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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

**☑** QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2013

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 0-21699

# VIROPHARMA INCORPORATED

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

23-2789550

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

730 Stockton Drive Exton, Pennsylvania 19341

(Address of Principal Executive Offices and Zip Code)

610-458-7300

(Registrant's Telephone Number, Including Area Code)

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  $\boxtimes$  No  $\square$ 

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 ( $\S232.405$  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  $\boxtimes$  No  $\square$ 

https://www.sec.gov/Archives/edgar/data/946840/000110465913058946/a13-13609\_1... 22.05.2017

or a smaller reporting company filer" and "smaller reporting co	. See the definitions of "	'large accelerated filer", "acc	elerated filer", "non-accelerated
Large Accelerated Filer ⊠	Accelerated Filer □	Non-accelerated Filer □	Smaller Reporting Company □
Indicate by check mark whethe Yes □ No ☑	er the registrant is a shell	company (as defined in Rule	12b-2 of the Exchange Act).
Number of shares outstanding of 65,524,229 shares.	of the issuer's Common S	Stock, par value \$.002 per sha	are, as of July 22, 2013:

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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 Quarterly Report on Form 10-Q 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 manufacturing capacities; expected continued patient growth; potential to identify a partner for

VP20621; and, 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, on this Form 10-Q, our Form 10-Q for the fiscal quarter ended March 31, 2013 and our Form 10-K for the fiscal year ended December 31, 2012, 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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#### ViroPharma Incorporated Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share data)	June 30, 2013	D	ecember 31, 2012
Assets			
Current assets:			
Cash and cash equivalents	\$ 191,398	\$	175,518
Short-term investments	67,335		71,338
Accounts receivable	55,949		74,396
Inventory	87,834		64,384
Prepaid expenses and other current assets	28,305		25,361
Prepaid income taxes	19,309		29,097
Deferred income taxes	18,397		13,324
Total current assets	468,527		453,418
Intangible assets, net	494,392		617,539
Property, equipment and building improvements, net	12,289		10,848
Goodwill	96,264		96,759
Debt issue costs, net	2,082		2,551
Deferred income taxes	19,815		17,988
Other assets	19,737		20,849
Total assets	\$ 1,113,106	\$	1,219,952
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$ 16,412	\$	21,254
Contingent consideration	_		8,367
Accrued expenses and other current liabilities	72,941		83,503

Income taxes payable	410	904
Total current liabilities	89,763	114,028
Other non-current liabilities	35	1,898
Financing obligation	1,929	_
Contingent consideration	25,346	17,710
Deferred tax liability, net	120,050	167,484
Long-term debt	166,205	161,793
Total liabilities	403,328	462,913
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 65,457,373 shares at June 30, 2013 and 65,113,880 shares at		
December 31, 2012	163	163
Treasury shares, at cost. 16,042,202 shares at June 30, 2013 and 16,042,202 shares		
at December 31, 2012	(350,000)	(350,000)
Additional paid-in capital	806,682	789,719
Accumulated other comprehensive loss	(3,801)	(2,975)
Retained earnings	256,734	320,132
Total stockholders' equity	709,778	757,039
Total liabilities and stockholders' equity	\$ 1,113,106	\$ 1,219,952

See accompanying notes to unaudited consolidated financial statements.

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### ViroPharma Incorporated Consolidated Statements of Operations (unaudited)

Three Months Ended Six Months Ended June 30, June 30, (in thousands, except per share data) 2013 2012 2013 2012 **Revenues:** \$ Net product sales 103,711 \$ 94,639 \$ 210,860 \$ 230,439 **Costs and Expenses:** Cost of sales (excluding amortization of product 28,089 58,017 60,167 rights) 28,158 Research and development 17,165 16,621 34,361 32,020 Selling, general and administrative 46,235 40,883 88,958 79,046 Intangible amortization 7,683 8,787 16,582 17,614 104,245 Impairment loss 2,767 2,054 Other operating expenses 684 858 99,925 95,238 304,930 190,901 Total costs and expenses 3,786 (599) (94,070) 39,538 Operating income (loss) Other Income (Expense): Interest income 153 142 319 278 (3,518)(7,290)(6,965)Interest expense (3,681)Other expense, net (493)(4,783)(4,648)(3,548)Income (loss) before income tax expense (benefit) (235)(8,758)(105,689)29,303 (2,928)(42,291)Income tax expense (benefit) (833)15,142 598 14,161 (5,830)(63,398)Net income (loss)

# Net income (loss) per share:

Basic Diluted	\$ \$	0.01 0.01	\$ \$	(0.08) \$ (0.08) \$	(0.97) \$ (0.97) \$	0.20 0.19
Shares used in computing net income (loss) per share: Basic		65,355		69.390	65.281	69.951
Diluted		68,917		69,390	65,281	73,028

See accompanying notes to unaudited consolidated financial statements.

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# ViroPharma Incorporated

Consolidated Statements of Comprehensive Income (Loss) (unaudited)

	Three Months Ended June 30,					Six Months Ended June 30,			
(in thousands)		2013		2012	2013		2012		
Net income (loss)	\$	598	\$	(5,830)	\$	(63,398)	\$	14,161	
Other comprehensive income (loss), before tax:									
Foreign currency translations adjustments		(278)		(639)		(805)		364	
Unrealized gain (loss) on available for sale		` ′		` ′		· í			
securities									
Unrealized holding gain (loss) arising during									
period		(44)		(1)		(32)		1	
Less: Reclassification adjustment for gains		. ,				. ,			
included in net income		_							
Income tax benefit		(16)				(11)			
Unrealized gain (loss) on available for sale					_				
securities, net of tax		(28)		(1)		(21)		1	
Other comprehensive income (loss), net of tax	-	(306)		(640)	_	(826)	_	365	
contracting media (1888), not of the		(300)	-	(0.0)	_	(828)	_		
Comprehensive income (loss)	\$	292	\$	(6,470)	\$	(64,224)	\$	14,526	

See accompanying notes to unaudited consolidated financial statements.

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# ViroPharma Incorporated

Consolidated Statements of Stockholders' Equity (unaudited)

	Preferred Stock Common Stock Treasury Shares									
	Number	Nı	umber of	N	lumber of		Additional	other comprehensive	Retained	Total stockholders'
(in thousands)	shares Am	ount s		nount		Amount	capital	loss	Earnings	equity
Balance, December 31,										
2012	\$	-6	5,114\$	1631	6,042\$	(350,000	)\$789,719	\$ (2,975)	\$320,132	\$ 757,039
Exercise of common										
stock options	_	_	281	_	_	_	3,300	_	_	3,300
Conversion of senior										
convertible notes		_	1	_			11	_		11
Restricted stock vested		_	34	_			· -	_		_
Employee stock										
purchase plan		_	27	_			558	_		558
	_	_	_	_	_	_	12,286	<u> </u>	_	12,286

Share-based compensation										
Other comprehensive										
loss	_	_	_	_	_	_	_	(826)	_	(826)
Stock option tax										
benefits	_		_	_	_	_	808	_		808
Net loss		_	_	_	_				(63,398)	(63,398)
Balance, June 30, 2013	\$	<u>6</u> :	5,457\$	16310	5,042\$(3	350,000)\$	806,682\$	(3,801)\$	256,734 \$	709,778

See accompanying notes to unaudited consolidated financial statements.

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# ViroPharma Incorporated

Consolidated Statements of Cash Flows (unaudited)

		Six Montl June	ded
(in thousands)	_	2013	 2012
Cash flows from operating activities:			
Net income (loss)	\$	(63,398)	\$ 14,161
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Non-cash impairment charge		104,245	_
Non-cash share-based compensation expense		12,286	10,360
Non-cash interest expense		4,890	4,557
Non-cash charge for contingent consideration		42	1,846
Non-cash charge for option amortization		2,169	1,656
Non-cash investment premium amortization		501	1,072
Deferred tax provision		(54,176)	(11,357)
Depreciation and amortization expense		18,211	19,040
Other, net		2,093	2,481
Changes in assets and liabilities:			
Accounts receivable		18,230	23,635
Inventory		(24,098)	18,117
Prepaid expenses and other current assets		(3,266)	(9,272)
Prepaid income taxes and income taxes payable		9,325	(2,539)
Other assets		(1,223)	(7,484)
Accounts payable		(4,582)	(4,950)
Accrued expenses and other current liabilities		(11,831)	13,779
Other non-current liabilities		(160)	(224)
Net cash provided by operating activities		9,258	74,878
Cash flows from investing activities:			
Purchase of property, equipment and building improvements		(1,189)	(585)
Purchase of short-term investments		(38,180)	(77,408)
Maturities of short-term investments		41,650	90,103
Net cash provided by investing activities		2,281	12,110
Cash flows from financing activities:			
Payment for treasury shares acquired		_	(71,523)
Net proceeds from issuance of common stock		3,858	5,947
Excess tax benefits from share-based payment arrangements		808	4,832
Net cash provided by (used in) financing activities		4,666	(60,744)
Effect of exchange rate changes on cash		(325)	(383)
Net increase in cash and cash equivalents		15,880	25,861

Cash and cash equivalents at beginning of period Cash and cash equivalents at end of period

175,518	 331,352
\$ 191,398	\$ 357,213

See accompanying notes to unaudited consolidated financial statements.

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#### ViroPharma Incorporated

Notes to the Unaudited 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 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, 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 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.

In April 2013, the Food and Drug Administration FDA) provided us responses to questions related to the regulatory and development path for Plenadren. The FDA has indicated the data filed in the European Union (EU) and approved by the European Medicines Agency (EMA) related to use of Plenadren for treatment of adrenal insufficiency in adults are not sufficient for assessment of benefit/risk in a marketing authorization submission in the United States and that additional clinical data would be required. We are currently reviewing the FDA feedback and will seek to meet with the FDA to discuss potential Phase 3 study design. Our decision whether to pursue regulatory approval for Plenadren in the United States will be dependent upon, among other things, additional feedback from the FDA regarding potential Phase 3 study design and the availability of orphan drug exclusivity. We also are currently exploring commercialization opportunities in additional geographies.

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 *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

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#### ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements

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.

Currently our product development portfolio is primarily focused on the following programs: C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection 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 Enhanze™ 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 rHuPH20 in adolescents and adults with HAE for prevention of HAE attacks. On August 1, 2013, we announced that after discussion with representatives of the Center for Biologics Evaluation and Research (CBER) division of the U.S. Food and Drug Administration, we are going to discontinue our Phase 2 study. The discontinuation of the study is a precaution related to the emergence of anti-rHuPH20 non-neutralizing antibodies in study patients. We are investigating an alternative optimized, low volume standalone formulation of C1esterase inhibitor for subcutaneous administration and expect to begin a Phase 3 subcutaneous registration study mid 2014. We plan to evaluate potential future plans involving rHuPH20, however, there can be no assurance that we will be able to conduct additional studies with the combination of Cirryze and rHuPH2O. We are also investigating recombinant forms of C1-INH.

We are investigating potential new uses for our C1 esterase inhibitor product with a goal of pursuing additional indications in patient populations with other C1 INH mediated diseases. To that end, we are supporting investigator-initiated studies (IISs) evaluating C1 INH as a treatment for patients with Neuromyelitis Optica (NMO) and Autoimmune Hemolytic Anemia (AIHA); both of these studies were initiated in 2012. We've also completed enrollment into a clinical trial in Antibody-Mediated Rejection (AMR) post renal transplantation with data expected in the fourth quarter of 2013 and are also evaluating the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH). ViroPharma plans to continue to conduct both clinical and non-clinical studies to evaluate additional therapeutic uses for its C1 INH product in the future.

We are currently enrolling patients into 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 in one trial, and those who have failed therapy with other anti-CMV agents in another trial. Interim data from these studies was presented in June of 2013. We expect to complete enrollment into both studies in mid 2014. CMV is a common virus, but in immune compromised individuals, including transplant recipients, it can lead to serious illness or death. The U.S. Food and Drug Administration (FDA) and the European Commission have granted orphan drug designation to maribavir for treatment of clinically significant cytomegalovirus viremia and disease in at-risk patients, and the prevention and treatment of cytomegalovirus disease in patients with impaired cell mediated immunity, respectively.

We have also been developing VP20621 for the prevention of *C. difficile*-associated diarrhea (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 completed enrollment of patients in December 2012 and disclosed the results of this study in April 2013. We will complete the evaluation of these Phase 2 data however, we are seeking a partner to complete the development and commercialization of the asset as it is not considered core to our strategy. Our decision whether to pursue further development of

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#### ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements

VP20621 will be dependent upon, among other things, our ability to find a partner, our final assessment of the results of the Phase 2 data set and the cost of future clinical studies.

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 FA, a rare, hereditary, progressive neurodegenerative disease. We initiated a single and multiple oral dose safety and tolerability study in patients in 2013. The company anticipates completion of enrollment in the first half of 2014.

In December 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.

#### **Basis of Presentation**

The consolidated financial information at June 30, 2013 and for the three and six months ended June 30, 2013 and 2012, is unaudited but includes all adjustments (consisting only of normal recurring adjustments), which in the opinion of management, are necessary to state fairly the consolidated financial information set forth therein in accordance with accounting principles generally accepted in the United States of America. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2012 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

#### **Immaterial Correction**

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 was 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 have

revised the amounts previously reported for the three and six months ended June 30, 2012. We will correct our results for the nine months ended September 30, 2012 when that period is presented in our subsequent periodic filings. The effect of reflecting the correction of this immaterial error in the second quarter of 2012 is shown in the table below.

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#### ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements

		Three r	nonths	ended June 3	0, 201	2
	As	s Reported	Ac	ljustment	A	s Revised
Net product sales Cost of sales (excluding amortization of product	\$	94,639	\$	_	\$	94,639
rights)		24,721		3,368		28,089
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)
		Six me	onths e	ended June 30,	, 2012	
	As	Reported	Ac	ljustment	A	s Revised
Net product sales	\$	230,439	\$	_	\$	230,439
Cost of sales (excluding amortization of product rights)		56,799		3,368		60,167
Income tax expense		16,883		(1,741)		15,142
Net income		15,788		(1,627)		14,161
Basic net income per share		,		( ) /	Φ	
	· ·	0.23	Q.	(0.07)	•	(1) 7(1)
Diluted net income per share	\$ \$	0.23 0.22	\$ \$	(0.02) $(0.02)$	\$ \$	0.20 0.19

# **Subsequent Events**

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

#### **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.

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### ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements

# **Adoption of Standards**

In March 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-05, Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity (Topic 830, EITF Issue 11-A), which specifies that a cumulative translation adjustment (CTA) should be released into earnings when an entity ceases to have a controlling financial interest in a subsidiary or group of assets within a consolidated foreign entity and the sale or transfer results in the complete or substantially complete liquidation of the foreign entity. When an entity sells either a part or all of its investment in a consolidated foreign entity, CTA would be recognized in earnings only if the

sale results in the parent no longer having a controlling financial interest in the foreign entity. CTA would be recognized in earnings in a business combination achieved in stages (i.e., a step acquisition). The ASU does not change the requirement to release a pro rata portion of the CTA of the foreign entity into earnings for a partial sale of an equity method investment in a foreign entity. The ASU is effective for fiscal years (and interim periods within those fiscal years) beginning on or after December 15, 2013. Early adoption will be permitted for both public and nonpublic entities. The ASU should be applied prospectively from the beginning of the fiscal year of adoption. We do not anticipate the initial adoption of the provisions of this guidance to have a material impact on our consolidated results of operations, cash flows, and financial position.

In February 2013, the FASB issued 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 did 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 an 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 did not have a material impact on our consolidated results of operations, cash flows, and financial position.

#### Note 2. Short-Term Investments

Short-term investments consist of fixed income securities with remaining maturities of greater than three months at the date of purchase. At June 30, 2013, 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.

The following summarizes the Company's available for sale investments at June 30, 2013:

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(in thousands)		Cost		Gross unrealized gains	_	Gross unrealized losses	_	Fair value
Debt securities: U.S. Treasury	\$	26,033	\$	1	\$	8	\$	26,026
Corporate bonds	*	41,331	•	45	-	67	-	41,309

Total	\$ 67,364	\$ 46	\$ 75	\$ 67,335
Maturities of investments were as follows:				
Less than one year	\$ 42,597	\$ 4	\$ 17	\$ 42,584
Greater than one year	24,767	42	58	24,751
Total	\$ 67,364	\$ 46	\$ 75	\$ 67,335

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

(in thousands)		Cost	unr	Gross cealized gains	unr	ross ealized esses	F	air value
Debt securities:	_			,				
U.S. Treasury	\$	29,000	\$	8	\$		\$	29,008
Corporate bonds		42,334		10		14		42,330
Total	\$	71,334	\$	18	\$	14	\$	71,338
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	\$	71,334	\$	18	\$	14	\$	71,338

# Note 3. Inventory

Inventory is stated at the lower of cost or market using actual cost. The following represents the components of inventory at June 30, 2013 and December 31, 2012:

(in thousands)		June 30, 2013		
Raw Materials	\$	41,368	\$	41,642
Work In Process		34,815		15,810
Finished Goods		11,651		6,932
Total	\$	87,834	\$	64,384
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Notes to the Unaudited Consolidated Financial Statements — (Continued)

# Note 4. Intangible Assets

The following represents the balance of the intangible assets at June 30, 2013:

(in thousands)	Gross Intangible Assets		Accumulated Amortization		]	Net Intangible Assets
Cinryze Product rights	\$	521,000	\$	97,814	\$	423,186
Plenadren Product rights		63,227		9,999		53,228
Buccolam Product rights		6,182		1,133		5,049
Auralis Contract rights		8,812		2,796		6,016
Vancocin Intangibles		7,407		494		6,913
Total	\$	606,628	\$	112,236	\$	494,392

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

	Gross		Net
	Intangible	Accumulated	Intangible
(in thousands)	Assets	Amortization	Assets

Cinryze Product rights	\$ 521,000	\$ 87,394	\$ 433,606
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
Vancocin Intangibles	168,099	54,773	113,326
Total	\$ 770,161	\$ 152,622	\$ 617,539

#### 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 prevents another company from marketing a product with the same active ingredient as Cinryze 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 rely on Cinryze data for approval before 2020 as a result of data protection provisions contained in the Affordable Health Care for America Act.

As of June 30, 2013, the carrying amount of this intangible asset is approximately \$423.2 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 affect approximately 10,000 people in the United States, 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

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Notes to the Unaudited Consolidated Financial Statements — (Continued)

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 and several compounds have 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 an estimated useful life of 25 years for the Cinryze product rights was appropriate.

#### 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.

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.

In March 2013, the net price at which our authorized generic distributor sold generic vancomycin fell sharply due to pricing pressures in the generic marketplace. This significant decline caused us to test the recoverability of the Vancocin intangible asset. Step one of the impairment test failed and we performed a step two analysis. Under step two, we are required to reduce the carrying value of the intangible asset to its estimated fair value, and as a result have recorded an impairment of approximately \$104.2 million reducing the carrying amount of the intangible assets to approximately \$7.4 million at March 31, 2013. The fair value of the intangible asset was estimated using an income approach based on present value of the probability adjusted future cash flows. In determining the probability adjusted cash flows, we took into consideration the current and anticipated impact of the significant net price reduction that has occurred in the generic marketplace on both net sales of our authorized generic and sales of branded Vancocin. Based on the revised cash flow projections, the useful life of the asset was also reduced to 3.75 years from 16.75 years as of March 31, 2013 which represents the period over which we expect to receive substantially all of the net present value of the adjusted cash flows. Should future events occur that cause further reductions in revenue or operating results we would incur an additional impairment charge, which would be significant relative to the carrying value of the intangible assets as of June 30, 2013.

#### **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

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#### ViroPharma Incorporated

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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.

#### 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.

#### Note 5. 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 Statement of Financial Accounting Standard 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 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 6. Property, Equipment and Building Improvements

The depreciable lives for the major categories of property and equipment are 30 years for the building, 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.

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 June 30, 2013, our minimum lease payments under the Amended Lease total approximately \$40.4 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 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 began recording the CIP asset and a corresponding financing obligation during the first quarter of 2013 when construction started. During the six months ended June 30, 2013 we recorded approximately \$1.9 million of construction in progress related to the lease. 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.

Property, equipment and building improvements consists of the following:

(in thousands)	J	une 30, 2013	December 31, 2012		
Land	\$	156	\$	156	
Building		3,039		3,039	
Construction in progress, lease		1,929		_	
Computers and equipment		13,720		13,387	
Leasehold improvements		6,809		6,053	
		25,653		22,635	
Less: accumulated depreciation and amortization		13,364		11,787	
Property, equipment and building improvements, net	\$	12,289	\$	10,848	

#### Note 7. Long-Term Debt

Long-term debt as of June 30, 2013 and December 31, 2012 is summarized in the following table:

(in thousands)	June 30, 2013		Do	ecember 31, 2012
Senior convertible notes	\$	166,205	\$	161,793
less: current portion				
Total debt principal	\$	166,205	\$	161,793

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.

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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 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.

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

As of June 30, 2013, 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 \$1.4 million at June 30, 2013.

The senior convertible notes were convertible into shares of our common stock during the second quarter of 2013 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. During the quarter note holders converted notes with a face value of \$12 thousand and we issued the holders 634 shares of our common stock.

Our senior convertible notes continue to be convertible into shares of our common stock during the third quarter of 2013.

As of June 30, 2013, senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$166.2 million and a fair value of approximately \$340.6 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.

As of the date of this filing, we have not drawn any amounts under the Credit Facility and are in compliance with our covenants. In March 2013, we entered into Amendment No. 3 to the Credit Agreement (the "Amendment"). Pursuant to the Amendment, our lenders agreed to waive compliance with a specified financial covenant (the "Financial Covenant") until we notify the lenders that we are in compliance with the Financial Covenant. During this period, non-compliance with the Financial Covenant shall not result in a default or event of default under the Credit Agreement. Additionally, we are not permitted to request advances of funds or letters of credit under the Credit Facility and the lenders shall have no obligation to fund any Borrowing or to make any Loan or any other extension of credit to the Company under the Credit Agreement during this period.

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Notes to the Unaudited Consolidated Financial Statements — (Continued)

At June 30, 2013, \$100.0 million of our cash and availability under the credit agreement is subject to the minimum liquidity covenant (iv), described above.

As of June 30, 2013, 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 \$0.7 million as of June 30, 2013.

#### Financing Obligation

On August 29, 2012, we entered into an amended and restated lease (the Amended Lease) to expand our corporate headquarters. ASC 840, Leases, is the authoritative literature related to accounting for leases. The lease arrangement involves the construction of expanded office space in which 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 we are considered the owner of the construction project for accounting purposes and must record a non-cash construction in progress asset (CIP) and a corresponding non-cash financing obligation for the construction costs funded by the Landlord. We began recording the CIP asset and a corresponding financing obligation during the first quarter of 2013 when construction started. During the six months ended June 30, 2013 we recorded CIP of approximately \$1.9 million with a corresponding financing obligation. Once the construction is complete we will depreciate the core and shell asset and will begin to apply a portion of the lease payments as a reduction in the principal of the obligation and apportion of the lease payments will be reflected as interest expense on the financing obligation.

# Note 8. 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 June 30, 2013 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. However, our ability to repurchase shares is currently limited by certain terms of our Credit Agreement.

Senior convertible notes

Our senior convertible notes were convertible into shares of our common stock during the second quarter of 2013 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. During the quarter note holders converted notes with a face value of \$12 thousand and we issued the holders 634 shares of our common stock.

Our senior convertible notes continue to be convertible into shares of our common stock during the third quarter of 2013.

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#### Note 9. Share-based Compensation

Our share-based compensation program consists 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 generally vesting over a one year period.

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;
- 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 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.

Our share-based compensation expense is comprised of the following:

	Three Months Ended June 30,			Six Mont Jun	hs End e 30,		
(in thousands)		2013		2012	 2013		2012
Stock options	\$	4,495	\$	4,095	\$ 9,016	\$	7,976
Performance shares		1,536		1,047	2,732		1,837
Restricted shares		212		263	444		444
Employee Stock Purchase Plan		48		52	94		103
Total	\$	6,291	\$	5,457	\$ 12,286	\$	10,360

Our share-based compensation expense is recorded as follows:

	Three Months Ended June 30,				ded			
(in thousands)		2013		2012		2013		2012
Research and development	\$	1,201	\$	1,152	\$	2,479	\$	2,235
Selling, general and administrative		5,090		4,305		9,807		8,125
Total	\$	6,291	\$	5,457	\$	12,286	\$	10,360
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# ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements — (Continued)

We currently have three share-based award 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.

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 2012.

As of June 30, 2013, there were 2,461,413 shares available for grant under the Plans.

The following table lists information about these equity plans at June 30, 2013:

	1995 Plan	2001 Plan	2005 Plan	Combined
Shares authorized for issuance	4,500,000	500,000	15,350,000	20,350,000
Shares outstanding	4,500,000	500,000	12,888,587	17,888,587
Shares available for grant			2,461,413	2,461,413

Employee Stock Option Plans

We granted 2,042,825 stock options during the six months ended June 30, 2013. The weighted average fair value of the grants was estimated at \$ 13.93 per share using the Black-Scholes option-pricing model using the following assumptions:

Expected dividend yield	-	
Range of risk free interest rate	1.10% - 1.39%	)
Weighted-average volatility	57.90%	
Range of volatility	57.81% - 58.06%	6
Range of expected option life (in years)	5.50 - 6.25	

We have 10,465,899 option grants outstanding at June 30, 2013 with exercise prices ranging from \$1.84 per share to \$32.69 per share and a weighted average remaining contractual life of 6.95 years. The following table lists the outstanding and exercisable option grants as of June 30, 2013:

	Number of options	Weighted average exercise price		Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)	
Outstanding	10,465,899	\$	17.31	6.95	\$	119,237
Exercisable	5,798,991	\$	13.17	5.42	\$	90,129

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Notes to the Unaudited Consolidated Financial Statements — (Continued)

The following table summarizes information regarding our stock option awards at June 30, 2013:

	Shares Under Option	Weighted Average Exercise Price		
Balance at December 31, 2012	8,814,831	\$	15.26	
Granted	2,042,825	\$	25.59	
Exercised	(280,776)	\$	11.76	
Forfeited	(104,459)	\$	20.51	
Cancelled	(6,522)	\$	22.10	
Balance at June 30, 2013	10,465,899	\$	17.31	

As of June 30, 2013, there was \$52.7 million of total unrecognized compensation cost related to unvested share-based payments (including share options) granted under the Plans. That cost is expected to be recognized over a weighted-average period of 2.93 years.

#### Performance Awards

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 2013, approximately 253,000 PSUs subject to company specific performance metrics were granted with weighted average grant date fair value of \$23.37 per share and approximately 28,000 PSUs subject to the TSR metric were granted with weighted average grant date fair value of \$32.63 per share. 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:

	Six Months Ended June 30,							
(in thousands)	2013			2012				
Closing stock price on grant date	\$	23.37	\$	28.16				
Performance period starting price	\$	23.83	\$	24.94				
Term of award (in years)		2.99		2.99				
Volatility		43.13%	ó	65.06%				
Risk-free interest rate		0.43%	ó	0.45%				
Expected dividend yield		0.00%	ó	0.00%				
Fair value per TSR PSU	\$	32.63	\$	45.37				
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#### ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements — (Continued)

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 June 30, 2013, there was approximately \$9.0 million of unrecognized compensation cost related to all PSUs that is expected to be recognized over a weighted-average period of approximately 1.99 years.

The following table summarizes select information regarding our PSUs as of June 30, 2013:

	Share Units (in thousands)	avera	ighted- age grant fair value
Balance at December 31, 2012	350,739	\$	24.86
Granted	281,030	\$	24.30
Exercised	_	\$	_
Forfeited	(12,037)	\$	24.60
Vested	_	\$	_
Balance at June 30, 2012	619,732	\$	24.61

Restricted Stock Awards

We also grant our non-employee directors restricted stock awards that generally vest after one year of service. In 2013, 31,500 RSUs were granted with weighted average grant date fair values of \$25.25 per share. 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 June 30, 2013:

	Share Units (in		ighted- age grant
	thousands)	date	fair value
Balance at December 31, 2012	37,750	\$	31.12
Granted	31,500	\$	25.25
Vested	(33,583)	\$	31.51
Balance at June 30, 2013	35,667	\$	25.57

As of June 30, 2013, there was approximately \$ 0.6 million of unrecognized compensation cost related to RSUs which is expected to be recognized over a weighted average period of 0.78 years.

Employee Stock Purchase Plan

During the first six months of 2013, 13,010 shares were sold to employees. During the year ended December 31, 2012, 29,927 shares were sold to employees. As of June 30, 2013 there are approximately 357,141 shares available for issuance under this plan.

Previously under this plan, there were two plan periods: January 1 through June 30 (Plan Period One) and July 1 through December 31 (Plan Period Two).

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Notes to the Unaudited Consolidated Financial Statements — (Continued)

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.

For the Initial Offering Period in 2013, the fair value of approximately \$60,700 was estimated using the Type B model with a risk free interest rate of 0.04%, volatility of 29.6% and an expected option life of 0.33 years. This fair value was amortized over the four month period ending April 30, 2013.

For Plan Period One in 2013, the fair value of approximately \$97,500 was estimated using the Type B model with a risk free interest rate of 0.08%, volatility of 28.00% and an expected option life of 0.50 years. This fair value is being amortized over the six month period ending October 31, 2013.

#### Note 10. Income Tax Expense (Benefit)

Our income tax expense (benefit) was (\$0.8) million and (\$2.9) million for the three months ended June 30, 2013 and 2012, respectively, and (\$42.3) million and \$15.1 million for the six months ended June 30, 2013 and June 30, 2012, 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 the six months ended June 30, 2013 and June 30, 2012, were 40.0% and 51.7%, respectively.

The effective tax rate for the six months ended June 30, 2013 is higher than the statutory U.S. tax rate due to the impact of state income taxes. Because of the impairment of the Vancocin intangible assets, the impact of other items such as share-based compensation, foreign losses on which the benefit is lower than the U.S. rate and non-deductible expenses including amortization expense do not have a significant impact on the effective tax rate for the period ended June 30, 2013. The effective tax rate for the six months ended June 30, 2012 is higher than the statutory U.S. tax rate due to state income taxes and certain share-based compensation that is not tax deductible. In addition, the effective tax rate in the first six months of 2012 is higher than the statutory U.S. tax rate due to 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. These increases to the effective tax rate are partially offset by tax benefits related to orphan drug credits, manufacturing deductions and charitable contributions. The effective tax rate in both periods was impacted by the change in

fair value of contingent consideration that is not included for tax purposes. Tax expense (benefit) for the quarters ended June 30, 2013 and 2012 are a combination of the six month effective tax rate and adjustments for changes in the effective tax rate from the prior quarter.

During the six months ended June 30, 2013, we had no material changes to our liability for uncertain tax positions. 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 one state and one foreign jurisdiction. At this time, we do not believe that the results of these examinations will have a material impact on our financial statements.

## Note 11. Accumulated Other Comprehensive Loss

The following table presents the changes in the components of accumulated other comprehensive loss for the six months ended June 30, 2013:

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(in thousands)		mulative anslation	Unrealized gains (losses) on available for sale securities			Accumulated other comprehensive loss		
Balance at December 31, 2012	\$	(2,976)	\$	1 (21)	\$	(2,975)		
Other comprehensive loss before reclassifications Amounts reclassified from accumulated other		(805)		(21)		(826)		
comprehensive income			_		_			

Net current period other comprehensive loss	 (805)	(21)	(826)
Balance at June 30, 2013	\$ (3,781)	\$ (20)	\$ (3,801)

The unrealized gains (losses) are reported net of federal and state income taxes.

# Note 12. Earnings (loss) per share

	Three Months Ended June 30,			Six Months Ended June 30,			nded	
(in thousands, except per share data)		2013		2012		2013		2012
Basic Earnings (Loss)Per Share								
Net income (loss)	\$	598	\$	(5,830)	\$	(63,398)	\$	14,161
Common stock outstanding (weighted average)		65,355		69,390		65,281		69,951
Basic net income (loss) per share	\$	0.01	\$	(0.08)	\$	(0.97)	\$	0.20
Diluted Earnings (Loss) Per Share								
Net income (loss)	\$	598	\$	(5,830)	\$	(63,398)	\$	14,161
Diluted net income (loss)	\$	598	\$	(5,830)	\$	(63,398)	\$	14,161
Common stock outstanding (weighted average) Add potentially dilutive stock awards and		65,355		69,390		65,281		69,951
warrants		3,562		_		_		3,077
Common stock equivalents		68,917		69,390		65,281		73,028
Diluted net income (loss) per share	\$	0.01	\$	(0.08)	\$	(0.97)	\$	0.19

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

	Three Month June 3		Six Months Ended June 30,		
(in thousands)	2013	2012	2013	2012	
Stock awards Shares from senior convertible	3,358	5,572	6,160	1,997	
notes	10,863	10,864	10,863	10,864	

#### Note 13. 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

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observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of June 30, 2013:

	Tot	al Carrying						
	,	Value at Fair Value Me					ie 30,	2013
(in thousands)	Jui	ne 30, 2013		(Level 1)		(Level 2)		(Level 3)
Cash and cash equivalents	\$	191,398	\$	191,398	\$		\$	
Short term investments	\$	67.335	\$	67.335	\$		\$	

https://www.sec.gov/Archives/edgar/data/946840/000110465913058946/a13-13609\_1... 22.05.2017

Contingent consideration, long-term \$ 25,346 \$ — \$ 25,346

The following table provides a rollforward of activity in Level 3:

(in thousands)	
Balance December 31, 2012	\$ 26,077
Change in fair value from re-measurement	44
Impact of foreign currency translation	(775)
Balance June 30, 2013	\$ 25,346

Valuation Techniques — Cash, 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 three and six months ended June 30, 2013.

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 at June 30, 2013 is \$205.0 million with a carrying value of \$166.2 million and a fair value of approximately \$340.6 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.

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#### Note 14. Acquisitions, License and Research Agreements

In November 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 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 \$36 million to \$128 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$24 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$104 million of the contingent payments are related to commercial milestones based on the success of the product.

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.

We incurred approximately \$1.4 million of transaction costs as part of this acquisition.

Meritage Pharma, Inc.

In December 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 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. 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. In July 2013 Meritage enrolled fifty percent (50%) of subjects planned for the Phase 2 study enrollment thus satisfying the condition of the Second Option Milestone and accordingly we made a \$2.5 million milestone payment in July 2013 and increased the carrying value of our cost method investment in July 2013. We have the option to provide Meritage up to an additional \$5.0 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 investment. As of June 30, 2013, 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 results of operations over the expected term of the option agreement which is expected to be December 2014. We recognized approximately \$1.1 million and \$0.6 million of amortization

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expense related to this asset during the three months ended June 30, 2013 and 2012, respectively, and \$2.2 million and \$1.7 million of amortization expense related to this asset during the six months ended June 30, 2013 and 2012, respectively.

Intellect Neurosciences, Inc. License Agreement

In September 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 initiated a single and multiple oral dose safety and tolerability study in patients in 2013. The company anticipates completion of enrollment in the first half of 2014. 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'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.

#### Halozyme Therapeutics License Agreement

In May 2011, Halozyme Therapeutics Inc. (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhanze<sup>™</sup> 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 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. On August 1, 2013, we announced that after discussion with representatives of the Center for Biologics Evaluation and Research (CBER) division of the U.S. Food and Drug Administration, we are going to discontinue our Phase 2 study of rHuPH20 technology in combination with a C1 esterase inhibitor.

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

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 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

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#### ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements — (Continued)

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

#### 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 15. Litigation and Claims

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 Company has moved to dismiss the complaint and an oral argument was held on June 10, 2013, but no decision has been issued. 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 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.

# Note 16. Supplemental Cash Flow Information

	Six Mont	hs Ended
	Jun	e 30,
(in thousands)	2013	2012

Supplemental disclosure of non-cash transactions:

Non-cash increase in construction in progress and financing obligation Unrealized loss on available for sale securities, net of tax	\$	1,929 (21)	\$	— (11)
Non- cash increase in goodwill related to the acquisition of Lev				06.165
Pharmaceuticals, Inc.		_		86,165
Supplemental disclosure of cash flow information:	•	<b>7.</b> 70	Φ.	24440
Cash paid for income taxes	\$	758	\$	24,119
Cash paid for interest		2,404		2,589
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# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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, 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 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 various countries throughout 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.

In April 2013, the Food and Drug Administration (FDA) provided us responses to questions related to the regulatory and development path for Plenadren. The FDA has indicated that the data filed in the European Union (EU) and approved by the European Medicines Agency (EMA) related to use of Plenadren for treatment of adrenal insufficiency in adults are not sufficient for assessment of benefit/risk in a marketing authorization submission in the United States and that additional clinical data would be required. We are currently reviewing the FDA feedback and will seek to meet with the FDA to discuss a potential Phase 3 study design. Our decision whether to pursue regulatory approval for Plenadren in the United States will be dependent upon, among other things, additional feedback from the FDA regarding a potential Phase 3 study design and the availability of orphan drug exclusivity. We also are currently exploring commercialization opportunities in additional geographies.

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

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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.

Currently our product development portfolio is primarily focused on the following programs: C1 esterase inhibitor [human], maribavir for cytomegalovirus (CMV) infection 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 Enhanze™ 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 rHuPH20 in adolescents and adults with HAE for prevention of HAE attacks. On August 1, 2013, we announced that after discussion with representatives of the Center for Biologics Evaluation and Research (CBER) division of the U.S. Food and Drug Administration, we are going to discontinue our Phase 2 study. The discontinuation of the study is a precaution related to the emergence of anti-rHuPH20 non-neutralizing antibodies in study patients. We are investigating an alternative optimized, low volume standalone formulation of C1 esterase inhibitor for subcutaneous administration and expect to begin a Phase 3 subcutaneous registration study mid 2014. We plan to evaluate potential future plans involving rHuPH20, however, there can be no assurance that we will be able to conduct additional studies with the combination of Cinryze and rHuPH2O. We are also investigating recombinant forms of C1-INH.

We are investigating potential new uses for our C1 esterase inhibitor product with a goal of pursuing additional indications in patient populations with other C1 INH mediated diseases. To that end, we are supporting investigator-initiated studies (IISs) evaluating C1 INH as a treatment for patients with Neuromyelitis Optica (NMO) and Autoimmune Hemolytic Anemia (AIHA); both of these studies were initiated in 2012. We've also completed enrollment into a clinical trial in Antibody-Mediated Rejection (AMR) post renal transplantation with data expected in the fourth quarter of 2013 and are also evaluating the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH). ViroPharma plans to continue to conduct both clinical and non-clinical studies to evaluate additional therapeutic uses for its C1 INH product in the future.

We are currently enrolling patients into 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 in one trial, and those who have failed therapy with other anti-CMV agents in another trial. Interim data from these studies was presented in June of 2013. We expect to complete enrollment into both studies in

mid 2014. CMV is a common virus, but in immune compromised individuals, including transplant recipients, it can lead to serious illness or death. The U.S. Food and Drug Administration (FDA) and the European Commission have granted orphan drug designation to maribavir for treatment of clinically significant cytomegalovirus viremia and disease in at-risk patients, and the prevention and treatment of cytomegalovirus disease in patients with impaired cell mediated immunity, respectively.

We have also been developing VP20621 for the prevention of *C. difficile*-associated diarrhea (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 completed enrollment of patients in December 2012 and disclosed the results of this study in April 2013. We will complete the evaluation of these Phase 2 data; however, we are seeking a partner to complete the development and commercialization of the asset as it is not considered core to our strategy. Our decision whether to pursue further development of

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VP20621 will be dependent upon, among other things, our ability to find a partner, our final assessment of the results of the Phase 2 data set, and the cost of future clinical studies.

In September 2011, we entered into a licensing agreement for the worldwide rights to develop VP20629, or indole-3-propionic acid for the treatment of FA, a rare, hereditary, progressive neurodegenerative disease. We initiated a single and multiple oral dose safety and tolerability study in patients in 2013. We anticipate completion of enrollment in the first half of 2014. We intend to file for Orphan Drug Designation upon review of the Phase 2 proof of concept data.

In December 2011, we entered into an exclusive development and option agreement with Meritage Pharma, Inc. (Meritage), a private company based in San Diego, California 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 March 31, 2013, we experienced the following:

Business Activities

Hereditary Angioedema (HAE):

- Shipped approximately 22,000 doses of Cinryze to U.S. specialty pharmacy/specialty distributors (SP/SD's) and approximately 2,100 doses to wholesalers, pharmacies and customers in the EU and other territories;
- Launched Cinryze commercially in three additional countries in Europe; and,,
- On August 1, 2013, we announced we are going to discontinue our Phase 2 study of rHuPH20 technology, in combination with a C1 esterase inhibitor;

Cytomegalovirus (CMV):

- Announced that the European Commission has granted orphan drug designation for maribavir for treatment
  of cytomegaloviral (CMV) disease in patients with impaired cell mediated immunity; and,
- Announced updated data from the two ongoing, Phase 2 dose ranging studies investigating maribavir for both first line treatment of cytomegalovirus (CMV) viremia and treatment of resistant/refractory CMV;

Pediatric Epilepsy:

 Launched Buccolam commercially in three additional countries in Europe and completed pricing and reimbursement activities in several European countries with launches planned during the remainder of 2013;

#### C. difficile infection (CDI):

- Released positive data from Phase 2 study with VP-20621 (non-toxigenic Clostridium difficile) which
  demonstrated high rates of colonization and statistically significant reductions in recurrence of C. difficile
  infections; and.
- Announced company plans to seek a partner to complete the development and commercialization of VP-20621 as this asset no longer fits into the core development plans of ViroPharma;

#### Financial Results

- Increased net sales of Cinryze to \$94.6 million as compared to \$76.6 million in the second quarter of 2012;
- Net sales of Vancocin decreased to \$4.0 million from \$15.9 million in the second quarter of 2012;
- Generated net sales of \$8.3 million in Europe compared to \$3.8 million in the second quarter of 2012; and,
- Reported net income of \$0.6 million in the second quarter of 2013;

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#### Liquidity

- Generated net cash from operations of \$9.3 million during the six months ended June 30, 2013; and,
- Ended the second quarter of 2013 with working capital of \$378.8 million, which includes cash and cash equivalents and short-term investments of \$258.7 million.

During the remainder of 2013 and going forward, we expect to face a number of challenges, which include the following:

# **Commercial**

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 product, for reasons that include, but are not limited to, competition and/or changes in reimbursement practices or 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 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.

From the first quarter of 2012 through the fourth quarter of 2012, Cinryze inventory in the channel had 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. In the first quarter of 2013, we rebuilt channel inventories to the upper end of our normal range. During the second quarter of 2013 inventories declined from the first quarter of 2013 but still remain within normal levels. Inventory levels will

fluctuate based upon our SP/SD's buying decisions. We plan to build safety stock during the remainder of 2013, which will impact our working capital.

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 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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In March 2013, the net price at which our authorized generic distributor sold generic vancomycin fell sharply due to pricing pressures in the generic marketplace. This significant decline caused us to test the recoverability of the Vancocin intangible asset. Step one of the impairment test failed and we performed a step two analysis. Under step two, we are required to reduce the carrying value of the intangible asset to its estimated fair value, and as a result have recorded an impairment of approximately \$104.2 million reducing the carrying amount of the intangible assets to approximately \$7.4 million at March 31, 2013. The fair value of the intangible asset was estimated using an income approach based on present value of the probability adjusted future cash flows. In determining the probability adjusted cash flows, we took into consideration the current and anticipated impact of the significant net price reduction that has occurred in the generic marketplace on both net sales of our authorized generic and sales of branded Vancocin. Based on the revised cash flow projections, the useful life of the asset was also reduced to 3.75 years from 16.75 years as of March 31, 2013 which represents the period over which we expect to receive substantially all of the net present value of the adjusted cash flows. Should future events occur that cause further reductions in revenue or operating results we would incur an additional impairment charge, which would be significant relative to the carrying value of the intangible assets as of June 30, 2013.

#### Litigation and investigation

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 Company has moved to dismiss the complaint and an oral argument was held on June 10, 2013, but no decision has been issued. 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 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.

#### Clinical

We are currently undertaking studies on the viability of subcutaneous administration of Cinryze. Clinical studies using Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) technology in combination with Cinryze are subject to laboratory sampling to monitor for the development of antibodies to rHuPH20. The clinical significance of antibodies to rHuPH20 are not known and have not been associated with adverse clinical effects. On August 1, 2013, we announced we are going to discontinue our Phase 2 study of rHuPH20 technology, in combination with a C1 esterase inhibitor.

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. Interim data from these studies were presented in June of 2013, We expect to complete enrollment into both studies in mid 2014, Result from these studies will periodically be evaluated. In the second quarter of 2013 we announced that the European Commission has granted orphan drug designation for maribavir for treatment of cytomegaloviral (CMV) disease in patients with impaired cell mediated immunity.

We have also been 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 completed enrollment of patients in December 2012 and disclosed the results of this study in April 2013. We will complete the evaluation of these Phase 2 data; however, we are seeking a partner to complete the development and commercialization of the asset as it is not considered core to our strategy. Our decision whether to pursue further development of VP20621 will be

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dependent upon, among other things, our ability to find a partner, our final assessment of the results of the Phase 2 data set, and the cost of future clinical studies.

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 initiated a single and multiple oral dose safety and tolerability study in patients in 2013. The company anticipates completion of enrollment in the first half of 2014. 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.

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.

#### Regulation

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.

### Competition

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.

# **Liquidity**

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.

Our actual results could differ materially from those results expressed in, or implied by, our expectations and assumptions described in this Quarterly Report on Form 10-Q. The risks described in this report, our Form 10-Q for the quarter ended June 30, 2013, 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" as described in our Form 10-Q for the Quarter ended March 31, 2013 and our Form 10-K for the year ended December 31, 2012 in Item 1A, which describe other important matters relating to our business.

#### **Results of Operations**

#### Three and Six Months Ended June 30, 2013 and 2012

(in thousands, except per share data)  Net product sales	For the three months ended June 30,				For the six months ended June 30,			
	2013		2012		2013		2012	
	\$	103,711	\$	94,639	\$	210,860	\$	230,439
Cost of sales (excluding amortization of								
product rights)	\$	28,158	\$	28,089	\$	58,017	\$	60,167
Operating income (loss)	\$	3,786	\$	(599)	\$	(94,070)	\$	39,538
Net income (loss)	\$	598	\$	(5,830)	\$	(63,398)	\$	14,161
Basic	\$	0.01	\$	(0.08)	\$	(0.97)	\$	0.20
Diluted	\$	0.01	\$	(0.08)	\$	(0.97)	\$	0.19
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The \$3.8 million in operating income for the three months ended June 30, 2013 increased \$4.4 million as compared to the same period in 2012. The increase in operating income is driven primarily by the following: an increase in net sales of \$9.1 million period over period due to higher sales of Cinryze partly offset by lower Vancocin revenues as a result of sales of our branded Vancocin into lower priced governmental programs; reduced margins from authorized generic vancomycin sales and an increase of \$5.4 million in selling, general and administrative expenses primarily related to the growth of our global organization and our European commercialization efforts. Research and development expenses increased \$0.5 million in the three months ended June 30, 2013 compared to the same period in 2012. Other operating expense for the three months ended June 30, 2013 and 2012 includes the changes in the fair value of the contingent consideration related to our acquisition of DuoCort and charges associated with the funding of manufacturing improvements at our contract suppliers.

The \$94.1 million operating loss for the six months ended June 30, 2013 decreased \$133.6 million when compared to the same period in 2012. The primary drivers of this decrease are the following: the Vancocin intangible impairment charge of \$104.2 million; lower net sales of \$19.6 million due to lower Vancocin revenues as generic vancomycin did not enter the marketplace until the second quarter of 2012 partly offset by higher Cinryze revenue and increased selling, general and administrative expenses of \$9.9 million primarily due to our European commercialization efforts and the growth of our global organization. Other operating expense for the six months ended June 30, 2013 and 2012 includes the expense associated with change in the fair value of the contingent consideration related to our acquisition of DuoCort and charges associated with the funding of manufacturing improvements at our contract suppliers.

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 and Plenadren during the third quarter of 2012. The revenues from these sales are not material to our consolidated revenues for the three and six months ended June 30, 2013 and 2012.

Revenues

Revenues consisted of the following:

		For the three months ended June 30,				For the six months ended June 30,				
(in thousands)	2013		2012			2013	2012			
Net product sales								_		
Cinryze	\$	94,638	\$	76,642	\$	194,127	\$	144,805		
Vancocin		4,017		15,908		7,630		82,078		
Other		5,056		2,089		9,103		3,556		
Total revenues	\$	103,711	\$	94,639	\$	210,860	\$	230,439		
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## 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.

From the first quarter of 2012 through the fourth quarter of 2012, Cinryze inventory in the channel had 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. In the first quarter of 2013, we rebuilt channel inventories to the upper end of our normal range. During the second quarter of 2013 inventories declined from the first quarter of 2013 but still remain within normal levels. Inventory levels will fluctuate based upon our SP/SD's buying decisions. We plan to build safety stock during the remainder of 2013, which will impact our working capital.

Our U.S. sales of Cinryze may be influenced by SP buying decisions related to their desired inventory levels and patient prescription demand, all of which could be at different levels from period to period.

Our net sales of Cinryze in the U.S. during the three and six months ended June 30, 2013 increased 22.0% and 32.6%, respectively, over the same periods in the prior year due to consistent patient adds, stable dosing rate, net realized price growth of approximately 7% and an increase in channel inventories. Cinryze revenue in the EU during the three and six months ended June 30, 2013 was approximately \$3.3 million and \$5.9 million, respectively, compared to \$1.7 million and \$2.9 million during the three and six months ended June 30, 2012, respectively, as we continue the launch of Cinryze in countries in Europe.

During the three months ended June 30, 2013, net sales of Vancocin decreased 74.7% compared to the same period in 2012 due to the relative increase in the sales of our branded Vancocin into lower priced governmental programs and reduced net selling price of our authorized generic. During the six months ended June 30, 2013, net sales of Vancocin decreased 90.7% compared to the same period in 2012 due to the introduction of authorized generic vancomycin and reduced net selling price of our authorized generic. 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.

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.

Cost of sales (excluding amortization of product rights)

Cost of sales is flat for the three months ended June 30, 2013 as compared to the three months ended June 30, 2012 and decreased slightly for the six months ended June 30, 2013 by \$2.2 million compared to the six months ended June 30, 2012 on lower sales.

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.

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

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

	For the three months ended June 30,					For the six months ended June 30,					
(in thousands)	2013		2012			2013	2012				
Direct											
Cinryze & C1											
esterase inhibitor	\$	5,121	\$	4,863	\$	9,338	\$	9,262			
CMV		1,784		1,712		3,327		2,446			
Non-toxigenic strain											
of C. difficle											
(VP20621)		310		2,254		1,555		5,008			
VP-20629		316		251		968		263			
Plenadren		820		358		1,722		434			
New Initiatives		784		576		1,661		1,319			
Other assets		171		180		353		356			
Indirect											
Development		7,859		6,427		15,437		12,932			
Total	\$	17,165	\$	16,621	\$	34,361	\$	32,020			

# **Direct Expenses**

Our costs associated with our Cinryze & C1 esterase programs during the three and six months ended June 30, 2013 were relatively flat when compared to the three and six months ended June 30, 2012 as higher spending in the current year period related to our Phase 2 study of subcutaneous administration of Cinryze in combination with rHuPH20 was offset by the costs incurred in the prior year period related to achieving approval of our industrial scale manufacturing line

Our direct expenses related to our CMV were relatively flat in the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 due to the continuation of our two Phase 2 clinical studies initiated during the first and third quarters of 2012 to evaluate maribavir for the treatment of CMV infections in transplant recipients.

The costs of VP20621 in the three and six months ended June 30, 2013 decreased compared to the same periods in 2012 as we completed our Phase 2 clinical trial initiated during the second quarter of 2012.

Our direct expenses related to our VP20629, being developed for the treatment of Friedreich's Ataxia (FA), increased during the three and six months ended June 30, 2013 compared to the same periods in 2012 as we began pre-clinical efforts during the second half of 2012.

The Plenadren costs incurred are related to our ongoing 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

Selling, general and administrative expenses (SG&A) increased for the three months ended June 30, 2013 by \$5.4 million compared to the same period in the prior year primarily due to increases in compensation expense and employee cost of \$5.6 million, increased medical education cost of \$1.2 million and higher marketing costs of \$0.8 million partly offset by lower corporate cost of \$1.1 million, lower miscellaneous expenses of \$0.6 million and lower legal fees of \$0.5 million. For the six months ended June 30, 2013, SG&A

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increased \$9.9 million compared to the same period in 2012 primarily driven by increased compensation expense and employee cost of \$10.0 million, increased medical education expenses of \$2.2 million and higher marketing costs of \$0.7 million partly offset by lower corporate cost of \$2.7 million.

Our European commercialization efforts accounted for approximately \$4.7 million of the increase for the three months ended June 30, 2013 compared to the same period in the prior year as spending in the U.S. was essentially flat period over period and approximately \$8.1 million of the increase for the six months ended June 30, 2013 compared to the same period in 2012, primarily due to higher compensation cost and the higher spending in the areas of medical affairs and education 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 three and six months ended June 30, 2013 were \$7.7 million and \$16.6 million, respectively, as compared to \$8.8 million and \$17.6 million, respectively, for the same periods in 2012. Our amortization expense is lower in the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2013 as a result of the impairment of our Vancocin intangible assets during the first quarter of 2013.

## Impairment loss

In March of 2013, the net price at which our authorized generic distributor sold generic vancomycin fell sharply due to pricing pressures in the generic marketplace. This significant decline caused us to test the recoverability of the Vancocin intangible asset. Step one of the impairment test failed and we performed a step two analysis. Under step two, we are required to reduce the carrying value of the intangible asset to its estimated fair value, and as a result have recorded an impairment of approximately \$104.2 million reducing the carrying amount of the intangible assets to approximately \$7.4 million at March 31, 2013. The fair value of the intangible asset was estimated using an income approach based on present value of the probability adjusted future cash flows. In determining the probability adjusted cash flows, we took into consideration the current and anticipated impact of the significant net price reduction that has occurred in the generic marketplace on both net sales of our authorized generic and sales of branded Vancocin. Based on the revised cash flow projections, the useful life of the asset was also reduced to 3.75 years from 16.75 years as of March 31, 2013 which represents the period over which we expect to receive substantially all of the net present value of the adjusted cash flows. Should future events occur that cause further reductions in revenue or operating results we would incur an additional impairment charge, which would be significant relative to the carrying value of the intangible assets as of June 30, 2013.

Other operating expenses

The change during the three and six months ended June 30, 2013 compared to the same periods during 2012 is primarily due to the changes in the fair values of the contingent consideration liabilities incurred as part of our acquisition of DuoCort and the funding of manufacturing enchantments at certain of our manufacturing partners.

Other Income (Expense)

## Interest Income

Interest income for three and six months ended June 30, 2013 was \$0.2 million and \$0.3 million, respectively, and \$0.1 million and \$0.3 million for the three and six months ended June 30, 2012, respectively.

## Interest Expense

	For the three months ended June 30,					For the six months ended June 30,				
(in thousands)	2013		2012		2013		2012			
Interest expense Amortization of debt discount Amortization of finance costs	\$	1,200 2,247 234	\$	1,207 2,077 234	\$	2,400 4,422 468	\$	2,408 4,088 469		
Total interest expense	\$	3,681	\$	3,518	\$	7,290	\$	6,965		

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Interest expense consists of interest on our senior convertible notes and also commitment fees on the unused credit facility. The amortization of debt discount relates solely to the senior convertible notes and the amortization of finance costs relates to the amortization of debt issue cost on both the senior convertible notes and the \$200 million credit facility.

# Other expense, net

Our other expense, net, includes foreign exchange gains and losses in the three and six month periods ended June 30, 2013 and 2012. Additionally, the three and six months ended June 30, 2013 includes approximately \$1.1 million and \$2.2 million, respectively, and the three and six months ended June 30, 2012 includes approximately \$0.6 million and \$1.7 million, respectively, of amortization expense of the deferred asset related to the Meritage transaction.

# Income Tax Expense (Benefit)

Our income tax expense (benefit) was (\$0.8) million and (\$2.9) million for the three months ended June 30, 2013 and 2012, respectively and (\$42.3) million and \$15.1 million for the six months ended June 30, 2013 and June 30, 2012, 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 the six months ended June 30, 2013 and June 30, 2012, were 40.0% and 51.7%, respectively.

The effective tax rate for the six months ended June 30, 2013 is higher than the statutory U.S. tax rate due to the impact of state income taxes. Because of the impairment of the Vancocin intangible assets, the impact of other items such as share-based compensation, foreign losses on which the benefit is lower than the U.S. rate and non-deductible expenses including amortization expense do not have a significant impact on the effective tax rate for the six months ended June 30, 2013. The effective tax rate for the six months ended June 30, 2012 is higher than the statutory U.S. tax rate due to state income taxes and certain share-based compensation that is not tax deductible. In addition, the effective tax rate in the first six months of 2012 is higher than the statutory U.S. tax rate due to 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. These increases to the effective tax rate are partially offset by tax benefits related to orphan drug credits, manufacturing deductions and charitable contributions. The effective tax rate in both periods was impacted by the change in fair value of contingent consideration that is not included for tax purposes. Tax expense (benefit) for the quarters ended June 30, 2013 and 2012 are a combination of the six month effective tax rate and adjustments for changes in the effective tax rate from the prior quarter.

Because of the impairment of the Vancocin intangible assets, we anticipate that our effective tax rate will be lower than in 2012. Excluding the tax impact from the intangible asset impairment we would have expected our effective tax rate in 2013 to be higher than the statutory rate because of losses incurred in foreign jurisdictions. Our tax rate, excluding the intangible impairment, will vary based on the operating results of each legal entity and actual permanent differences. Our effective tax rates in future years will depend primarily on our foreign operating results and should decline if our product launches are successful and generate profits.

Our last U.S. tax examination was for the 2008 fiscal year and it concluded in the first quarter of 2011 with no material adjustments. We are currently under examination in one state and one foreign jurisdiction. 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 commercial sales of Cinryze and Buccolam in Europe during the fourth quarter of 2011 and Plenadren during the third quarter of 2012. The revenues from these sales are not material to our consolidated revenues for three and six months ended June 30, 2013 and 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 where 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 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

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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.

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. In March of 2013, the net price at which our authorized generic distributor sold generic vancomycin fell sharply due to pricing pressures in the generic marketplace. This significant decline caused us to test the recoverability of the Vancocin intangible asset. Step one of the impairment test failed and we performed a step two analysis. Under step two, we are required to reduce the carrying value of the intangible asset to its estimated fair value, and as a result have recorded an impairment of approximately \$104.2 million reducing the carrying amount of the intangible assets to approximately \$7.4 million at March 31, 2013. Should future events occur that cause further reductions in revenue or operating results we would incur an additional impairment charge, which would be significant relative to the carrying value of the intangible assets as of June 30, 2013.

Our ability to generate positive cash flow is also impacted by the timing of anticipated events in our Cinryze, 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 stages 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 initiatives to develop 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 the commencement date. At June 30, 2013, our minimum lease payments under the Amended Lease total approximately \$40.4 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. 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.

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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 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 only and must record a construction in progress asset (CIP) and a corresponding financing obligation for the construction costs funded by the landlord.

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 and Medicare Part D coverage gap are immaterial relative to our operating income and cash flow. 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.

Capital Resources

While we anticipate that cash flows from operations, 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 June 30, 2013, we had cash, cash equivalents and short-term investments of \$258.7 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 June 30, 2013, the annualized weighted average nominal interest rate on our short-term investments was 0.32% and the weighted average length to maturity was 11.1 months. At June 30, 2013, we also had a \$200 million revolving Credit Agreement with certain lenders. As of the date of this filing, we have not drawn any amounts under the Credit Agreement and are in compliance with our covenants. In March 2013, we entered into Amendment No. 3 to the Credit Agreement (the "Amendment"). Pursuant to the Amendment, our lenders agreed to waive compliance with a specified financial covenant (the "Financial Covenant") until we notify the lenders that we are in compliance with the Financial Covenant. During this period, noncompliance with the Financial Covenant shall not result in a default or event of default under the Credit Agreement. Additionally, during this period, we are not permitted to request advances of funds or letters of credit under the Credit Facility, and the lenders shall have no obligation to fund any Borrowing or to make any Loan or any other extension of credit to the Company under the Credit Agreement during this period.

At June 30, 2013, \$100.0 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.

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# Overall Cash Flows

During the six months ended June 30, 2013, we generated \$9.3 million of net cash from operating activities, primarily from our net loss after adjustments for non-cash items including the non-cash impairment charge, and the accounts receivable collected during the quarter offset by the increase in inventories as we replenish the Cinryze channel, and decreases in our accounts payable and accrued expenses and other current liabilities. Cash provided by investing activities of \$2.3 million resulted primarily from maturities of short-term investments, net of investment purchases. Our net cash provided from financing activities for the six months ended June 30, 2013 was \$4.7 million and due to the proceeds and excess tax benefits from stock option exercises. During the six months ended June 30, 2012, we generated \$74.9 million of net cash from operating activities, primarily from our net income after adjustments for non-cash items, and the net decrease in accounts receivable and inventories. Cash provided by investing activities during the six months ended June 30, 2012of \$12.1 million resulted primarily from maturities of short-term investments, net of investment purchases. Our net cash used in financing activities for the six months ended June 30, 2012 was \$60.7 million which relates to the common stock repurchases under our share repurchase program net of proceeds and excess tax benefits from stock option exercises.

## **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 June 30, 2013 have spent approximately \$64.8 million in direct research and development costs related to Cinryze since acquisition. We are solely responsible for the costs of Cinryze development. During 2013, 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 subcutaneous formulation. 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, multi-center, dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze in combination with Halozyme's recombinant human hyaluronidase enzyme (rHuPH20) in adolescents and adults with HAE for prevention of HAE attacks. On August 1, 2013, we announced that after discussion with representatives of the Center for Biologics Evaluation and Research (CBER) division of the U.S. Food and Drug Administration, we are going to discontinue our Phase 2 study. The discontinuation of the study is a precaution related to the emergence of anti-rHuPH20 non-neutralizing antibodies in study patients. We are investigating an alternative optimized, low volume standalone formulation of C1esterase inhibitor for subcutaneous administration and expect to begin a Phase 3 subcutaneous registration study mid 2014. While we have conducted preclinical and Phase 1 clinical studies involving the subcutaneous administration of C1 esterase inhibitor, we have not yet conducted these studies with the low volume formulation we plan to utilize in our Phase 3 registration study. As a result, there can be no assurances that such future studies of the low volume formulation will be successful. Moreover, while we currently expect our Phase 3 study with the low volume subcutaneous formulation will initiate in mid-2014, and that the study would be conducted during approximately the same timeframe that we anticipated for the rHuPH2O combination product, our clinical development of this low volume formulation may be delayed or discontinued by a number of factors, including but not limited to a determination that the number of doses required is higher than we anticipate, injection site reactions are observed, regulatory authorities raise additional questions that we have not anticipated or costs of goods are higher than we anticipate. We are investigating potential new uses for our C1 esterase inhibitor product with a goal of pursuing additional indications in patient populations with other C1 INH mediated diseases. To that end, we are supporting investigator-initiated studies (IISs) evaluating C1 INH as a treatment for patients with Neuromyelitis Optica (NMO) and Autoimmune Hemolytic Anemia (AIHA); both of these studies were initiated in 2012. We've also completed enrollment into a clinical trial in Antibody-Mediated Rejection (AMR) post renal transplantation with data expected in the fourth quarter of 2013 and are also evaluating the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH). ViroPharma plans to continue to conduct both clinical and non-clinical studies to evaluate additional therapeutic uses for its C1 INH product in the future. 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.

<u>CMV program</u>—We acquired the rights to maribavir in September 2003 and through June 30, 2013 have spent approximately \$107.9 million in direct research and development costs. For the remainder of 2013, we expect our research and development activities related to maribavir to increase. We are currently enrolling patients into 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 in one trial, and those who have failed therapy with other anti-CMV agents in another trial. Interim data from these studies was presented in June of 2013. We expect to complete enrollment into both studies in mid 2014.

<u>VP20621</u>— We acquired VP20621 in February 2006 and through June 30, 2013 have spent approximately \$39.9 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 of patients in December 2012 and disclosed the results of this study in April 2013. We will complete the evaluation of these Phase 2 data however, we are seeking a partner to complete the development and commercialization of the asset as it is not considered core to our strategy. Our decision whether to pursue further development of VP20621 will be dependent upon, among other things, our ability to find a partner, our final assessment of the results of the Phase 2 data set and the cost of future clinical studies. In the event we are successful in finding a

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partner, we do not expect to incur significant additional expenses related to VP20621. However, if we are not successful in finding a partner, our research and development expenses related to VP20621 could increase in future periods.

<u>VP20629</u>— In September 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 initiated a single and multiple oral dose safety and tolerability study in patients in 2013. The company anticipates completion of enrollment in the first half of 2014. 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. Through June 30, 2013 have spent approximately \$8.8 million related to VP20629, including the up-front licensing fee.

<u>Plenadren</u>— We acquired Plenadren in November 2011. The costs incurred to date relate to our open label trial and registry study.

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. In July 2013 Meritage enrolled fifty percent (50%) of subjects planned for the Phase 2 study enrollment thus satisfying the condition of the Second Option Milestone and accordingly we made a \$2.5 million milestone payment in July 2013 and increased the carrying value of our cost method investment. We retain the option to provide Meritage up to an additional \$5.0 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 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 \$36 million to \$128 million, contingent on the achievement of certain milestones. Up to SEK 160 million or approximately \$24 million of the contingent payments relate to specific regulatory milestones; and up to SEK 700 million or approximately \$104 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 (Halozyme) granted us an exclusive worldwide license to use Halozyme's proprietary Enhanze<sup>™</sup> 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

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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. On August 1, 2013, we announced that after discussion with representatives of the Center for Biologics Evaluation and Research (CBER) division of the U.S. Food and Drug Administration, we are going to discontinue our Phase 2 study.

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 price of \$18.52 per share. At June 30, 2013 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. However, our ability to repurchase shares is currently limited by certain terms of our Credit Agreement.

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 rates of 8.0% as they are accreted to par value.

As of June 30, 2013 senior convertible notes representing \$205.0 million of principal debt are outstanding with a carrying value of \$166.2 million and a fair value of approximately \$340.6 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

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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 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. 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 of 2013 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. During the quarter note holders converted notes with a face value of \$12 thousand and we issued the holders 634 shares of our common stock.

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The senior convertible notes are convertible into shares of our common stock during the third quarter of 2013 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.

# 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.

At June 30, 2013, \$100.0 million of our cash and availability under the credit agreement is subject to the minimum liquidity covenant (iv), described above.

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. In March 2013, we entered into Amendment No. 3 to the Credit Agreement (the "Amendment"). Pursuant to the Amendment, our lenders agreed to waive compliance with a specified financial covenant (the "Financial Covenant") until we notify the lenders that we are in compliance with the Financial Covenant. During this period, non-compliance with the Financial Covenant shall not result in a default or event of default under the Credit Agreement. Additionally, we are not permitted to request advances of funds or letters of credit under the Credit Facility, and the lenders shall have no obligation to fund any Borrowing or to make any Loan or any other extension of credit to the Company under the Credit Agreement during this period.

# **Contractual Obligations**

We have commitments to purchase a minimum number of liters of plasma per year through 2016 from our supplier. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturers. The total minimum purchase commitments for these continuing arrangements as of June 30, 2013 are approximately \$421.9 million.

In March 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. In August 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. Upon the commencement date, the lease payments will escalate annually based upon a consumer price index specified in the lease.

At June 30, 2013, our minimum lease payments under the Amended Lease total approximately \$40.4 million.

# **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

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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 is within normal levels.

Chargebacks and rebates are the most subjective sales related accruals. While we currently have no contracts with private third party payors, such as HMO's, we do have contractual arrangements with governmental agencies, including Medicaid. We establish accruals for chargebacks and rebates related to these contracts in the period in which we record the sale as revenue. These accruals are based upon historical experience of government agencies' market share, governmental contractual prices, our current pricing and then-current laws, regulations and interpretations. We analyze the accrual at least quarterly and adjust the balance as needed. These analyses have been adjusted to reflect the U.S. healthcare reform acts and their effect 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 staring 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 depend 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.

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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.

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.

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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 4 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 prevents another company from marketing a product with the same active ingredient as Cinryze 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 rely on Cinryze data for approval before 2020 as a result of data protection provisions contained in the Affordable Health Care for America Act.

As of June 30, 2013, the carrying amount of this intangible asset is approximately \$423.2 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 followon 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 and several compounds have 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.

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#### 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.

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.

In March of 2013, the net price at which our authorized generic distributor sold generic vancomycin fell sharply due to pricing pressures in the generic marketplace. This significant decline caused us to test the recoverability of the Vancocin intangible asset. Step one of the impairment test failed and we performed a step two analysis. Under step two, we are required to reduce the carrying value of the intangible asset to its estimated fair value, and as a result have recorded an impairment of approximately \$104.2 million reducing the carrying amount of the intangible assets to approximately \$7.4 million at March 31, 2013. The fair value of the intangible asset was estimated using an income approach based on present value of the probability adjusted future cash flows. In determining the probability adjusted cash flows, we took into consideration the current and anticipated impact of the significant net price reduction that has occurred in the generic marketplace on both net sales of our authorized generic and sales of branded Vancocin. Based on the revised cash flow projections, the useful life of the asset was also reduced to 3.75 years from 16.75 years as of March 31, 2013 which represents the period over which we expect to receive substantially all of the net present value of the adjusted cash flows. Should future events occur that cause further reductions in revenue or operating results we would incur an additional impairment charge, which would be significant relative to the carrying value of the intangible assets as of June 30, 2013.

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

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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 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 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.

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

## ITEM 3. 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 June 30, 2013, was approximately \$67.3 million and 0.32%, respectively. The weighted average length to maturity was 11.1 months. A one percent change in the interest rate would have resulted in a \$0.2 million impact to interest income for the quarter ended June 30, 2013.

At June 30, 2013, we had principal outstanding of \$205.0 million of our senior convertible notes. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007. The senior convertible notes are convertible into shares of our common stock at an initial conversion price of \$18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the "measurement period") in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to our option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The

senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of June 30, 2013, the fair value of the principal of the \$205.0 million convertible senior notes outstanding was approximately \$340.6 million, based on the Level 2 valuation hierarchy of the fair value measurements standard. The carrying value of the debt at June 30, 2013 is \$166.2 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.

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

## **ITEM 4. 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 June 30, 2013. Based on that evaluation, our management, including our CEO and CFO, concluded that as of June 30, 2013 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.

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# **Changes in Internal Control over Financial Reporting**

During the second quarter of 2013, there were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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# **PART II - OTHER INFORMATION**

# ITEM 1. 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 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 Company has moved to dismiss the complaint and an oral argument was held on June 10, 2013, but no decision has been issued. 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 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.

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#### **ITEM 1A. Risk Factors**

We are providing the following information regarding changes that have occurred to previously disclosed risk factors from our Annual Report on Form 10-K for the year ended December 31, 2012. In addition to the other information set forth below and elsewhere in this report, you should carefully consider the factors discussed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013. The risks described in our Quarterly Report on Form 10-Q are not the only risks facing our Company. 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.

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;
- changes in pricing 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, 76 and 92 percent of our revenue in 2011, 2012 and the first half of 2013, respectively, and we expect Cinryze will continue to account for a significant percentage of our future revenues. 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. In addition, our sales of Cinryze are influenced by buying decisions by specialty pharmacies (SPs) related to their desired inventory levels and patient prescription demand, all of which could be at different levels from period to period. Changes in the level of inventory held by SPs could vary from period to period and negatively impact our results of operations.

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In addition, clinical studies of the subcutaneous administration of C1-inhibitors by us and one of our competitors could enroll patients who are currently purchasing commercial intravenous Cinryze which could reduce our revenues for the duration of such clinical trials.

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

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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 our evaluation of additional indications on C-1 mediated diseases. For example, we have commenced clinical studies of C1-INH in Antibody-Mediated Rejection (AMR) post renal transplantation and are also evaluating the potential effect of C1-INH in Refractory Paroxysmal Nocturnal Hemoglobinuria (PNH). We are also supporting investigator-initiated studies (IISs) evaluating C1 INH as a treatment for patients with Neuromyelitis Optica (NMO) and Autoimmune Hemolytic Anemia (AIHA). We plan to continue to conduct both clinical and non-clinical studies to evaluate additional therapeutic uses for its C1 INH product in the future however, as these are early stage investigations, there can be no assurance that such studies will be successful or support future development. In addition, there can be no assurance that these studies will be completed in the timeframes we anticipate, or at all.

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 rHuPH20 in adolescents and adults with hereditary angioedema (HAE) for prevention of HAE attacks. The FDA has informed us that the administration of Cinryze with rHuPH20 will be reviewed as a combination product and must therefore meet the specific regulatory requirements for combination prescription drug products. Combination products can raise challenging regulatory and policy challenges for the FDA. Differences in regulatory pathways for each component can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications. In addition, our ability to successfully commercialize a subcutaneous form of Cinryze® may be negatively impacted in the event that a competitor is able to successfully complete development, receive regulatory approval and launch a subcutaneous formulation of their C1-inhibitor.

# 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. We have periodically presented interim data from two Phase 2 open label clinical studies being conducted with maribavir, one in Europe evaluating maribavir as a treatment for patients with asymptomatic cases of CMV and a second Phase 2 open label study of maribavir as a treatment for patients with refractory cases of CMV. We plan to continue to periodically evaluate the data generated from these open label studies. 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 our ongoing studies and the results seen by a small number of NPP and emergency-use IND patients may not be predictive of the final results of the studies currently being conducted. In addition, several other companies are developing product candidates which could compete with maribavir for patients to be enrolled in clinical studies and such products could be commercialized before maribavir which would reduce the revenue potential for maribavir.

# 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 recently disclosed data from a Phase 2 doseranging 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. We are seeking a partner to continue development of this program as it is not considered a core strategic asset. There can be no assurance that we will be successful in finding a partner or that we will continue clinical development of this product candidate.

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# VP20629, or indole-3-propionic acid

In September 2011, we entered into 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 recently initiated a single and repeat dose study in patients. We may not be successful in completing such studies in the time frame we anticipate and 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. In March 2013, the FDA indicated the data filed in the European Union and approved by the European Medicines Agency related to use of Plenadren for treatment of adrenal insufficiency in adults are not sufficient for assessment of benefit/risk in a marketing authorization submission in the United States and that additional clinical data would be required. We are currently reviewing the FDA feedback and will seek to meet with the FDA to discuss the potential Phase 3 study design. Our decision whether to pursue regulatory approval for Plenadren in the United States will be dependent upon, among other things, additional feedback from the FDA regarding the potential Phase 3 study design. 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 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, unsafe or fails to meet specific regulatory requirements, including but not limited to those for combination products;
- 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 or reach the market before our product candidates.

Even if we believe that the clinical data sufficiently demonstrates the safety and efficacy of a product candidate, regulators may disagree with us, which could delay, limit or prevent the approval of such product candidate. In addition, regulatory approval may take longer than we expect as a result of a number of factors, including failure to qualify for priority review of our application. All statutes

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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.

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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 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 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 as compared to lower cost alternative treatments;
- 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.

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 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

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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, including during inspections during the second quarter of 2013. These observations included FDA comments generally related to requested improvements in root cause analysis, standard operating procedures and training and included a few previous observations that FDA felt were not fully addressed by the prior corrective actions undertaken. Responses to the observations on 483 have been provided to the FDA however, the responses to the most recent observations have not yet been accepted by the FDA. In addition, responses to prior observations 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, *Cinryze* Solutions, 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 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.

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 are currently evaluating the feasibility of additional therapeutic uses and potential indications as well as other modes of administration for Cinryze. We are also conducting clinical studies to assess additional therapeutic uses of Cinryze as well as continuing to study the sub-cutaneous administration of Cinryze. We have also initiated clinical studies for other product candidates, including VP20629, or indole-3-propionic acid for the treatment of Friedreich's Ataxia and maribavir for treatment of cytomegalovirus (CMV). We must complete significant laboratory, animal and clinical testing on these product candidates before submitting marketing applications in the United States and abroad

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The rate of completion of clinical trials depends upon many factors, including the rates of initiation of clinical sites and enrollment of patients. If we are unable to initiate a sufficient number of clinical sites and accrue sufficient clinical patients who are eligible to participate in the trials during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. In addition, the FDA, Independent Safety Monitoring Boards or Institutional Review Boards may require us to delay, restrict, or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, we may be unable to submit a NDA to the FDA or marketing petitions to other regulatory authorities such as the EMEA for our product candidates within the time frame we currently expect, or at all. Once an NDA or other form of petition for marketing authority is submitted, it must be approved by the FDA or other regulatory authority before we can commercialize the product described in the application. The cost of human clinical trials varies dramatically based on a number of factors, including:

- the number, order and timing of clinical indications pursued;
- the number of patients required for enrollment;
- the length of time required to enroll these patients;
- the costs and difficulty of obtaining clinical supplies of the product candidate; and
- the difficulty in obtaining sufficient patient populations and clinicians.

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

In 2003, Congress enacted the Pediatric Research Equity Act requiring the development and submission of pediatric use data for new drug products. In Europe, a Pediatric Investigational Plan must be agreed before a 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.

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## ITEM 6. Exhibits

List of Exhibits:

- 10.1\* ViroPharma Incorporated Annual Incentive Plan.
- 31.1\* Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

- 31.2\* Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\* Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Income (Loss) (iv) the Consolidated Statements of Stockholders' Equity; (v) the Consolidated Statements of Cash Flows; and, (vi) the Notes to the Consolidated Financial Statements.
- \* Filed herewith.

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Date: August 1, 2013

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

## VIROPHARMA INCORPORATED

By: /s/ Vincent J. Milano

Vincent J. Milano

President and Chief Executive Officer (Principal Executive Officer)

(1 fine par Executive Officer)

By: /s/ Charles A. Rowland, Jr.

Charles A. Rowland, Jr.

Vice President, Chief Financial Officer

(Principal Financial Officer)

By: /s/ John J. Kirby

John J. Kirby

Vice President, Chief Accounting Officer

(Principal Accounting Officer)

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