenues and operating income from these sales are not material to our consolidated revenues and operating income for 2012 or 2011.

Five customers represent approximately 85% of our trade accounts receivable at December 31, 2012 and five customers represent approximately 92% of our 2012 net product sales.

We, 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*

We currently outsource all manufacturing of our products to single source manufacturers. A change in these suppliers 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, rebates and estimated returns and do not bear interest. At December 31, 2012 and 2011, there was no allowance for doubtful accounts as all net amounts recorded are deemed collectible. We do not have any off-balance sheet exposure related to our customers.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)***Inventories*

Inventories are stated at the lower of cost or market using actual cost. At December 31, 2012 and 2011, inventory consists of finished goods, work-in-process (WIP) and certain raw materials required to produce inventory of finished product.

*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.

We lease certain of our 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.

On August 29, 2012, we entered into an amended and restated lease to expand our corporate headquarters. The lease arrangement involves the construction of expanded office space where we are involved in the design and construction of the expanded space and have the obligation to fund the tenant improvements to the expanded structure and to lease the entire building following completion of construction. This arrangement is referred to as build-to suit lease. We have concluded that under the guidance of ASC 840, Leases, we are considered the owner of the construction project for accounting purposes and must record a construction in progress asset (CIP) and a corresponding financing obligation for the construction costs funded by the landlord. We anticipate to begin recording the CIP asset and a corresponding financing obligation during the first quarter of 2013 when construction is anticipated to start. Once the construction is complete we will depreciate the core and shell asset over 30 years. A portion of the lease payments will be reflected as principal and interest payments on the financing obligation.

*Goodwill and Intangible Assets*

We review the carrying value of goodwill and indefinite-lived intangible assets, to determine whether impairment may exist. In September 2011, the Financial Accounting Standards Board issued ASU 2011-08, Testing Goodwill for Impairment (the Update). The objective of this Update is to simplify how entities test goodwill for impairment. The amendments in the Update provide the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The two-step goodwill impairment test consists of the following steps. The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)**

We tested our goodwill during the fourth quarter of 2012 and there was no impairment as a result of the test.

We test our long-lived fixed and intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two, if necessary, as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include projections of future cash flows and the timing and number of generic/competitive entries into the market, affecting the undiscounted cash flows, and if necessary, the fair value of the asset and whether impairment exists. These assumptions are subjective and could result in a material impact on operating results in the period of impairment.

On an ongoing periodic basis, we evaluate the useful life of our long-lived assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives.

Accounting Standards Codification (ASC) 350-30-35 provides guidance on determining the finite useful life of a recognized intangible asset wherein it defines the useful life of an intangible asset is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of an entity.

It also states that the estimate of the useful life of an intangible asset to an entity shall be based on an analysis of all pertinent factors, in particular, all of the following factors with no one factor being more presumptive than the other:

- a. The expected use of the asset by the entity.
- b. The expected useful life of another asset or a group of assets to which the useful life of the intangible asset may relate.
- c. Any legal, regulatory, or contractual provisions that may limit the useful life. The cash flows and useful lives of intangible assets that are based on legal rights are constrained by the duration of those legal rights. Thus, the useful lives of such intangible assets cannot extend beyond the length of their legal rights and may be shorter.
- d. The entity's own historical experience in renewing or extending similar arrangements, consistent with the intended use of the asset by the entity, regardless of whether those arrangements have explicit renewal or extension provisions. In the absence of that experience, the entity shall consider the assumptions that market participants would use about renewal or extension consistent with the highest and best use of the asset by market participants, adjusted for entity-specific factors in this paragraph.
- e. The effects of obsolescence, demand, competition, and other economic factors (such as the stability of the industry, known technological advances, legislative action that results in an uncertain or changing regulatory environment, and expected changes in distribution channels).

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)**

- f. The level of maintenance expenditures required to obtain the expected future cash flows from the asset (for example, a material level of required maintenance in relation to the carrying amount of the asset may suggest a very limited useful life). As in determining the useful life of depreciable tangible assets, regular maintenance may be assumed but enhancements may not.

Further, if an income approach is used to measure the fair value of an intangible asset, in determining the useful life of the intangible asset for amortization purposes, an entity shall consider the period of expected cash flows used to measure the fair value of the intangible asset adjusted as appropriate for the entity-specific factors noted.

Long-lived 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 contract rights acquired as part of the Auralis acquisition are being amortized on a straight-line basis over their estimated useful lives of 12 years and the product rights acquired under the Auralis and DuoCort acquisitions are being amortized on a straight-line basis over their estimated useful lives of 10 years. We 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.

In September 2011, the EC granted a Centralized PUMA for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. This asset was previously classified as an indefinite-lived intangible asset. As a result of this approval, we began to amortize this asset over its estimated useful life of 10 years.

Due to the approval and launch of Buccolam, coupled with the approval and launch of Cinryze in Europe, we decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision resulted in the impairment of the IPR&D asset and the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during 2011.

*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 is generally recorded upon delivery to either our wholesalers or distributors and 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.

Product return accruals are estimated based on our history of damage and product expiration returns and are recorded in the period in which we record the product sales. There is a no returns

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)**

policy with sales of generic Vancocin to our distributor and Cinryze has a no returns policy. Returns of product for our European sales depends on the country of sale in Europe. Where returns are not mandated by laws or regulations, we generally have a no returns policy. Where returns are required to be taken back, we defer revenue recognition until we receive information from our distribution partners that the drug has been consumed.

While we currently have no contracts with private third party payors, such as HMO's. We 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 product sales. These accruals are based upon historical experience of government agencies' market share, governmental contractual prices, our current pricing and current laws, regulations and interpretations.

Under the Patient Protection and Affordable Care Act (PPACA), we are required to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients starting on January 1, 2011. For Vancocin sales subject to this discount, we recognize this cost using an effective rebate percentage for all sales to Medicare patients throughout the year. For applicable Cinryze sales, we recognize this cost at the time of sale for product expected to be purchased by a Medicare Part D insured patient when we estimate they are within the coverage gap.

Revenue from the launch of a new or significantly unique product may be deferred until estimates can be made for chargebacks, rebates, returns and all of the above conditions are met which is typically based on dispensed prescription data and other information obtained during the period following launch.

In April 2012, we began selling an authorized generic version of our prescription Vancocin capsules under a supply agreement with a distributor. The distributor has agreed to purchase all of its authorized generic product requirements from us and pay a specified invoice supply price for such products. We are also entitled to receive a percentage of the gross margin on net sales of the authorized generic products sold by the distributor. We recognize revenue from shipments to the distributor at the invoice supply price along with our percentage of the gross margin on net sales of the authorized generic products sold by the distributor when the distributor reports to us its gross margin on net sales of the products and our portion thereof. Any adjustments to the net sales previously reported to us related to the distributor's estimated sales discounts and other deductions are recognized in the period the distributor reports the adjustments to us. There is a no returns policy with sales of generic Vancocin to our distributor.

*Customers*

We have principally sold our products directly to wholesale drug distributors and specialty pharmacies/specialty distributors (SP/SD) in the United States who then distribute the product to pharmacies, hospitals, patients, physicians and long-term care facilities, among others. For Cinryze, our customers are SP/SD's who will distribute the product to physicians, hospitals and patients. For Vancocin, our customers are wholesalers who then distribute the product to pharmacies, hospitals and long term care facilities, among others. In April 2012, we began selling an authorized generic version of our prescription Vancocin capsules under a supply agreement with a distributor.

In the fourth quarter of 2011, we began to sell product to drug distributors in Europe, mainly wholesalers, who then distribute the product to pharmacies, hospitals, and physicians.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)**

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

	Percentage of total revenues		
	2012	2011	2010
Customer A	43%	27%	25%
Customer B	25%	24%	24%
Customer C	11%	20%	21%
Customer D	9%	17%	16%
Customer E	4%	9%	10%
Total	92%	97%	96%

*Research and development expenses and Collaborations*

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.

We evaluate 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 partners related to development activities are reflected as a research and development expense.

*Income taxes*

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences 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 the 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.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)***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 measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. All grants under share-based payment programs are accounted for at fair value and that cost is recognized over the period during which an employee is required to provide service in exchange for the award—the requisite service period (vesting period).

Compensation expense for options granted to non-employees is determined as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of awards granted to non-employees is re-measured each period until the related service is complete.

*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, share-based payments and warrants.

*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. There is no segment or business unit management that reviews separate or discrete financial information. The Company does not operate separate lines of business or separate business entities with respect to any of its products or product candidates.

*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 (loss). Transaction gains and losses are recorded within operating results.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)***Subsequent Events*

We have evaluated all subsequent events through the date the consolidated financial statements were issued, and have not identified any such events.

*New Accounting Standards*

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (Topic 220)*. The standard requires that public and non-public companies present information about reclassification adjustments from accumulated other comprehensive income in their annual financial statements in a single note or on the face of the financial statements. Public companies will also have to provide this information in their interim financial statements. The standard requires that companies present either in a single note or parenthetically on the face of the financial statements, the effect of significant amounts reclassified from each component of accumulated other comprehensive income based on its source and the income statement line items affected by the reclassification. If a component is not required to be reclassified to net income in its entirety, companies must instead cross reference to the related footnote for additional information. The standard allows companies to present the information either in the notes or parenthetically on the face of the financial statements provided that all of the required information is presented in a single location. The new disclosure requirements are effective for fiscal years, and interim periods within those years, beginning after December 15, 2012. The adoption of the provisions of this guidance will not have a material impact on our consolidated results of operations, cash flows, and financial position.

In July 2012, the FASB issued ASU 2012-02, *Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* (the revised standard). The objective of this ASU is to simplify how entities test indefinite-lived intangible assets other than goodwill for impairment. The amendments in the ASU provide the option to first assess qualitative factors to determine whether, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) the asset is impaired and it is necessary to calculate the fair value of the asset in order to compare that amount to the carrying value to determine the amount of the impairment, if any. If an entity believes, as a result of its qualitative assessment, that it is not more-likely-than-not (a likelihood of more than 50%) that the fair value of a asset is less than its carrying amount, no further testing is required. The revised standard includes examples of events and circumstances that might indicate that the indefinite-lived intangible asset is impaired. The approach in the ASU is similar to the guidance for testing goodwill for impairment contained in ASU 2011-08, *Intangibles—Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. The revised standard, which may be adopted early, is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and does not change existing guidance on when to test indefinite-lived intangible assets for impairment. The adoption of the provisions of this guidance is not expected to have a material impact on our consolidated results of operations, cash flows, and financial position.

In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, and the IASB issued IFRS 13, *Fair Value Measurement*. The new guidance results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between U.S. GAAP and IFRS. The ASU is effective for interim and annual periods beginning on or after

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 2. Basis of Presentation (Continued)**

December 15, 2011, with early adoption prohibited. The new guidance changes certain fair value measurement principles and disclosure requirements. We adopted this ASU January 1, 2012. The adoption of the provisions of this guidance did not have a material impact on our consolidated results of operations, cash flows, and financial position.

In June 2011, the FASB issued ASU 2011-05, *Presentation of Comprehensive Income* (Topic 220). This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to enhance comparability between entities that report under US GAAP and those that report under IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. Under the ASU, an entity can elect to present items of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts, net income and other comprehensive income, would need to be displayed under either alternative. The statement(s) would need to be presented with equal prominence as the other primary financial statements. This ASU does not change items that constitute net income and other comprehensive income, when an item of other comprehensive income must be reclassified to net income or the earnings-per-share computation (which will continue to be based on net income). The new US GAAP requirements are effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. We adopted this ASU January 1, 2012. The adoption of the provisions of this guidance did not have a material impact on our consolidated results of operations, cash flows, and financial position.

In September 2011, the FASB issued ASU 2011-08, *Intangibles—Goodwill and Other* (Topic 350): Testing Goodwill for Impairment (the revised standard). The objective of this ASU is to simplify how entities test goodwill for impairment. The amendments in the ASU provide the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The revised standard includes examples of events and circumstances that might indicate that a reporting unit's fair value is less than its carrying amount. These include macro-economic conditions such as deterioration in the entity's operating environment, entity-specific events such as declining financial performance, and other events such as an expectation that a reporting unit will be sold. An entity should also consider in its qualitative assessment the "cushion" between a reporting unit's fair value and carrying amount if determined in a recent fair value calculation. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of the provisions of this guidance did not have a material impact on our consolidated results of operations, cash flows, and financial position.

**Note 3. Short-Term Investments**

Short-term investments consist of fixed income and debt securities with remaining maturities of greater than three months at the date of purchase. At December 31, 2012, all of our short-term investments are classified as available for sale investments and measured as Level 1 instruments of the fair value measurements standard.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 3. Short-Term Investments (Continued)**

The following summarizes the Company's available for sale investments at December 31, 2012:

(in thousands)	Cost	Gross unrealized gains	Gross unrealized losses	Fair value
Debt securities:				
U.S. Treasury	\$ 29,000	\$ 8	\$ —	\$ 29,008
Corporate bonds	42,334	10	14	42,330
	<u>\$ 71,334</u>	<u>\$ 18</u>	<u>\$ 14</u>	<u>\$ 71,338</u>
Maturities of investments were as follows:				
Less than one year	\$ 34,553	\$ 10	\$ 3	\$ 34,560
Greater than one year	36,781	8	11	36,778
Total	<u>\$ 71,334</u>	<u>\$ 18</u>	<u>\$ 14</u>	<u>\$ 71,338</u>

The following summarizes the Company's available for sale investments at December 31, 2011:

(in thousands)	Cost	Gross unrealized gains	Gross unrealized losses	Fair value
Debt securities:				
U.S. Treasury	\$ 48,351	\$ 14	\$ 3	\$ 48,362
Corporate Bonds	80,143	43	70	80,116
Total	<u>\$ 128,494</u>	<u>\$ 57</u>	<u>\$ 73</u>	<u>\$ 128,478</u>
Maturities of investments were as follows:				
Less than one year	\$ 99,190	\$ 42	\$ 39	\$ 99,193
Greater than one year	29,304	15	34	29,285
Total	<u>\$ 128,494</u>	<u>\$ 57</u>	<u>\$ 73</u>	<u>\$ 128,478</u>

**Note 4. Inventory**

Inventory is stated at the lower of cost or market using actual cost. The following represents the components of the inventory at December 31, 2012 and December 31, 2011:

(in thousands)	2012	2011
Raw Materials	\$ 41,642	\$ 50,045
Work In Process	15,810	6,035
Finished Goods	6,932	4,236
Total	<u>\$ 64,384</u>	<u>\$ 60,316</u>

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 5. Property, Equipment and Building Improvements**

Property, equipment and building improvements consists of the following at December 31, 2012 and 2011:

(in thousands)	2012	2011
Land	\$ 156	\$ 156
Building	3,039	3,039
Computers and equipment	13,387	12,019
Leasehold improvements	6,053	6,001
	<u>22,635</u>	<u>21,215</u>
Less: accumulated depreciation and amortization	11,787	9,232
Property, equipment and building improvements, net	<u>\$ 10,848</u>	<u>\$ 11,983</u>

The depreciable lives for the major categories of property and equipment are 30 years for buildings, 3 to 5 years for computers and equipment and up to the shorter of the respective lease term or the expected economic useful life for building improvements, not to exceed 15 years. We recorded depreciation expense of approximately \$2.9 million, \$2.4 million and \$1.8 million during the years ended December 31, 2012, 2011 and 2010, respectively.

**Note 6. Intangible Assets**

The following represents the balance of the intangible assets at December 31, 2012:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Cinryze Product rights	\$ 521,000	\$ 87,394	\$ 433,606
Vancocin Intangibles	168,099	54,773	113,326
Plenadren Product rights	65,136	7,048	58,088
Buccolam Product rights	6,566	876	5,690
Auralis Contract rights	9,360	2,531	6,829
Total	<u>\$ 770,161</u>	<u>\$ 152,622</u>	<u>\$ 617,539</u>

The following represents the balance of the intangible assets at December 31, 2011:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Cinryze Product rights	\$ 521,000	\$ 66,554	\$ 454,446
Vancocin Intangibles	168,099	48,074	120,025
Plenadren Product rights	61,277	510	60,767
Buccolam Product rights	6,271	209	6,062
Auralis Contract rights	8,938	1,579	7,359
Total	<u>\$ 765,585</u>	<u>\$ 116,926</u>	<u>\$ 648,659</u>

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 6. Intangible Assets (Continued)****Cinryze**

In October 2008, Cinryze was approved by the FDA for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE. Because the treatment indication is directed at a small population in the United States, orphan drug status was awarded by the FDA and orphan drug exclusivity was granted on the date of approval. Orphan drug exclusivity awards market exclusivity for seven years. These seven years of exclusivity prevent the FDA from approving another product with the same active ingredient for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE through October 2015. In addition, a biosimilar version of Cinryze could not be approved before 2020 as a result of data protection provisions contained in the relevant biosimilar regulations.

As of December 31, 2012, the carrying amount of this intangible asset is approximately \$433.6 million. We are amortizing this asset over its estimated 25 year useful life, through October 2033, or 18 years beyond the orphan exclusivity period and 13 years beyond the data protection period for biosimilar versions.

Our estimate of the useful life of Cinryze was based primarily on the following four considerations: 1) the exclusivity period granted to Cinryze as a result of marketing approval by the FDA with orphan drug status; 2) the landscape subsequent to the exclusivity period and the ability of follow-on biologics (FOB) entrants to compete with Cinryze; 3) the financial projections of Cinryze for both the periods of exclusivity and periods following exclusivity; and 4) barrier to entry for potentially competitive products.

When determining the post exclusivity landscape for Cinryze we concluded that barriers to entry for competitors to Cinryze are greater than other traditional biologics. They include, but are not limited to the following. Cinryze treats a known population base of approximately 4,600 patients. HAE is generally thought to inflict approximately 10,000 people in the United States, but many of whom have not yet been diagnosed. Therefore the market upside for potential competitors is limited. The capital investment for a potential competitor to construct a manufacturing facility is prohibitive and would limit the number of participants willing to enter the prophylactic HAE market. In order to qualify for the abbreviated approval process for biosimilar versions of biologics licensed under full BLAs ("reference biologics") a biosimilar applicant generally must submit analytical, animal, and clinical data showing that the proposed product is "highly similar" to the reference product and has no "clinically meaningful differences" from the reference product in terms of the safety, purity, and potency, although FDA may waive some or all of these requirements. FDA cannot license a biosimilar until 12 years after it first licensed the reference biologic. It is therefore likely that a biosimilar would have to conduct clinical trials to show that a FOB is highly similar to Cinryze and has no clinically meaningful differences. To conduct these trials, one must produce enough drug to sustain a trial and attract the required number of HAE patients to prove safety and efficacy comparable to Cinryze. Patients on Cinryze are those HAE patients who experience life threatening laryngeal attacks, or frequent attacks that inhibit their quality of life and/or ability to work. To obtain patients for a clinical trial, the FOB company will have to convince patients to stop taking this life saving drug and test a new unproven product. We believe that this would be met with great resistance from both patients and doctors and would limit the ability of a FOB company to perform clinical trials.

At present, one C1 inhibitor has received approval from FDA for the acute indication with de minimus impact on the prophylactic market, primarily due to the payor environment. Though we might see competition at some point in the future, we believe it would be limited.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 6. Intangible Assets (Continued)**

Based on the expected cash flows and value generated in the years following both the end of exclusivity and the potential entry of FOB competition, we concluded that an estimated useful life of 25 years for the Cinryze product rights was appropriate.

**Vancocin**

We acquired Vancocin from Lilly in November 2004 and determined that the identifiable intangible assets acquired had a 25 year useful life based on consideration of the various factors in ASC 350-30-35. Additionally, an income approach was used by an outside independent valuation expert to determine the fair value of these assets and a 25 year period of expected cash flows was used in this asset valuation process. As of December 31, 2012, the carrying amount of the assets is approximately \$113.3 million with a remaining estimated useful life of 17 years.

We paid Lilly an upfront cash payment of \$116.0 million and were obligated to pay additional purchase price consideration based on annual net sales of Vancocin through 2011. We were obligated to pay Lilly additional amounts based on 35% of annual net sales between \$45 and \$65 million of Vancocin in 2005 through 2011. In June 2011, we satisfied our obligations to Lilly to make additional purchase price consideration payments under the purchase agreement. In aggregate we have paid \$51.1 million to Lilly in additional purchase price consideration. We accounted for these additional payments 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 was 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.

On April 9, 2012, FDA denied the citizen petition filed on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of Abbreviated New drug Applications (ANDAs) referencing Vancocin capsules and informed us that final guidance for vancomycin bioequivalence consistent with the FDA's citizen petition response was forthcoming.

The FDA also informed us in the same correspondence that the recent supplemental New Drug Application (sNDA) for Vancocin which was approved on December 14, 2011 would not qualify for three additional years of exclusivity, as the agency interpreted Section 505(v) of the FD&C Act to require a showing of a significant new use (such as a new indication) for an old antibiotic such as Vancocin in order for such old antibiotic to be eligible for a grant of exclusivity. FDA also indicated that it approved three ANDA's for generic vancomycin capsules. In June 2012, FDA approved a fourth ANDA for generic vancomycin capsules.

As a result of the actions of FDA, we performed step one of the impairment test in the first quarter of 2012 based on our current forecast (base case) of the impact of generics on our Vancocin and vancomycin cash flows. The sum of the undiscounted cash flows exceeded the carrying amount as of March 31, 2012 by approximately \$210 million. During the third quarter of 2012, we experienced larger than anticipated erosion in the sales volume and net realizable price in the Vancocin Branded Market and the entrance of a fourth generic competitor which prompted us to determine it appropriate to perform the step one of the impairment test again as of September 30, 2012. The sum of the undiscounted cash flows exceeded the carrying amount as of September 30, 2012 by approximately \$34 million.

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## ViroPharma Incorporated

### Notes to the Consolidated Financial Statements (Continued)

#### Note 6. Intangible Assets (Continued)

As part of this analysis, we concluded that the erosion in vancomycin revenue in the third quarter of 2012 was due to customers working down their inventory and increased generic competition. We believe that once the channel inventory is normalized to the new levels, our sales will begin to reflect the ongoing underlying prescription activity. Additionally, we will benefit from the expiration of the Genzyme royalty beginning in 2015. There were no events during the fourth quarter of 2012 that indicated the need to perform another step one of the impairment test for Vancocin. However, should future events occur that cause further reductions in revenue or operating results we would incur an impairment charge, which would be significant relative to the carrying value of the intangible assets as of December 31, 2012.

#### Auralis and Buccolam

On May 28, 2010, we acquired Auralis, a UK based specialty pharmaceutical company. With the acquisition of Auralis we added one marketed product and several development assets to our portfolio. We recognized an intangible asset related to certain supply agreements for the marketed product and one of the development assets. Additionally, we recognized in-process research and development (IPR&D) assets related to the development assets which are currently not approved. We determined that these assets meet the criterion for separate recognition as intangible assets and the fair value of these assets have been determined based upon discounted cash flow models. The contract rights acquired as part of the Auralis acquisition are being amortized on a straight-line basis over their estimated useful lives of 12 years and the product rights acquired are being amortized on a straight-line basis over their estimated useful lives of 10 years. In 2011, the European Commission granted a Centralized PUMA for Buccolam, for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years of age. This asset was previously classified as an IPR&D asset. As a result of this approval we began to amortize this asset over its estimated useful life of 10 years.

Due to the approval and launch of Buccolam, coupled with the approval and launch of Cinryze in Europe, we decided to alter our development and commercialization plans for the remaining Auralis IPR&D asset. The decision resulted in the impairment of the IPR&D asset and a portion of the Auralis Contract rights. Accordingly, we recorded a charge of approximately £5.4 million (approximately \$8.5 million) during the third quarter of 2011.

#### Plenadren

On November 15, 2011, we acquired DuoCort, a company focused on improving glucocorticoid replacement therapy for treatment of AI. The acquisition of DuoCort further expands our orphan disease commercial product portfolio. On November 3, 2011, the EC granted European Marketing Authorization for Plenadren® (hydrocortisone, modified release tablet), an orphan drug for treatment of adrenal insufficiency in adults, which will bring these patients their first pharmaceutical innovation in over 50 years. We recognized an intangible asset related to the Plenadren product rights. The product rights acquired are being amortized on a straight-line basis over their estimated useful lives of 10 years.

Amortization expense for the years ended December 31, 2012, 2011 and 2010 was \$35.3 million, \$31.0 million and \$29.4 million, respectively.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 7. Goodwill**

On October 21, 2008, we completed our acquisition of Lev Pharmaceuticals, Inc. The terms of the merger agreement provided for a contingent value right (CVR) to the former shareholders of \$0.50 per share, or approximately \$87.5 million, if Cinryze reaches at least \$600 million in cumulative net product sales by October 2018. During the second quarter of 2012, we recognized cumulative sales of Cinryze in excess of the \$600 million threshold; accordingly, we recorded the liability in the second quarter of 2012 with a corresponding increase to goodwill. We made this CVR payment along with certain other contingent acquisition related payments totaling approximately \$92.3 million in the third and fourth quarters of 2012. These payments, net of related tax benefits, are reflected as an increase to goodwill of approximately \$86.3 million, in accordance with SFAS 141, Accounting for Business Combinations, which was effective GAAP at the time of the acquisition.

On November 15, 2011, we acquired DuoCort, a company focused on improving glucocorticoid replacement therapy for treatment of AI. As a result of this acquisition we initially recorded goodwill of approximately \$7.3 million. During the third quarter of 2012, we obtained new information about certain facts and circumstances that existed at the acquisition date related to acquired deferred tax assets. Based on this new information, in the third quarter of 2012 we released approximately SEK 22.8 million, or \$3.5 million, of valuation allowance related to the deferred tax assets with a corresponding reduction of goodwill. All other changes in the carrying value of goodwill since acquisition is attributable to foreign currency fluctuations.

In May 2010, we acquired a 100% ownership interest in Auralis Limited, a UK based specialty pharmaceutical company. As a result of this acquisition we recorded initial goodwill of approximately \$5.9 million. The change in the carrying value of goodwill since the acquisition date is attributable to foreign currency fluctuations.

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

Accrued expenses and other current liabilities consist of the following at December 31, 2012 and 2011:

(in thousands)	2012	2011
Rebates and returns	\$ 33,261	\$ 48,115
Payroll, bonus and employee benefits liabilities	13,189	10,470
Clinical development and research liabilities	10,073	4,872
Selling and commercial liabilities	6,662	4,149
VAT payable	5,537	713
Interest payable	1,377	1,375
Other current liabilities	13,404	6,289
	<u>\$ 83,503</u>	<u>\$ 75,983</u>

**Note 9. Long-Term Debt**

Long-term debt as of December 31, 2012 and December 31, 2011 is summarized in the following table:

(in thousands)	2012	2011
Senior convertible notes	\$ 161,793	\$ 153,453
less: current portion	<u>—</u>	<u>—</u>
Long-term debt	<u>\$ 161,793</u>	<u>\$ 153,453</u>

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 9. Long-Term Debt (Continued)**

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.

The debt and equity components of our senior convertible debt securities were 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 is 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. Accordingly, the senior convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value.

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

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 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

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 9. Long-Term Debt (Continued)**

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 our common stock on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options (\$18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants (\$24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants.

Initially, the purchased call options and warrants sold with the terms described above were based upon the \$250.0 million offering, and the number of shares we would purchase under the call option and the number of shares we would sell under the warrants was 13.25 million, to correlate to the \$250.0 million principal amount. 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. 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 a result of the above negotiated sale and purchase transactions we are now entitled to receive approximately 10.87 million shares of our 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, which correlates to \$205 million of convertible notes outstanding.

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

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 9. Long-Term Debt (Continued)**

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.

As of December 31, 2012, 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 an unamortized balance of \$1.6 million at December 31, 2012.

The senior convertible notes were convertible into shares of our common stock during the second and fourth quarters of 2012 at the election of the holders as the last reported sale price of our common stock for the 20 or more trading days in the 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeded 130% of the conversion price, \$18.87 per share. No notes were converted.

As of December 31, 2012 senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$161.8 million and a fair value of approximately \$284.6 million, based on the Level 2 valuation hierarchy of the fair value measurements standard.

*Credit Facility*

On September 9, 2011, we entered into a \$200 million, three-year senior secured revolving credit facility (the "Credit Facility"), the terms of which are set forth in a Credit Agreement dated as of September 9, 2011 (the "Credit Agreement") with JPMorgan Chase Bank, N.A., as administrative agent, BMO Harris Financing Inc., TD Bank, N.A. and Morgan Stanley Bank, NA as co-syndication agents and certain other lenders.

The Credit Facility is available for working capital and general corporate purposes, including acquisitions which comply with the terms of the Credit Agreement. The Credit Agreement provides separate sub-limits for letters of credit up to \$20 million and swing line loans up to \$10 million.

The Credit Agreement requires us to maintain (i) a maximum senior secured leverage ratio of less than 2.00 to 1.00, (ii) a maximum total leverage ratio of less than 3.50 to 1.00, (iii) a minimum interest coverage ratio of greater than 3.50 to 1.00 and (iv) minimum liquidity equal to or greater than the sum of \$100 million plus the aggregate amount of certain contingent consideration payments resulting from business acquisitions payable by us within a specified time period. The Credit Agreement also contains certain other usual and customary affirmative and negative covenants, including but not limited to, limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with affiliates.

Our obligations under the Credit Facility are guaranteed by certain of our domestic subsidiaries (the "Subsidiary Guarantors") and are secured by substantially all of our assets and the assets of the Subsidiary Guarantors. Borrowings under the Credit Facility will bear interest at an amount equal to a rate calculated based on the type of borrowing and our senior secured leverage ratio (as defined in the Credit Agreement) from time to time. For loans (other than swing line loans), we may elect to pay interest based on adjusted LIBOR plus between 2.25% and 2.75% or an Alternate Base Rate (as defined in the Credit Agreement) plus between 1.25% and 1.75%. We will also pay a commitment fee of between 35 to 45 basis points, payable quarterly, on the average daily unused amount of the Credit Facility based on our senior secured leverage ratio from time to time.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 9. Long-Term Debt (Continued)**

As of the date of this filing, we have not drawn any amounts under the Credit Facility and are in compliance with our covenants. However, as a result of the negative impact of approval of generic vancomycin on our consolidated operating results, our ability to borrow the full \$200 million provided under the Credit Facility during portions of 2013 and 2014 may be limited or prohibited. Limitations on our ability to borrow under the Credit Facility could impact our liquidity and limit our ability to fund general corporate requirements, such as research and development expenses, or to make acquisitions.

At December 31, 2012, approximately \$110.0 million of our cash and availability under the credit agreement is subject to the minimum liquidity covenant (iv), described above.

As of December 31, 2012, we have accrued \$0.2 million in interest payable for the revolver. Financing costs of approximately \$1.7 million incurred to establish the Credit Facility were deferred and are being amortized to interest expense over the life of the Credit Facility, with an unamortized balance of \$0.9 million as of December 31, 2012.

**Note 10. Acquisitions, License and Research Agreements***DuoCort Pharma AB Acquisition*

On November 15, 2011, we acquired a 100% ownership interest in DuoCort, a private company based in Helsingborg, Sweden focused on improving glucocorticoid replacement therapy for treatment of adrenal insufficiency (AI). We paid approximately 213 million Swedish Krona (SEK) or approximately \$32.1 million in upfront consideration. We have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$37 million to \$132 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$25 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$108 million of the contingent payments are related to commercial milestones based on the success of the product.

The following tables summarize the consideration transferred to acquire DuoCort and the amounts of identified assets acquired and liabilities assumed at the acquisition date.

The consideration transferred was as follows:

	<u>(in thousands)</u>
Cash	\$ 32,121
Contingent Consideration	21,027
Total	<u>\$ 53,148</u>

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 10. Acquisitions, License and Research Agreements (Continued)**

The total consideration was allocated to the net assets acquired and liabilities assumed as follows:

	<u>(in thousands)</u>
<b>Assets acquired:</b>	
Cash	\$ 80
Inventory	246
Other current assets	591
Product rights	63,821
Goodwill	7,264
<b>Total assets</b>	<u>\$ 72,002</u>
<b>Liabilities assumed:</b>	
Trade and other payables	\$ 1,721
Loans payable	301
Deferred tax liabilities	16,832
<b>Total liabilities</b>	<u>\$ 18,854</u>
<b>Consideration transferred</b>	<u>\$ 53,148</u>

The DuoCort contingent consideration consists of three separate contingent payments. The first will be payable upon the regulatory approval to manufacture bulk product in the EU. The second contingent payment is based on the attainment of specified revenue targets and the third contingent payment is payable upon regulatory approval of the product in the United States.

The fair value of the first and third contingent consideration payments recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the probability adjusted contingent payments and the expected approval dates. The fair value of the second contingent consideration payment recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and expected revenue target attainment dates.

These fair values are based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent considerations are classified as liabilities and are subject to the recognition of subsequent changes in fair value through our results of operations.

The fair value of the product rights asset has been determined using an income approach based upon a discounted cash flow model. That measure is based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. Key assumptions include a discount rate of 20.5%, the weighted average cost of capital implied by DuoCort's business enterprise value, and probability weighted cash flows.

The fair value of inventory represents net realizable value for finished goods less a normal profit on selling efforts. The fair value of the remaining assets and liabilities acquired are based on the price that would be received on the sale of the asset or the price paid to transfer the liability to a market participant and approximates its carrying value on the measurement date.

As a result of the transaction, we recognized \$7.3 million of goodwill which is not deductible for tax purposes.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 10. Acquisitions, License and Research Agreements (Continued)**

The DuoCort results of operations have been included in the Consolidated Statement of Operations beginning November 15, 2011.

The results of operations of DuoCort since the acquisition date and had the acquisition occurred on January 1, 2011 are immaterial to our consolidated results of operation. We incurred approximately \$1.4 million of transaction cost as part of this acquisition.

*Meritage Pharma, Inc.*

On December 22, 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private development-stage company based in San Diego, CA focused on developing oral budesonide suspension (OBS) as a treatment for eosinophilic esophagitis (EoE). EoE is a newly recognized chronic disease that is increasingly being diagnosed in children and adults. It is characterized by inflammation and accumulation of a specific type of immune cell, called an eosinophil, in the esophagus. EoE patients may have persistent or relapsing symptoms, which include dysphagia (difficulty in swallowing), nausea, stomach pain, chest pain, heartburn, loss of weight and food impaction.

As consideration for the agreement, we made an initial \$7.5 million non-refundable payment to Meritage and have the option to provide Meritage up to an additional \$12.5 million for the development of OBS. Meritage will utilize the funding to conduct additional Phase 2 clinical assessment of OBS. We have an exclusive option to acquire Meritage, at our sole discretion, by providing written notice at any time during the period from December 22, 2011 to and including the date that is the earlier of (a) the date that is 30 business days after the later of (i) the receipt of the final study data for the Phase 2 study and (ii) identification of an acceptable clinical end point definition for a pivotal induction study agreed to by the FDA. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

We have determined that Meritage is a variable interest entity (VIE), however because we do not have the power to direct the activities of Meritage that most significantly impact its economic performance we are not the primary beneficiary of this VIE at this time. Further, we have no oversight of the day-to-day operations of Meritage, nor do we have sufficient rights or any voting representation to influence the operating or financial decisions of Meritage, nor do we participate on any steering or oversight committees. Therefore, we are not required to consolidate Meritage into our financial statements. This consolidation status could change in the future if the option agreement is exercised, or if other changes occur in the relationship between Meritage and us.

We valued the non-refundable \$7.5 million upfront payment using the cost method. In June 2012, Meritage completed the delivery of all the documents and notifications needed to satisfy the conditions of the First Option Milestone, as defined in the agreement. As a result of achieving this milestone we made a \$5.0 million milestone payment in the third quarter of 2012 and increased the carrying value of our cost method investment. We have the option to provide Meritage up to an additional \$7.5 million for the development of OBS.

Under the cost method, the fair value of the investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 10. Acquisitions, License and Research Agreements (Continued)**

investment. As of December 31, 2012, we were not aware of any such adverse effects, as such no fair value estimate has been prepared.

The asset is recorded as an other long-term asset on our consolidated balance sheets and is amortized through other income (expense) in our consolidated results of operations over the expected term of the option agreement which is expected to be December 2014. We recognized approximately \$3.8 million of amortization expense during 2012 related to this asset.

*Intellect Neurosciences, Inc. License Agreement*

On September 30, 2011, we entered into a license agreement with INS for the worldwide rights to its clinical stage drug candidate, VP20629, which we expect to develop for the treatment of Friedreich's Ataxia (FA), a rare, hereditary, progressive neurodegenerative disease. We expect to initiate a single and repeat dose phase 1 study in patients in 2013 and expect to initiate a subsequent Phase 2 study after completion of the Phase 1 study. Following completion of the Phase 2 study, a Phase 3 study is planned. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data. Under the terms of the agreement, we have exclusive worldwide rights to develop and commercialize VP20629 for the treatment, management or prevention of any disease or condition covered by INS' patents. We paid INS a \$6.5 million upfront licensing fee and may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales. We are solely responsible for the costs of VP20629 development.

*Halozyyme Therapeutics License Agreement*

In May 2011, Halozyyme Therapeutics (Halozyyme) granted us an exclusive worldwide license to use Halozyyme's proprietary Enhance™ technology, a proprietary drug delivery platform using Halozyyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with a C1 esterase inhibitor. We intend to apply rHuPH20 initially to develop a novel subcutaneous formulation of Cinryze for routine prophylaxis against attacks. Under the terms of the license agreement, we paid Halozyyme an initial upfront payment of \$9 million. In the fourth quarter of 2011, we made a milestone payment of \$3 million related to the initiation of a Phase 2 study begun in September 2011 to evaluate the safety, and pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. Pending successful completion of an additional series of clinical and regulatory milestones we may make further milestone payments to Halozyyme which could reach up to an additional \$41 million related to HAE and up to \$30 million of additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyyme until specified events have occurred. Upon regulatory approval, Halozyyme will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

*Auralis Acquisition*

In May 2010, we acquired a 100% ownership interest in Auralis, a UK based specialty pharmaceutical company for approximately \$14.5 million in upfront consideration for the acquisition of the company and its existing pharmaceutical licenses and products. We have also agreed to pay an

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 10. Acquisitions, License and Research Agreements (Continued)**

additional payment of £10 million Pounds Sterling contingent upon the first regulatory approval of Buccolam, a product in late stage development.

In September of 2011, the EC granted a Centralized PUMA for Buccolam, and accordingly the additional consideration was paid. The U.S. dollar equivalent of the payment was approximately \$15.8 million. The fair value of the contingent consideration recognized on the acquisition date (\$9.0 million) was estimated by applying a discount rate based on an implied rate of return from the acquisition to the risk probability weighted asset cash flows and the expected approval date. This fair value was based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration was classified as a liability and was subject to the recognition of subsequent changes in fair value.

The results of Auralis's operations have been included in the Consolidated Statement of Operations beginning June 1, 2010.

The following tables summarize the consideration transferred to acquire Auralis and the amounts of identified assets acquired and liabilities assumed at the acquisition date.

The purchase price was as follows:

	<u>(in thousands)</u>
Cash	\$ 14,514
Contingent Consideration	9,000
Total purchase price	<u>\$ 23,514</u>

The total cost of the acquisition was allocated to Auralis assets acquired and liabilities assumed as follows:

	<u>(in thousands)</u>
<b>Assets acquired:</b>	
Cash	\$ 1,362
Trade receivable	741
Inventory	1,623
Property, plant and equipment	23
Contract rights	11,600
IPR&D	10,500
Goodwill	5,851
Deferred tax assets	317
<b>Total assets</b>	<u>\$ 32,017</u>
<b>Liabilities assumed:</b>	
Trade and other payables	\$ 519
Loan Payable	1,545
Deferred tax liabilities	6,439
<b>Total liabilities</b>	<u>\$ 8,503</u>
<b>Total purchase price</b>	<u>\$ 23,514</u>

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 10. Acquisitions, License and Research Agreements (Continued)***Sanquin Rest of World (ROW) Agreement*

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 Ceter) 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, Ceter and Ceter 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.

On December 6, 2012, we entered into a first amendment to ROW Agreement. The first amendment to the ROW Agreement (the "First Amendment") expands our territory to worldwide, with the exception of all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil) and Israel, which remain the subject of the Restated US Agreement. The First Amendment also grants Sanquin the license to commercialize Cinryze in certain countries in which Sanquin has pre-existing marketing arrangements, including Belgium, Luxembourg, The Netherlands, Finland, Turkey, Indonesia, and Egypt (the "Sanquin Licensed Territories"). In the event that the marketing arrangements in the Sanquin Licensed Territories expire or are terminated, VP SPRL has a right of first refusal to include such country in its territory and/or to exclude such country from the countries covered by its license to Sanquin. As a result of the First Amendment, we have worldwide rights to commercialize C1-INH products other than in the Sanquin Licensed Territories. In connection with the First Amendment, we made a payment of \$1.3 million to Sanquin, reflected as research and development expense in our consolidated statement of operations.

Additionally, under the First Amendment, Sanquin agreed to withdraw its Ceter and Cebitor product from certain markets in which it is currently being sold in order to transition to Cinryze and its future forms and formulations. The transition will be on a country by country basis and on a schedule agreed by VP SPRL and Sanquin to avoid supply interruptions to patients using Sanquin's Ceter and/or Cebitor products. The First Amendment also provides that in the countries in which Sanquin is licensed to commercialize VP SPRL C1-INH product, Sanquin shall have the right to liaise with regulators to set the reimbursement price, unless regulators require VP SPRL to do so.

We and Sanquin also agreed to certain provisions restricting the sale of competitive products relating to C1-INH without the other's consent. We may not directly or indirectly commercially exploit competitive products in our territory without Sanquin's consent. On a country by country basis, following the applicable transition date in each country, Sanquin agrees not to directly or indirectly commercially exploit competitive products to any person anywhere in the world. The First Amendment provides Sanquin with the right to sell and supply Ceter and/or Cebitor before the transition date and VP SPRL's C1-INH product thereafter to a named manufacturer provided that the named manufacturer uses the products solely in connection with the manufacturer's manufacture of certain plasma products under its own marketing authorization and corporate brand

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 10. Acquisitions, License and Research Agreements (Continued)***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 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 5,000,000 shares of preferred stock from time to time in such series and with such preference and rights as it may designate.

*Share Repurchase Program*

On March 9, 2011, our Board of Directors authorized the use of up to \$150 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. On September 14, 2011, our Board of Directors authorized the use of up to an additional \$200 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. On September 7, 2012, our Board of Directors authorized the use of up to an additional \$200 million to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017. Purchases may be made by means of open market transactions, block transactions, privately negotiated purchase transactions or other techniques from time to time.

During 2012, through open market purchases, we reacquired approximately 6.9 million shares at a cost of approximately \$180.3 million or an average price of \$26.20 per share and during 2011, we reacquired approximately 9.2 million shares at a cost of approximately \$169.7 million or an average price of \$18.52 per share.

At December 31, 2012 we have approximately \$200.0 million available under these authorizations to repurchase shares of our common stock and/or our 2% Senior Convertible Notes due 2017.

**Note 12. Share-based Compensation**

Beginning in 2011, our stock-based compensation program consisted of a combination of: time vesting stock options with graduated vesting over a four year period; performance and market vesting common stock units, or PSUs, tied to the achievement of pre-established company performance metrics and market based goals over a three-year performance period; and, time vesting restricted stock awards, or RSUs, granted to our non-employee directors vesting over a one year period. Grants under our former stock based compensation program consisted only of time vesting stock options.

The fair values of our share-based awards are determined as follows:

- Stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model and compensation expense is recognized over the applicable vesting period;

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 12. Share-based Compensation (Continued)**

- PSUs subject to company specific performance metrics, which include both performance and service conditions, are based on the market value of our stock on the date of grant. Compensation expense is based upon the number of shares expected to vest after assessing the probability that the performance criteria will be met. Compensation expense is recognized over the vesting period, adjusted for any changes in our probability assessment;
- PSUs subject to our total shareholder return, or TSR, market metric relative to a peer group of companies, which includes both market and service conditions, are estimated using a Monte Carlo simulation. Compensation expense is based upon the number and value of shares expected to vest. Compensation expense is recognized over the applicable vesting period. All compensation cost for the award will be recognized if the requisite service period is fulfilled, even if the market condition is never satisfied; and,
- Time vesting RSUs are based on the market value of our stock on the date of grant. Compensation expense for time vesting RSUs is recognized over the vesting period.

The vesting period for our stock awards is the requisite service period associated with each grant.

Share-based compensation expense consisted of the following for the years ended December 31, 2012, 2011 and 2010:

(in thousands)	December 31,		
	2012	2011	2010
Stock options	\$ 16,689	\$ 12,154	\$ 11,043
Performance shares	3,244	1,535	—
Restricted shares	974	401	—
Employee Stock Purchase Plan	225	152	129
Non-employee stock options	—	—	4
Total	<u>\$ 21,132</u>	<u>\$ 14,242</u>	<u>\$ 11,176</u>

Our share-based compensation expense is recorded as follows:

(in thousands)	December 31,		
	2012	2011	2010
Research and development	\$ 4,522	\$ 3,335	\$ 3,329
Selling, general and administrative	16,610	10,907	7,847
Total	<u>\$ 21,132</u>	<u>\$ 14,242</u>	<u>\$ 11,176</u>

We currently have 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 our 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.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 12. Share-based Compensation (Continued)**

In May 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 in May of 2010. In April 2012, the 2005 Plan was amended and an additional 2,500,000 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 in May of 2012.

As of December 31, 2012, there were 4,693,750 shares available for grant under the Plans.

The following table lists information about these equity plans at December 31, 2012:

	<u>1995 Plan</u>	<u>2001 Plan</u>	<u>2005 Plan</u>	<u>Combined</u>
Shares authorized for issuance	4,500,000	500,000	15,350,000	20,350,000
Shares outstanding	4,500,000	500,000	10,656,250	15,656,250
Shares available for grant	<u>—</u>	<u>—</u>	<u>4,693,750</u>	<u>4,693,750</u>

*Employee Stock Option Plans*

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 2012, 2011 and 2010 had weighted average fair values of \$14.08, \$11.41 and \$6.68 per option. The grant date 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>2012</u>	<u>2011</u>	<u>2010</u>
Expected dividend yield	—	—	—
Range of risk free interest rate	1.0%-1.6%	1.4%-2.9%	1.9%-3.4%
Weighted-average volatility	61.3%	67.8%	71.4%
Range of volatility	58.0%-62.3%	62.3%-69.3%	69.3%-72.4%
Range of expected option life (in years)	5.50-6.25	5.50-6.25	5.50-6.25

The 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.

We estimate forfeiture rates for all share-based awards and monitor stock options exercises and employee termination patterns in estimating the forfeiture rate.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 12. Share-based Compensation (Continued)**

The following table lists option grant activity for the three-year period ended December 31, 2012:

	Share Options	Weighted average exercise price per share
Balance at December 31, 2009	7,590,195	\$ 10.68
Granted	2,114,784	10.12
Exercised	(649,311)	5.53
Forfeited	(66,393)	10.21
Expired	(435,943)	22.74
Balance at December 31, 2010	8,553,332	10.45
Granted	1,859,778	18.08
Exercised	(1,547,787)	9.20
Forfeited	(274,057)	13.62
Expired	(106,025)	27.47
Balance at December 31, 2011	8,485,241	12.03
Granted	2,047,899	24.61
Exercised	(1,415,090)	8.96
Forfeited	(300,719)	17.53
Expired	(2,500)	14.91
Balance at December 31, 2012	8,814,831	\$ 15.26

Included in the 2012 options exercises of 1,415,090 are 41,010 shares with a weighted average exercise price of \$29.29 per share that were withheld for minimum withholding tax purposes for optionees who elected to net share settle this obligation.

The total intrinsic value of share options exercised during the year ended December 31, 2012, 2011 and 2010 was approximately \$27.3 million, \$18.2 million and \$5.9 million, respectively.

We have 8,814,831 option grants outstanding at December 31, 2012 with exercise prices ranging from \$1.77 per share to \$32.69 per share and a weighted average remaining contractual life of 6.77 years. The following table lists the outstanding and exercisable option grants as of December 31, 2012:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding	8,814,831	\$ 15.26	6.77	\$ 72,046
Exercisable	4,533,274	\$ 11.85	5.25	\$ 49,464

As of December 31, 2012, there was \$34.3 million of total unrecognized compensation cost related to unvested share options granted under the Plans. This cost is expected to be recognized over a weighted-average period of 2.7 years. The total fair value of shares vested during the year ended December 31, 2012 was \$13.1 million.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 12. Share-based Compensation (Continued)***Performance Awards*

Beginning in 2011, employees receive annual grants of performance award units, or PSUs, in addition to stock options which give the recipient the right to receive common stock that is contingent upon achievement of specified pre-established company performance goals over a three year performance period. The performance goals for the PSUs granted, which are accounted for as equity awards, are based upon the following performance measures: (i) our revenue growth over the performance period, (ii) our adjusted net income as a percent of sales at the end of the performance period, and (iii) our relative total shareholder return, or TSR, compared to a peer group of companies at the end of the performance period.

In 2012 and 2011, approximately 186,000 and 155,000 PSUs subject to Company specific performance metrics were granted with weighted average grant date fair values of \$28.16 and \$17.84 per share, respectively. In 2012 and 2011, approximately 21,000 and 17,000 PSUs subject to the TSR metric were granted with weighted average grant date fair values of \$45.37 and \$24.38 per share, respectively. The number of PSUs reflected as granted represents the target number of shares that are eligible to vest subject to the attainment of the performance goals. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 200% of the PSUs granted. Shares of our common stock are issued on a one-for-one basis for each PSU earned. Participants vest in their PSUs at the end of the performance period.

The fair value of the PSUs subject to Company specific performance metrics is equal to the closing price of our common stock on the grant date.

The fair value of the market condition PSUs was determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

	2012	2011
Closing stock price on grant date	\$ 28.16	\$ 17.84
Performance period starting price	\$ 24.94	\$ 16.85
Term of award (in years)	2.99	2.99
Volatility	65.06%	69.75%
Risk-free interest rate	0.45%	1.19%
Expected dividend yield	0.00%	0.00%
Fair value per TSR PSU	\$ 45.37	\$ 24.38

The performance period starting price is measured as the average closing price over the last 30 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of our common stock and the common stocks of the comparator group of companies and stock price volatilities of the comparator group of companies.

At December 31, 2012, there was approximately \$5.9 million of unrecognized compensation cost related to all PSUs that is expected to be recognized over a weighted-average period of approximately 1.79 years.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 12. Share-based Compensation (Continued)**

The following summarizes select information regarding our PSU awards as of December 31, 2012:

	Share Units	Weighted-average grant date fair value
Balance at December 31, 2010	—	\$ —
Granted	173,107	18.50
Vested	—	—
Forfeited	(8,415)	18.49
Balance at December 31, 2011	164,692	18.50
Granted	206,900	29.88
Forfeited	(20,853)	24.38
Balance at December 31, 2012	<u>350,739</u>	<u>\$ 24.86</u>

*Restricted Stock Awards*

Beginning in 2011, we also grant our non-employee directors restricted stock awards that generally vest after one year of service. In 2012 and 2011, 37,750 and 27,000 RSUs were granted with weighted average grant date fair values of \$31.12 and \$17.30 per share, respectively. The fair value of a restricted stock award is equal to the closing price of our common stock on the grant date.

The following summarizes select information regarding our restricted stock awards as of December 31, 2012:

	Share Units	Weighted-average grant date fair value
Balance at December 31, 2010	—	\$ —
Granted	27,000	17.30
Vested	—	—
Forfeited	—	—
Balance at December 31, 2011	27,000	17.30
Granted	37,750	31.12
Vested	(27,000)	17.30
Balance at December 31, 2012	<u>37,750</u>	<u>\$ 31.12</u>

As of December 31, 2012, there was approximately \$0.27 million of unrecognized compensation cost related to RSUs that is expected to be recognized over a weighted average period of 0.97 years.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 12. Share-based Compensation (Continued)***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, 29,927, 29,982 and 48,909 shares were sold to employees during 2012, 2011 and 2010. As of December 31, 2012 there are approximately 370,151 shares available for issuance under this plan.

Under this plan, employees may purchase common stock through payroll deductions in semi-annual offerings at a price equal to the lower of 85% of the closing price on the applicable offering commencement date or 85% of the closing price on the applicable offering termination date. Since the total payroll deductions from the plan period are used to purchase shares at the end of the offering period, the number of shares ultimately purchased by the participants is variable based upon the purchase price. Shares issued under the employee stock purchase plan are new shares. There are two plan periods: January 1 through June 30 ("Plan Period One") and July 1 through December 31 ("Plan Period Two"). The plan qualifies under Section 423 of the Internal Revenue Code.

In November 2012, the plan was amended to revise Plan Period One to May 1 through October 31 and to revise Plan period Two to November 1 through April 30 along with minor administrative changes. The plan amendments are effective January 1, 2013 and provide an Initial Offering Period from January 1, 2013 through April 30, 2013.

The fair value of shares issued under the plan during 2012 was approximately \$225,000. The fair value was estimated using the Type B model, with the following assumptions:

	<u>2012 Plan Period Two</u>	<u>2012 Plan Period One</u>
Risk free interest rate	0.15%	0.06%
Volatility	48.60%	47.70%
Expected option life (in years)	0.5	0.5

Under Plan Period Two, 15,490 shares were sold to employees on December 31, 2012 at \$19.35 per share, which represents the closing price on the offer termination date of \$22.76 per share at 85%.

Under Plan Period One, 14,437 shares were sold to employees on June 30, 2012 at \$20.15 per share, which represents the closing price on the offer termination date of \$23.70 per share at 85%.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 13. Income Taxes**

For the years ended December 31, 2012, 2011 and 2010, the following table summarizes the components of income before income taxes and the provision for income taxes:

(in thousands)	Year ended December 31,		
	2012	2011	2010
Income (loss) before income taxes:			
Domestic	\$ 52,373	\$ 252,381	\$ 210,819
Foreign	(33,352)	(44,374)	(9,933)
Income before income taxes	<u>\$ 19,021</u>	<u>\$ 208,007</u>	<u>\$ 200,886</u>
Income tax expense (benefit):			
Current:			
Federal	\$ 29,672	\$ 79,850	\$ 45,727
State and local	2,731	6,601	9,684
Foreign	853	337	(33)
Subtotal	<u>33,256</u>	<u>86,788</u>	<u>55,378</u>
Deferred:			
Federal	\$ (17,519)	1,318	26,926
State and local	5,628	(8,136)	(4,198)
Foreign	(7,955)	(12,622)	(2,828)
Subtotal	<u>(19,846)</u>	<u>(19,440)</u>	<u>19,900</u>
Income tax expense	<u>\$ 13,410</u>	<u>\$ 67,348</u>	<u>\$ 75,278</u>
Effective income tax rate	70.5%	32.4%	37.5%

For the years ended December 31, 2012, 2011 and 2010, the following table reconciles the federal statutory income tax rate to the effective income tax rate:

(% of pre-tax income)	Year ended December 31,		
	2012	2011	2010
U.S. federal statutory income tax rate	35.0%	35.0%	35.0%
State and local income tax, net of federal tax benefit	11.1	1.7	1.8
Share-based compensation	2.3	0.3	0.6
Orphan drug credit	(11.8)	(0.2)	(0.2)
Change in valuation allowance	16.8	(2.2)	0.1
Manufacturing deduction	(6.9)	(4.1)	—
Foreign rate differential	16.7	1.0	0.1
Charitable contributions	(8.3)	(0.2)	—
Non-deductible amortization	7.0	—	—
Contingent consideration	6.2	0.6	0.2
Other	2.4	0.5	(0.1)
Effective income tax rate	<u>70.5%</u>	<u>32.4%</u>	<u>37.5%</u>

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 13. Income Taxes (Continued)**

In 2012, 2011 and 2010, respectively, \$7.1 million, \$3.2 million and \$1.6 million related to current stock option tax benefits were allocated directly to stockholders' equity.

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

(in thousands)	December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	\$ 21,260	\$ 17,893
Charitable contribution carryforward	4,281	—
Capitalized research and development costs	4,574	6,503
Non-deductible reserves	10,383	6,118
Depreciation	576	273
Intangible asset amortization	9,733	11,179
Equity compensation	15,132	10,783
Other	2,036	1,267
Subtotal	67,975	54,016
Valuation allowance	(4,786)	(4,876)
Deferred tax assets	63,189	49,140
Deferred tax liabilities:		
Intangible asset amortization	191,420	198,334
Convertible note	6,213	6,335
Prepaid expenses	1,728	1,388
Deferred tax liabilities	199,361	206,057
Net deferred tax assets (liability)	\$ (136,172)	\$ (156,917)

At December 31, 2012 and 2011, deferred tax assets and liabilities were classified on the Company's balance sheets as follows:

(in thousands)	December 31,	
	2012	2011
Current assets	\$ 13,324	\$ 10,055
Non-current assets	17,988	11,786
Current liabilities	—	(52)
Non-current liabilities	(167,484)	(178,706)
Net deferred tax liability	\$ (136,172)	\$ (156,917)

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 13. Income Taxes (Continued)**

The following table summarizes the change in the valuation allowance:

(in thousands)	Year ended December 31,		
	2012	2011	2010
Valuation allowance at beginning of year	\$ 4,876	\$ 6,238	\$ 5,949
Tax expense (benefit)	3,200	(4,662)	289
Acquisitions	(3,298)	3,435	—
Foreign exchange	8	(135)	—
Valuation allowance at end of year	<u>\$ 4,786</u>	<u>\$ 4,876</u>	<u>\$ 6,238</u>

Due to uncertainty regarding the ability to realize the benefit of deferred tax assets relating to certain net operating loss carryforwards, valuation allowances have been established to reduce deferred tax assets to a level that is more likely than not to be realized. Realization of the remaining net deferred tax assets will depend on the generation of sufficient taxable income in the appropriate jurisdiction, the reversal of deferred tax liabilities, tax planning strategies and other factors prior to the expiration date of the carryforwards. A change in the estimates used to make this determination could require a reduction in deferred tax assets if they are no longer considered realizable.

As of December 31, 2012, our foreign subsidiaries have incurred cumulative losses and consequently no deferred tax liability has been established for any future distribution of funds from foreign subsidiaries.

The following table summarizes carryforwards of net operating losses and charitable contributions as of December 31, 2012.

(in thousands)	Amount	Expiration
Foreign net operating losses	\$ 39,768	Indefinite
Charitable contributions	10,962	2017
State net operating losses	119,293	2020-2024

At December 31, 2012 and 2011, the Company had no gross unrecognized tax benefits. The Company does not expect any material increase or decrease in its gross unrecognized tax benefits during the next twelve months.

The Company and its domestic subsidiaries file consolidated income tax returns in the U.S. and certain states. In addition, separate income tax returns are filed in other states. The Company's foreign subsidiaries file separate income tax returns in the foreign jurisdictions in which they are located.

Our policy is to record interest and penalties related to tax matters in income tax expense. Our last U.S. tax examination for 2008 concluded in the first quarter of 2011 with no material adjustments. We are currently under examination in a foreign tax jurisdiction and various state income tax returns are also currently under examination. At this time, we do not believe that the results of these examinations will have a material impact on our consolidated financial statements.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 14. Accumulated Other Comprehensive Income (Loss)**

The following table presents the changes in the components of accumulated other comprehensive income (loss):

(in thousands)	Cumulative Translation	Unrealized gains (losses) on securities	Accumulated other comprehensive income (loss)
Balance at December 31, 2009	\$ 914	\$ —	\$ 914
Current period other comprehensive income, net	(1,172)	—	(1,172)
Balance at December 31, 2010	(258)	—	(258)
Current period other comprehensive income, net	(3,145)	(11)	(3,156)
Balance at December 31, 2011	(3,403)	(11)	(3,414)
Current period other comprehensive income, net	427	12	439
Balance at December 31, 2012	<u>\$ (2,976)</u>	<u>\$ 1</u>	<u>\$ (2,975)</u>

**Note 15. Earnings per share**

(in thousands, except per share data)	For the years ended December 31,		
	2012	2011	2010
<b>Basic Earnings Per Share</b>			
Net income	\$ 5,611	\$ 140,659	\$ 125,608
Common stock outstanding (weighted average)	68,214	74,517	77,820
Basic net income per share	<u>\$ 0.08</u>	<u>\$ 1.89</u>	<u>\$ 1.61</u>
<b>Diluted Earnings Per Share</b>			
Net income	\$ 5,611	\$ 140,659	\$ 125,608
Add interest expense on senior convertible notes, net of income tax	—	7,548	7,193
Diluted net income	<u>\$ 5,611</u>	<u>\$ 148,207</u>	<u>\$ 132,801</u>
Common stock outstanding (weighted average)	68,214	74,517	77,820
Add shares from senior convertible notes	—	10,864	10,864
Add stock options and stock awards	3,550	2,695	1,397
Common stock equivalents	<u>71,764</u>	<u>88,076</u>	<u>90,081</u>
Diluted net income per share	<u>\$ 0.08</u>	<u>\$ 1.68</u>	<u>\$ 1.47</u>

The following common stock equivalents were excluded from the calculations of diluted earnings per share as their effect would be anti-dilutive:

(in thousands)	For the years ended December 31,		
	2012	2011	2010
Stock options	2,371	1,896	5,447
Shares from senior convertible notes	10,864	—	—

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 16. 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 tables provide the assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2012 and 2011:

(in thousands)	Total Carrying Value at	Fair Value Measurements at December 31, 2012		
	December 31, 2012	(Level 1)	(Level 2)	(Level 3)
Cash and cash equivalents	\$ 175,518	\$ 175,518	\$ —	\$ —
Short-term investments	\$ 71,338	\$ 71,338	\$ —	\$ —
Contingent consideration, short-term	\$ 8,367	\$ —	\$ —	\$ 8,367
Contingent consideration, long-term	\$ 17,710	\$ —	\$ —	\$ 17,710

(in thousands of dollars)	Total Carrying Value at	Fair Value Measurements at December 31, 2011		
	December 31, 2011	(Level 1)	(Level 2)	(Level 3)
Cash and cash equivalents	\$ 331,352	\$ 331,352	\$ —	\$ —
Short-term investments	\$ 128,478	\$ 128,478	\$ —	\$ —
Contingent consideration, short-term	\$ 7,293	\$ —	\$ —	\$ 7,293
Contingent consideration, long-term	\$ 12,896	\$ —	\$ —	\$ 12,896

The following table provides a rollforward of liabilities measured using Level 3 inputs:

	(in thousands of dollars)
Balance at December 31, 2010	\$ 10,973
Additions	21,027
Re-measurement	3,711
Impact of foreign exchange	306
Settlements	(15,828)
Balance at December 31, 2011	20,189
Additions	—
Re-measurement	4,514
Impact of foreign exchange	1,374
Settlements	—
Balance at December 31, 2012	\$ 26,077

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## ViroPharma Incorporated

### Notes to the Consolidated Financial Statements (Continued)

#### Note 16. Fair Value Measurement (Continued)

Valuation Techniques—Cash and cash equivalents and short-term investments are measured at fair value using quoted market prices and are classified within Level 1 of the valuation hierarchy. There were no changes in valuation techniques during the year ended December 31, 2012.

During the third quarter of 2011, we settled (paid) the contingent consideration liability related to the regulatory approval of Buccolam, acquired as part of the Auralis acquisition.

In the fourth quarter of 2011, we recognized contingent consideration liabilities related to our acquisition of DuoCort. The fair values of the contingent consideration is measured using significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration payments are classified as liabilities and are subject to the recognition of subsequent changes in fair value through our results of operations in other operating expenses.

The fair value of the contingent consideration payments related to regulatory approvals, is estimated by applying risk adjusted discount rates, 13% and 20.3%, to the probability adjusted contingent payments and the expected approval dates. The fair value of the contingent consideration payment related to the attainment of future revenue targets is estimated by applying a risk adjusted discount rate, 16%, to the potential payments resulting from probability weighted revenue projections and expected revenue target attainment dates. These fair value estimates are most sensitive to changes in the probability of regulatory approvals or the probability of the achievement of the revenue targets.

There were no changes in the valuation techniques during the period and there were no transfers into or out of Levels 1 and 2.

Our 2% senior convertible notes due March 2017 are measured at amortized cost in our consolidated balance sheets and not fair value. The principal balance outstanding is \$205.0 million with a carrying value of \$161.8 million and a fair value of approximately \$284.6 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

We believe that the fair values of our other financial instruments approximate their reported carrying amounts.

#### Note 17. 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 50% of the first 6% of participating employee contributions. The Company contributed approximately \$2.0 million, \$0.9 million and \$0.5 million to the 401(k) Plan in each of the years ended December 31, 2012, 2011 and 2010, 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 18. Commitments and Contingencies

We have committed to purchase up to 395,000 liters of plasma in 2013 and up to 450,000 liters of plasma per year in 2014 through 2017 from our suppliers which equates to a commitments in the range of approximately \$60 million to \$80 million per year. Additionally, we are required to purchase a

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 18. Commitments and Contingencies (Continued)**

minimum number of units that total approximately \$35 million per year from our third party toll manufacturers during 2013 through 2015.

Our future minimum contractual obligations and commercial commitments at December 31, 2012 are as follows (in thousands):

(in thousands)							
Contractual Obligations	Total	2013	2014	2015	2016	2017	Thereafter
Operating leases	\$ 46,561	\$ 1,935	\$ 2,884	\$ 3,063	\$ 3,130	\$ 3,116	\$ 32,433
Collaboration agreements	2,644	1,322	1,322	—	—	—	—
Purchase obligations	477,767	97,487	108,377	112,630	78,036	81,237	—
Total	<u>\$ 526,972</u>	<u>\$ 100,744</u>	<u>\$ 112,583</u>	<u>\$ 115,693</u>	<u>\$ 81,166</u>	<u>\$ 84,353</u>	<u>\$ 32,433</u>

We have severance agreements for certain employees and change of control agreements for executive officers and certain other employees. Under the 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 connection with the acquisition of DuoCort, we have also agreed to make additional payments ranging from SEK 240 million up to SEK 860 million or approximately \$37 million to \$132 million, contingent on the achievement of certain milestones.

In connection with the INS license agreement we may pay additional milestones up to \$120 million based upon defined events. We will also pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales. We are solely responsible for the costs of VP20629 development.

In connection with the Halozyme license agreement we may make further milestone payments to Halozyme which could reach up to an additional \$41 million related to HAE and up to \$30 million of additional milestone payments for three additional indications. Additionally, we will pay an annual maintenance fee of \$1 million to Halozyme until specified events have occurred. Upon regulatory approval, Halozyme will receive up to a 10% royalty on net sales of the combination product utilizing Cinryze and rHuPH20, depending on the existence of a valid patent claim in the country of sale.

In connection with the development and option agreement with Meritage we retain the option to provide Meritage up to an additional \$7.5 million for the development of OBS. We have an exclusive option to acquire Meritage, at our sole discretion. If we exercise this option, we have agreed to pay \$69.9 million for all of the outstanding capital stock of Meritage. Meritage stockholders could also receive additional payments of up to \$175 million, upon the achievement of certain clinical and regulatory milestones.

On March 14, 2008, we entered into a lease for our corporate office building. The lease agreement had a term of 7.5 years from the commencement date. On August 29, 2012, we entered into an amended and restated lease (the Amended Lease) to expand the corporate headquarters. The Amended Lease expires fifteen years from the "commencement date", which will occur when the landlord has substantially completed the expansion, including any tenant improvements. We currently expect the commencement date to occur during the fourth quarter of 2013.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 18. Commitments and Contingencies (Continued)**

We have the option to renew the lease for two consecutive terms for up to a total of ten years at fair market value, subject to a minimum price per square foot. The first renewal term may be for between three and seven years, at our option, and the second renewal term may be for ten years less the length of the first renewal term.

On May 17, 2012, a class action complaint was filed in the United States District Court for the Eastern District of Pennsylvania naming as defendants ViroPharma Incorporated and Vincent J. Milano. The complaint alleges, among other things, possible securities laws violations by the defendants in connection with certain statements made by the defendants related to the Company's Vancocin product. On October 19, 2012, the complaint was amended to include additional officers of the Company as named defendants and allege additional information as the basis for the claim. The defendants believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of this lawsuit.

In addition, we have received a notification that the Federal Trade Commission (FTC) is conducting an investigation into whether we engaged in unfair methods of competition with respect to Vancocin. The existence of an investigation does not indicate that the FTC has concluded that we have violated the law and we do not believe that we have engaged in unfair methods of competition with respect to Vancocin. We intend to continue to cooperate with the FTC investigation; however, at this time we cannot assess potential outcomes of this investigation.

In the fourth quarter of 2012, we became aware that certain Vancocin sales made to Government agencies under the Federal Supply Schedule contract between ViroPharma and the Veterans Administration (VA) were not compliant with the Trade Agreements Act. Absent a waiver, the Trade Agreements Act prohibits the sale to the government of products manufactured in non-designated countries, such as China. We have self-reported the discovery to the VA and will work with the VA to address this matter moving forward. The timing and outcome of these discussions are not certain. As such, we are not in a position to determine whether we have any liability or the extent of any such liability. Accordingly, we have not made any provisions for potential fines or penalties related to these potential violations in our consolidated financial statements as of December 31, 2012.

From time to time we are a party to litigation in the ordinary course of our business and may become a party to additional litigation in the future as several law firms have issued press releases indicating that they are commencing investigations concerning whether the Company and certain of its officers and directors have violated laws. 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.

**Note 19. 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.

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 19. Collaborations (Continued)**

Sanquin may conduct certain early stage research programs and we will provide to Sanquin €1,000,000 (approximately \$1.3 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 (ROW) Agreement. Sanquin has the right to approve any such clinical trials and development activities through the Joint Steering Committee.

We obtained, as part of the 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. In 2011, we began to commercialize Cinryze in European countries in which we have distribution rights. On December 6, 2012, we entered into a first amendment to the ROW Agreement. The amendment expands the territory to worldwide and also grants Sanquin the license to commercialize C1-INH derived product in certain countries in which Sanquin has pre-existing marketing arrangements. Additionally, under the amendment, Sanquin agrees to withdraw its Cetor and Cebitor product from certain markets in which it is currently being sold in order to transition to our C1-INH product, Cinryze, and its future forms and formulations. In connection with the amendment, we made a payment of \$1.3 million to Sanquin, reflected in research and development expense in our consolidated statement of operations.

**Note 20. Supplemental Cash Flow Information**

(in thousands)	For the years ended December 31,		
	2012	2011	2010
Supplemental disclosure of non-cash transactions:			
Unrealized losses on available for sale securities	\$ 13	\$ (11)	\$ —
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	\$ 40,629	\$ 93,648	\$ 52,484
Cash paid for interest	\$ 4,814	\$ 4,141	\$ 4,100

[Table of Contents](#)**ViroPharma Incorporated****Notes to the Consolidated Financial Statements (Continued)****Note 21. Quarterly Financial Information (unaudited)**

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

	<u>March 31,</u>	<u>June 30,(2)</u>	<u>September 30,</u>	<u>December 31,</u>
<b>2012 Quarter Ended</b>				
Net product sales	\$ 135,800	\$ 94,639	\$ 91,004	\$ 106,490
Cost of sales (excluding amortization of product rights)	32,079	28,089	21,552	26,827
Operating expenses	63,411	67,149	73,625	81,687
Other income (expense)	(2,250)	(8,159)	(4,614)	530
Income tax expense (benefit)	18,069	(2,928)	(4,220)	2,489
Net income (loss)	19,991	(5,830)	(4,567)	(3,983)
Basic net income (loss) per share(1)	\$ 0.28	\$ (0.08)	\$ (0.07)	\$ (0.06)
Diluted net income (loss) per share (1)	\$ 0.26	\$ (0.08)	\$ (0.07)	\$ (0.06)
<b>2011 Quarter Ended</b>				
Net product sales	\$ 127,035	\$ 128,808	\$ 142,956	\$ 145,575
Cost of sales (excluding amortization of product rights)	18,869	21,309	20,115	19,683
Operating expenses	48,131	65,191	63,856	56,597
Impairment loss	—	—	8,495	—
Other (expense) income	365	(2,618)	(5,970)	(5,898)
Income tax expense	23,954	16,894	16,281	10,219
Net income	36,446	22,796	28,239	53,178
Basic net income per share(1)	\$ 0.47	\$ 0.30	\$ 0.38	\$ 0.75
Diluted net income per share(1)	\$ 0.40	\$ 0.28	\$ 0.35	\$ 0.65

- (1) Net income per share amounts may not agree to the per share amounts for the full year due to the use of weighted average shares for each period.
- (2) The table above reflects an immaterial correction to our reported results for the second quarter of 2012. As part of our review of our operating results during the fourth quarter of 2012, we noted that our reported cost of sales for the second quarter of 2012 were understated by approximately \$3.4 million. We assessed the materiality of this error for the second quarter, the six months ended June 30, 2012 and the nine months ended September 30, 2012 in accordance with the guidance in SAB 99 (SAB Topic 1.M) Materiality, and determined that the error was immaterial to the three and six months ended June 30, 2012 and the nine months ended September 30, 2012. We will correct our results for the three and six months ended June 30, 2012 and the nine months ended September 30, 2012 when those periods are presented in our subsequent periodic filings.

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**ViroPharma Incorporated**

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

**Note 21. Quarterly Financial Information (unaudited) (Continued)**

The effect of reflecting the correction of this immaterial error in the second quarter of 2012, presented above, is shown in the table below.

	<u>As Reported</u>	<u>Adjustment</u>	<u>As Revised</u>
<b>Quarter Ended June 30, 2012</b>			
Net product sales	\$ 94,639	\$ —	\$ 94,639
Cost of sales (excluding amortization of product rights)	24,721	3,368	28,089
Operating expenses	67,149	—	67,149
Other income (expense)	(8,159)	—	(8,159)
Income tax benefit	(1,187)	(1,741)	(2,928)
Net loss	(4,203)	(1,627)	(5,830)
Basic net loss per share	\$ (0.06)	\$ (0.02)	\$ (0.08)
Diluted net loss per share	\$ (0.06)	\$ (0.02)	\$ (0.08)

