VIROPHARMA INC
Form 10-Q
October 28, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2009

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	**23-2789550**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

730 Stockton Drive

Exton, Pennsylvania 19341

(Address of Principal Executive Offices 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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

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

Number of shares outstanding of the issuer s Common Stock, par value $.002 per share, as of October 23, 2009: 77,442,716 shares.

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ViroPharma Incorporated

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share data)	September 30, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 288,930	$ 275,839
Accounts receivable, net	38,633	15,058
Inventory	40,421	27,168
Prepaid expenses and other current assets	8,426	5,120
Prepaid income taxes	4,630	6,867
Property and building held for sale	6,734	6,734
Deferred income taxes	9,675	24,094
Total current assets	397,449	360,880
Intangible assets, net	625,261	639,693
Property, equipment and building improvements, net	6,955	6,853
Goodwill		65,099
Debt issue costs, net	2,881	3,892
Other assets	10,919	9,712
Total assets	$ 1,043,465	$ 1,086,129
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 12,089	$ 5,719
Due to partners	193	1,279
Accrued expenses and other current liabilities	26,429	35,587
Income tax payable	888	882
Total current liabilities	39,599	43,467
Non-current income tax payable and other non-current liabilities	2,707	4,071
Deferred tax liability	128,038	128,254
Long-term debt	136,906	161,003
Total liabilities	307,250	336,795
Commitments and Contingencies		
Stockholders equity:		
Preferred stock, par value $0.001 per share. 5,000,000 shares authorized; Series A convertible participating preferred stock; no shares issued and outstanding		
Series A junior participating preferred stock, par value $0.001 per share. 200,000 shares designated; no shares issued and outstanding		
Common stock, par value $0.002 per share. 175,000,000 shares authorized; issued and outstanding 77,442,716 shares at September 30, 2009 and 77,397,621 shares at December 31, 2008	156	156
Additional paid-in capital	698,377	690,502
Accumulated other comprehensive gain (loss)	1,442	(655)
Retained earnings	36,240	59,331

Total stockholders equity	736,215	749,334
Total liabilities and stockholders equity	$ 1,043,465	$ 1,086,129

See accompanying notes to unaudited consolidated financial statements.

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ViroPharma Incorporated

Consolidated Statements of Operations

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues:				
Net product sales	$ 80,551	$ 65,913	$ 222,614	$ 182,287
Costs and Expenses:				
Cost of sales (excluding amortization of product rights)	10,216	2,460	28,266	6,764
Research and development	11,006	14,851	43,158	43,846
Selling, general and administrative	20,153	14,296	68,140	44,304
Intangible amortization	6,751	1,471	21,432	5,304
Goodwill impairment			65,099	
Total costs and expenses	48,126	33,078	226,095	100,218
Operating income (loss)	32,425	32,835	(3,481)	82,069
Other Income (Expense):				
Interest income	65	3,090	315	13,468
Interest expense	(2,817)	(3,232)	(8,803)	(9,576)
Gain on long-term debt repurchase			9,079	
Income (loss) before income tax expense	29,673	32,693	(2,890)	85,961
Income tax expense	9,601	5,587	20,201	19,686
Net income (loss)	20,072	27,106	(23,091)	66,275
Net income (loss) per share:				
Basic	$ 0.26	$ 0.39	$ (0.30)	$ 0.95
Diluted	$ 0.24	$ 0.33	$ (0.30)	$ 0.82
Shares used in computing net income per share:				
Basic	77,440	69,965	77,417	69,946
Diluted	89,179	84,592	77,417	84,409

See accompanying notes to unaudited consolidated financial statements.

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ViroPharma Incorporated

Consolidated Statements of Stockholders Equity

(unaudited)

(in thousands)	Preferred Stock Number of shares	Preferred Stock Amount	Common Stock Number of shares	Common Stock Amount	Additional paid-in capital	Accumulated other comprehensive loss	Retained Earnings	Total stockholders equity
Balance, December 31, 2008, as adjusted for the adoption of ASC Topic 470-20, see Note 2		$	77,398	$ 156	$ 690,502	$ (655)	$ 59,331	$ 749,334
Exercise of common stock options			13		22			22
Employee stock purchase plan			32		164			164
Share-based compensation					9,379			9,379
Cumulative translation adjustment						2,097		2,097
Termination of call spread options, net					274			274
Repurchase of conversion options on long-term debt					(1,964)			(1,964)
Net income							(23,091)	(23,091)
Balance, September 30, 2009		$	77,443	$ 156	$ 698,377	$ 1,442	$ 36,240	$ 736,215

See accompanying notes to unaudited consolidated financial statements.

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ViroPharma Incorporated

Consolidated Statements of Cash Flows

(unaudited)

(in thousands)	Nine Months Ended September 30, 2009	2008
Cash flows from operating activities:		
Net (loss) income	$ (23,091)	$ 66,275
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Non-cash share-based compensation expense	9,379	6,490
Non-cash interest expense	5,486	5,846
Gain on long-term debt repurchase	(9,079)	
Non-cash goodwill impairment	65,099	
Deferred tax provision	10,934	9,106
Depreciation and amortization expense	22,604	6,108
Changes in assets and liabilities:		
Accounts receivable	(23,314)	(5,234)
Inventory	(12,147)	(438)
Interest receivable		4,420
Prepaid expenses and other current assets	(3,282)	1,041
Prepaid income taxes/income taxes payable	2,200	704
Other assets	1,966	(2,589)
Due to partners	(1,086)	
Accounts payable	6,024	2,480
Accrued expenses and other current liabilities	(8,888)	(3,401)
Non-current income tax payable and other non-current liabilities and other	(1,255)	56
Net cash provided by operating activities	41,550	90,864
Cash flows from investing activities:		
Purchase of Vancocin assets	(7,000)	(7,000)
Purchase of property, plant and equipment	(1,308)	(2,360)
Maturities of short-term investments		350,221
Net cash (used in) provided by investing activities	(8,308)	340,861
Cash flows from financing activities:		
Long-term debt repurchase	(21,150)	
Termination of call spread options, net	274	
Net proceeds from issuance of common stock	186	306
Tax benefit on convertible note hedge		1,262
Net cash (used in) provided by financing activities	(20,690)	1,568
Effect of exchange rate changes on cash	539	(176)
Net increase in cash and cash equivalents	13,091	433,117
Cash and cash equivalents at beginning of period	275,839	179,691
Cash and cash equivalents at end of period	$ 288,930	$ 612,808

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

We market and sell Cinryze, which has been approved by the FDA for the prophylactic treatment of hereditary angioedema (HAE). The FDA also has approved the patient labeling for Cinryze to include self-administration for routine prophylaxis once patients are properly trained by their healthcare provider. Cinryze is a C1 inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was obtained in October 2008, when we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev), a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. In December 2008, we submitted a supplemental Biologics Application (sBLA) for Cinryze as a treatment for acute attacks of HAE based on a re-analysis and resubmission of data from a pivotal Phase 3 acute treatment study of Cinryze and interim data from an ongoing open label acute study of the drug. On June 4, 2009, we received a Complete Response letter from the U.S. Food and Drug Administration (FDA) related to our sBLA. We are currently evaluating with our partner Sanquin, the feasibility of additional territories, indications and/or other formulations for Cinryze. Part of this plan is obtaining Orphan Drug designation for Europe which was granted in October 2009.

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

We are developing three product candidates, Cinryze for additional indications and/or other formulations for the treatment of HAE, non-toxigenic strains of C. *difficile* (NTCD) for the treatment and prevention of CDI; and maribavir for the prevention and treatment of cytomegalovirus, or CMV disease. On August 6, 2009 we announced that dosing has begun in the Phase 1 clinical trial for NTCD. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as a single and repeat escalating doses in healthy young and older adults. On February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant (SCT) patients did not achieve its primary endpoint. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. Additionally, on February 13, 2009, we announced that enrollment in our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to the current standard of care. We discontinued dosing patients with maribavir in clinical trials and are evaluating our maribavir program in light of the Phase 3 clinical trial results.

Basis of Presentation

The consolidated financial information at September 30, 2009 and for the three and nine months ended September 30, 2009 and 2008, 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, 2008 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. We have evaluated all subsequent events through October 28, 2009, the date the financial statements were issued.

Adoption of Standards

In June 2009, the Financial Accounting Standards Board (FASB) issued ASC Topic 105, Generally Accepted Accounting Principles, which became the single source of authoritative nongovernmental U.S. generally accepted accounting principles (GAAP), superseding existing FASB, American Institute of Certified Public Accountants (AICPA), Emerging Issues Task Force (EITF), and related accounting literature. This pronouncement reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent

structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections and will be effective for financial statements issued for reporting periods that end after September 15, 2009. This will have an impact on our financial disclosures since all future references to authoritative accounting literature will be references in accordance with ASC Topic 105.

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Notes to the Unaudited Consolidated Financial Statements (Continued)

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

In May 2009, the FASB released a new accounting pronouncement which establishes the accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. This pronouncement requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. See Basis of Presentation for the related disclosures. The adoption this pronouncement did not have a material impact on our financial statements.

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

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

In May 2008, the FASB issued a new pronouncement that requires the issuer of convertible debt instruments with cash settlement features to separately account for the liability and equity components of the instrument. The debt is recognized at the present value of its cash flows discounted using the issuer s nonconvertible debt borrowing rate. The equity component is recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. This pronouncement which is part of ASC Topic 470 also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. We adopted this pronouncement on January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt. The adoption is discussed further in Note 2.

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

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

In December 2007, the FASB issued a pronouncement which establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. We adopted the pronouncement on January 1, 2009 with no impact on operating results or financial position.

In March 2008, the FASB issued guidance which changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how

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ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements (Continued)

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

In June 2008, the FASB issued guidance which stated that unvested share-based payment awards that contain rights to receive nonforfeitable dividends (whether paid or unpaid) are participating securities, and should be included in the two-class method of computing EPS. We adopted this pronouncement on January 1, 2009. We do not have share-based payment awards that contain rights to nonforfeitable dividends, thus this pronouncement does not impact our consolidated financial statements.

In June 2008, the FASB ratified guidance which provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument s contingent exercise and settlement provisions. We adopted this guidance on January 1, 2009 with no impact on operating results or financial position.

Reclassification

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

Note 2. Accounting Changes Adopted

We adopted the provisions of ASC Topic 470-20 as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new standard. In accordance with GAAP all prior periods presented herein have been adjusted to apply the new method retrospectively. Under this new method of accounting, the debt and equity components of our convertible debt securities are bifurcated and accounted for separately based on the value and related interest rate of a non-convertible debt security with the same terms. The fair value of a non-convertible debt instrument at the original issuance date was determined to be $148.1 million. The equity (conversion options) component of our convertible debt securities is included in Additional paid-in capital on our Consolidated Balance Sheet and, accordingly, the initial carrying value of the debt securities was reduced by $101.9 million. Our net income for financial reporting purposes was reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amount of $250.0 million as additional non-cash interest expense. The adoption of ASC Topic 470-20 has resulted in a reduction in the carrying value of our convertible debt by approximately $89.0 million as of December 31, 2008. In addition, the adoption of this standard reduced our deferred debt issuance costs as we were required to allocate the amount related to the conversion option to equity.

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

Condensed Consolidated Balance Sheet

(unaudited)

(in thousands, except share and per share data)	Revised December 31, 2008	Reported December 31, 2008
Assets		
Current assets:		
Total current assets	$ 360,880	$ 360,880

Goodwill	65,099	29,936
Debt issue costs, net	3,892	6,610
Total assets	$ 1,086,129	$ 1,053,684
Liabilities and Stockholders Equity		
Current liabilities:		
Accrued expenses and other current liabilities	$ 35,587	$ 35,650
Total current liabilities	43,467	43,467
Deferred tax liability	128,254	95,121
Long-term debt	161,003	250,000
Total liabilities	336,795	392,660
Commitments and Contingencies		
Additional paid-in capital	690,502	595,287
Retained earnings	59,331	66,236
Total stockholders equity	749,334	661,024
Total liabilities and stockholders equity	$ 1,086,129	$ 1,053,684

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ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements (Continued)

Consolidated Statements of Operations

(unaudited)

(in thousands, except per share data)	Three Months Ended September 30, Revised 2008	Three Months Ended September 30, Reported 2008	Nine Months Ended September 30, Revised 2008	Nine Months Ended September 30, Reported 2008
Operating income	$ 32,835	$ 32,835	$ 82,069	$ 82,069
Other Income (Expense):				
Interest income	3,090	3,090	13,468	13,468
Interest expense	(3,232)	(1,451)	(9,576)	(4,320)
Income before income tax expense	32,693	34,474	85,961	91,217
Income tax expense	5,587	7,399	19,686	22,623
Net income	$ 27,106	$ 27,075	$ 66,275	$ 68,594
Net income per share:				
Basic	$ 0.39	$ 0.39	$ 0.95	$ 0.98
Diluted	$ 0.33	$ 0.33	$ 0.82	$ 0.84
Shares used in computing net income per share:				
Basic	69,965	69,965	69,946	69,946
Diluted	84,592	84,592	84,409	84,409

Note 3. Inventory

Inventory is related to Cinryze and Vancocin and is stated at the lower of cost or market using the first-in first-out method. The following represents the components of the inventory at September 30, 2009 and December 31, 2008:

(in thousands)	September 30, 2009	December 31, 2008
Raw Materials	$ 21,571	$ 11,861
Work In Process	4,916	10,802
Finished Goods	13,934	4,505
Total	$ 40,421	$ 27,168

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ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements (Continued)

Note 4. Intangible Assets

The following represents the balance of the intangible assets at September 30, 2009:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Cinryze Product rights	$ 521,000	$ 19,663	$ 501,337
Vancocin Intangibles	154,099	30,175	123,924
Total	$ 675,099	$ 49,838	$ 625,261

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

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

In December 2008, FDA changed OGD s 2006 bioequivalence recommendation, which we have opposed since its original proposal in March 2006, by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin (Q1 and Q2 the same) to demonstrate bioequivalence through comparative in vitro dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin.

On August 4, 2009 the FDA s Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD s 2008 draft guidelines on bioequivalence for Vancocin. If FDA s proposed bioequivalence method for Vancocin becomes effective, the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

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

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ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements (Continued)

We are obligated to pay Eli Lilly and Company (Lilly) additional purchase price consideration based on net sales of Vancocin within a calendar year. The additional purchase price consideration is determined by the annual net sales of Vancocin, is paid quarterly and is due each year through 2011. We account for these additional payments as additional purchase price which requires that the additional purchase price consideration is recorded as an increase to the intangible assets of Vancocin, is allocated over the asset classifications described above and is amortized over the remaining estimated useful life of the intangible assets. In addition, at the time of recording the additional intangible assets, a cumulative adjustment is recorded to accumulated intangible amortization, in addition to ordinary amortization expense, in order to reflect amortization as if the additional purchase price had been paid in November 2004.

As of September 30, 2009, we have paid an aggregate of $37.1 million to Lilly in additional purchase price consideration, as our net sales of Vancocin surpassed the maximum obligation level of $65 million in 2009, 2008, 2007, 2006 and 2005. The $37.1 million paid to Lilly was based upon 35% of $20 million in 2009 and 2008, 35% of $17 million in 2007, 35% of $19 million in 2006 and 50% of $21 million in 2005. We are obligated to pay Lilly additional amounts based on 35% of annual net sales between $45 and $65 million of Vancocin during 2010 and 2011.

Note 5. Goodwill Impairment

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

Note 6. Property, Equipment and Building Improvements

At September 30, 2009 and December 31, 2008, we had $6.7 million of Property and Building classified as held for sale related to our previous corporate headquarters. During 2008, we incurred a $2.3 million impairment related to this building.

Note 7. Long-Term Debt

Long-term debt as of September 30, 2009 and December 31, 2008 is summarized in the following table:

(in thousands)	September 30, 2009	Adjusted December 31, 2008
Senior convertible notes	$ 136,906	$ 161,003
less: current portion		
Total debt principal	$ 136,906	$ 161,003

On March 26, 2007, we issued $250.0 million of 2% senior convertible notes due March 2017 (the senior convertible notes) in a public offering. Net proceeds from the issuance of the senior convertible notes were $241.8 million. The senior convertible notes are unsecured unsubordinated obligations and rank equally with any other unsecured and unsubordinated indebtedness. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007.

We adopted the requirements of ASC Topic 470-20 as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had outstanding convertible debt, as required by this new standard. Under this new method of accounting, the

debt and equity components of our convertible debt securities are bifurcated and accounted for separately. Under this new method of accounting, the convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value. See Note 2 for further explanation.

On March 24, 2009 we repurchased, in a privately negotiated transaction, $45.0 million in principal amount of our senior convertible notes due March 2017 for total consideration of approximately $21.2 million. The repurchase represented 18% of our then

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ViroPharma Incorporated

Notes to the Unaudited Consolidated Financial Statements (Continued)

outstanding debt and was executed at a price equal to 47% of par value. Following these repurchases, senior convertible notes representing $205.0 million of principal debt are outstanding with a carrying value of $ 136.9 million as of September 30, 2009. Additionally, in negotiated transactions, we sold approximately 2.38 million call options for approximately $1.8 million and repurchased approximately 2.38 million warrants for approximately $1.5 million which terminated the call options and warrants that were previously entered into by us in March 2007. We recognized a $9.1 million gain in the first quarter of 2009 as a result of this debt extinguishment. For tax purposes, the gain qualifies for deferral until 2014 in accordance with the provisions of the American Recovery and Reinvestment Act.

As of September 30, 2009, we have accrued $0.2 million in interest payable to holders of the senior convertible notes. Debt issuance costs of $4.8 million have been capitalized and are being amortized over the term of the senior convertible notes, with the balance to be amortized as of September 30, 2009 being $2.9 million.

The senior convertible notes are convertible into shares of our common stock at an initial conversion price of $18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the measurement period) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to ViroPharma s option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of September 30, 2009, the fair value of the principal of the $205.0 million convertible senior notes outstanding was approximately $156.8 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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

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

The purchased call options are expected to reduce the potential dilution upon conversion of the senior convertible notes in the event that the market value per share of ViroPharma common stock at the time of exercise is greater than $18.87, which corresponds to the initial conversion price of the senior convertible notes, but less than $24.92 (the warrant exercise price). The warrant exercise price is 75.0% higher than the price per share of $14.24 of the our on the pricing date. If the market price per share of ViroPharma common stock at the time of conversion of any senior convertible notes is above the strike price of the purchased call options ($18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants ($24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of ViroPharma common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants. We are entitled to receive approximately 10.87 million shares of its common stock at $18.87 from the call option holders and if the market price of ViroPharma common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants ($24.92), will owe the counterparties an aggregate of approximately 10.87 million shares of ViroPharma common stock.

The purchased call options and sold warrants are separate transactions entered into by us with the counterparties, are not part of the terms of the senior convertible notes, and will not affect the holders rights under the senior convertible notes. Holders of the senior convertible notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options

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and sold warrants meet the definition of derivatives under ASC Topic 815. 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 of ASC Topic 815.

Note 8. Share-based Compensation

We recorded share-based compensation expense as follows:

(in thousands)	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Research and development	$ 1,003	$ 842	$ 2,932	$ 2,177
Selling, general and administrative	1,597	1,562	6,447	4,313
Total	$ 2,600	$ 2,404	$ 9,379	$ 6,490

Employee Stock Option Plans

We currently have three option plans in place: a 1995 Stock Option and Restricted Share Plan (1995 Plan), a 2001 Equity Incentive Plan (2001 Plan) and a 2005 Stock Option and Restricted Share Plan (2005 Plan) (collectively, the Plans). On May 23, 2008, the 2005 Plan was amended and an additional 5,000,000 shares of common stock was reserved for issuance upon the exercise of stock options or the grant of restricted shares or restricted share units. This amendment was approved by stockholders at our Annual Meeting of Stockholders.

The following table lists the balances available by Plan at September 30, 2009:

	1995 Plan	2001 Plan	2005 Plan	Combined
Number of shares authorized	4,500,000	500,000	7,850,000	12,850,000
Number of options granted since inception	(6,997,515)	(1,255,472)	(5,426,012)	(13,678,999)
Number of options cancelled since inception	2,982,958	803,739	419,162	4,205,859
Number of shares expired	(480,293)	(1,375)		(481,668)
Number of shares available for grant	5,150	46,892	2,843,150	2,895,192

We issued stock options in the first nine-months of 2009. The weighted average fair value of each option grant was estimated at $6.75 per share using the Black-Scholes option-pricing model using the following assumptions:

Expected dividend yield		
Range of risk free interest rate	1.55%	3.18%
Weighted-average volatility	77.25%	
Range of volatility	73.80%	79.92%
Range of expected option life (in years)	5.50	6.25

We have 7,683,281 option grants outstanding at September 30, 2009 with exercise prices ranging from $0.99 per share to $38.70 per share and a weighted average remaining contractual life of 6.77 years. The following table lists the outstanding and exercisable option grants as of September 30, 2009:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding	7,683,281	$ 10.76	6.77	$ 14,233
Exercisable	4,208,780	$ 10.53	5.17	$ 11,396

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As of September 30, 2009, there was $20.4 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 2.54 years.

Employee Stock Purchase Plan

Under our plan, 32,558 shares were sold to employees during the first nine months of 2009. During the year ended December 31, 2008, 24,478 shares were sold to employees. As of September 30, 2009 there are approximately 516,217 shares available for issuance under this plan.

Under our plan, there are two plan periods: January 1 through June 30 (Plan Period One) and July 1 through December 31 (Plan Period Two). For Plan Period One in 2009, the fair value of approximately $124,700 was estimated using the Type B model provided by ASC Topic 718, with a risk free interest rate of 0.28%, volatility of 76.1% and an expected option life of 0.5 years. This fair value is being amortized over the six month period ending June 30, 2009.

Note 9. Income Tax Expense

Our income tax expense was $9.6 million and $5.6 million for the quarters ended September 30, 2009 and 2008, respectively and $20.2 million and $19.7 million for the nine months ended September 30, 2009 and September 30, 2008, respectively. Our income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences. The income tax expense in the first nine months of 2009 reflects the full impact of our gain on the repurchase of a portion of our convertible notes. In addition, our tax expense for the full year includes our current estimate of the impact of the orphan drug credit for maribavir.

During the nine months ended September 30, 2009, we paid approximately $1.2 million related to the settlement of the IRS audit of our 2006 federal income tax return. The payment was recorded as a reduction of our taxes payable liability that was previously recorded. We currently have various state returns under examination. The final outcomes of these examinations are not yet determinable at this time.

Included in other assets is approximately $3.2 million of non-current deferred tax assets related to our foreign operations.

Note 10. Comprehensive Income

The following table reconciles net income (loss) to comprehensive income (loss) for the three and nine months ended September 30, 2009 and 2008:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2009**	**2008**	**2009**	**2008**
Net income (loss)	$ 20,072	$ 27,106	$ (23,091)	$ 66,275
Other comprehensive:				
Unrealized gains on available for sale securities		434		1,141
Currency translation adjustments	1,888	(166)	2,097	(176)
Comprehensive income (loss)	$ 21,960	$ 27,374	$ (20,994)	$ 67,240

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Notes to the Unaudited Consolidated Financial Statements (Continued)

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

Note 11. Earnings (Loss) per share

(in thousands, except per share data)	Three Months Ended September 30, 2009	2008	Nine Months Ended September 30, 2009	2008
Basic Earnings (Loss) Per Share				
Net income (loss)	$ 20,072	$ 27,106	$ (23,091)	$ 66,275
Common stock outstanding (weighted average)	77,440	69,965	77,417	69,946
Basic net income (loss) per share	$ 0.26	$ 0.39	$ (0.30)	$ 0.95
Diluted Earnings (Loss) Per Share				
Net income (loss)	$ 20,072	$ 27,106	$ (23,091)	$ 66,275
Add interest expense on senior convertible notes, net of income tax	1,740	900		2,680
Diluted net income (loss)	$ 21,812	$ 28,006	$ (23,091)	$ 68,955
Common stock outstanding (weighted average)	77,440	69,965	77,417	69,946
Add shares from senior convertible notes	10,864	13,249		13,249
Add in-the-money stock options	875	1,378		1,214
Common stock assuming conversion and stock option exercises	89,179	84,592	77,417	84,409
Diluted net income (loss) per share	$ 0.24	$ 0.33	$ (0.30)	$ 0.82

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

(in thousands)	Three Months Ended September 30, 2009	2008	Nine Months Ended September 30, 2009	2008
Out-of-the-money stock options	5,857		5,752	
Shares from senior convertible notes			11,589	
In-the-money stock options			836	

Note 12. Fair Value Measurement

Valuation Hierarchy ASC Topic 820 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

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Notes to the Unaudited Consolidated Financial Statements (Continued)

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of September 30, 2009:

(in millions of dollars)	Total Carrying Value at September 30, 2009	Fair Value Measurements at September 30,2009 Using (Level 1)	(Level 2)	(Level 3)
Cash and cash equivalents	$ 288,930	$ 288,930	$	$
Total	$ 288,930	$ 288,930	$	$

Valuation Techniques Cash and cash equivalents are measured at fair value using quoted market prices and are classified within Level 1 of the valuation hierarchy. There were no changes in valuation techniques during the quarter ended September 30, 2009.

In the second quarter of 2009 we adopted the requirements of ASC Topic 820 that requires quarterly fair value disclosures for financial instruments rather than annual disclosure. We believe that the fair values of our current assets and current liabilities approximate their reported carrying amounts.

Note 13. Lev Pharmaceuticals, Inc. Acquisition

In October 2008, we acquired all the outstanding common stock of Lev Pharmaceuticals, Inc. (Lev). Lev was a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration of $453.1 million, or $2.75 per Lev share, comprised of $2.25 per share in cash and $0.50 per share in ViroPharma common stock, and contingent consideration (CVR s) of up to $1.00 per share which may be paid on achievement of certain regulatory and commercial milestones. The first CVR payment of $0.50 per share (or $87.5 million) would become payable when either (i) Cinryze is approved by the FDA for acute treatment of HAE and the FDA grants orphan exclusivity for Cinryze encompassing the acute treatment of HAE to the exclusion of all other human C1 inhibitor products or, (ii) orphan exclusivity for the acute treatment of HAE has not become effective for any third party s human C1 inhibitor product by October 21, 2010. The second CVR payment of $0.50 per share ($87.5 million) would become payable if Cinryze reaches at least $600.0 million in cumulative net product sales within 10 years of closing of the acquisition.

The value of the CVR s has not been included in the total cost of the acquisition, as the payment of these amounts is not reasonably assured at this time. Should any of the contingently issued payments be made, that value would be added to the purchase price. Additionally, as part of the purchase price allocation, we released the valuation allowance for ViroPharma s existing deferred tax assets that management believes are more likely than not to be realized as a result of the acquisition.

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

The results of Lev s operations have been included in the consolidated financial statements beginning October 21, 2008.

Note 14. Collaborations

In December 1999, we entered into a collaboration and license agreement with Wyeth (formerly American Home Products Corporation) to jointly develop products for use in treating hepatitis C virus in humans. Under the agreement, we licensed to Wyeth worldwide rights under certain patents and know-how owned by us or created under the agreement. We have the right to co-promote these products in the U.S. and Canada and Wyeth will promote the products elsewhere in the world. Wyeth has the right to manufacture any commercial products developed under the agreement.

In April 2008, we announced that ViroPharma and Wyeth, have jointly discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. We also announced that ViroPharma and Wyeth do not expect to continue to collaborate on future development of hepatitis C treatment candidates and the agreement expired in accordance with its terms during the third quarter of 2009.

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On January 1, 2009, we implemented the new accounting requirements on how parties to a collaborative agreement should disclose costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. In accordance with these requirements, we evaluated our collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments to and from our collaborative partners are not within the scope of other authoritative accounting literature, the income statement classification for these payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due to our collaborative partner related to development activities are reflected as a research and development expense. As of September 30, 2009, we owe Wyeth $0.2 million related to collaboration activities for HCV-796 activities.

Note 15. Supplemental Cash Flow Information

(in thousands)	Nine Months Ended September 30, 2009	2008
Supplemental disclosure of non-cash transactions:		
Employee share-based compensation	$ 9,379	$ 6,484
Liability classified share based compensation benefit		6
Unrealized gains on available for sale securities		1,141
Reversal of accrued deferred finance costs		151
Establishment of landlord allowance	104	1,996
Debt buy back deferred tax impact	308	
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 7,856	$ 8,818
Cash paid for interest	4,550	2,500
Cash received for stock option exercises	22	209
Cash received for employee stock purchase plan	164	175

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We market and sell Cinryze, which has been approved by the FDA for the prophylactic treatment of hereditary angioedema (HAE). The FDA also has approved the patient labeling for Cinryze to include self-administration for routine prophylaxis once patients are properly trained by their healthcare provider. Cinryze is a C1 inhibitor therapy for routine prophylaxis against HAE, also known as C1 inhibitor deficiency, a rare, severely debilitating, life-threatening genetic disorder. Cinryze was obtained in October 2008, when we completed our acquisition of Lev Pharmaceuticals, Inc. (Lev), a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. In December 2008, we submitted a supplemental Biologics Application (sBLA) for Cinryze as a treatment for acute attacks of HAE based on a re-analysis and resubmission of data from a pivotal Phase 3 acute treatment study of Cinryze and interim data from an ongoing open label acute study of the drug. On June 4, 2009, we received a Complete Response letter from the U.S. Food and Drug Administration (FDA) related to our sBLA. We are currently evaluating with our partner Sanquin, the feasibility of additional territories, indications and/or other formulations for Cinryze. Part of this plan is obtaining Orphan Drug designation for Europe which was granted in October 2009.

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

We are developing three product candidates, Cinryze for additional indications and/or other formulations for the treatment of HAE, non-toxigenic strains of C. *difficile* (NTCD) for the treatment and prevention of CDI; and maribavir for the prevention and treatment of cytomegalovirus, or CMV disease. On August 6, 2009 we announced that dosing has begun in the Phase 1 clinical trial for NTCD. The Phase 1 study will determine the safety and tolerability of NTCD dosed orally as a single and repeat escalating doses in healthy young and older adults. On February 9, 2009, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone marrow, transplant (SCT) patients did not achieve its primary endpoint. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. Additionally, on February 13, 2009, we announced that enrollment in our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to the current standard of care. We discontinued dosing patients with maribavir in clinical trials and are evaluating our maribavir program in light of the Phase 3 clinical trial results.

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

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

Executive Summary

Since June 30, 2009, we experienced the following:

Business Activities

Cinryze:

Shipped approximately 8,000 doses of Cinryze to specialty pharmacy/specialty distributors (SP/SD s); and

Began enrollment in our Phase 4 study;

C. difficile infection (CDI):

Initiated Phase 1 clinical trial for NTCD;

Vancocin scripts decreased 11.6% in the third quarter of 2009 as compared to the third quarter of 2008; and

The Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted to support a component of the FDA s Office of Generic Drugs draft guidelines on bioequivalence for Vancocin;

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CMV:

Recorded expenses of $2.2 million related to the wind-down of our Phase 3 clinical trials for maribavir, which has totaled $18.3 million for the nine months ended September 30, 2009;

Financial Results

Recorded net sales of Cinryze of $29.1 million;

Net sales of Vancocin decreased to $51.4 million from $65.9 million in the third quarter of 2008; and

Reported net income of $20.1 million in the third quarter of 2009;

Liquidity

Generated net cash from operations of $41.6 million; and

Ended the third quarter of 2009 with working capital of $357.9 million, which includes cash and cash equivalents of $288.9 million.

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

The commercial sale of approved pharmaceutical products is subject to risks and uncertainties. There can be no assurance that future Vancocin sales will meet or exceed the historical rate of sales for the product, for reasons that include, but are not limited to, generic and non-generic competition for Vancocin and/or changes in prescribing habits or disease incidence. Additionally, period over period fluctuations in net product sales are expected to occur as a result of wholesaler buying decisions.

We cannot assure you that generic competitors will not take advantage of the absence of patent protection for Vancocin to attempt to market a competing product. We are not able to predict the time period in which a generic drug may enter the market.

The FDA convened a meeting of its Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products on August 4, 2009. The Advisory Committee was asked if the proposed guidelines are sufficient for establishing bioequivalence for generic vancomycin oral capsules. The Advisory Committee voted unanimously in favor of the component of the proposed OGD recommendation that requires bioequivalence to be demonstrated through comparable dissolution in media of pH 1.2, 4.5 and 6.8 for potential vancomycin HCl capsule generic products that (a) contain the same active and inactive ingredients in the same amounts as Vancocin HCl capsules; (b) meet currently accepted standards for assay, potency, purity, and stability (equivalent to those in place for Vancocin HCl capsules); and (c) are manufactured according to cGMP. We have opposed both the substance of the FDA s bioequivalence method and the manner in which it was developed. In the event the OGD s revised approach regarding the conditions that must be met in order for a generic drug applicant to request a waiver of in-vivo bioequivalence testing for Vancocin remains in effect, the time period in which a generic competitor may enter the market would be reduced. There can be no assurance that the FDA will agree with the positions stated in our Vancocin related submissions or that our efforts to oppose the OGD s March 2006 and December 2008 recommendation to determine bioequivalence to Vancocin through in-vitro dissolution testing will be successful. We cannot predict the timeframe in which the FDA will make a decision regarding either our citizen petition for Vancocin or the approval of generic versions of Vancocin. If we are unable to change the recommendation set forth by the OGD in March 2006 as revised in December 2008 and voted upon by the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, the threat of generic competition will be high.

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

physicians and patients of Cinryze as a safe and effective treatment; our ability to effectively market and distribute Cinryze in the United States; cost effectiveness of HAE treatment using Cinryze; relative convenience and ease of administration of Cinryze; potential advantages of Cinryze over alternative treatments; the timing of the approval of competitive products including another C1 esterase inhibitor for the acute treatment of HAE; the market acceptance of competing approved products such as Berinert; patients ability to obtain sufficient coverage or reimbursement by third-party payors; sufficient supply and reasonable pricing of raw materials necessary to manufacture Cinryze; and manufacturing or supply interruptions and capacity which could impair our ability to acquire an adequate supply of Cinryze to meet demand for the product; and our ability to achieve expansion of manufacturing capabilities in the capacities and timeframes currently anticipated. In addition, our ability to develop life cycle management plans for Cinryze, including designing and commencing clinical studies for additional indications, seeking rights to additional geographic territories and pursuing regulatory approvals in such territories will impact our ability to generate future revenues from Cinryze.

We will face intense competition in acquiring additional products to expand further our product portfolio. Many of the companies and institutions that we will compete with in acquiring additional products to expand further our product portfolio have substantially greater capital resources, research and development staffs and facilities than we have, and greater resources to conduct business development activities. We may need additional financing in order to acquire new products in connection with our plans as described in this report.

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

We cannot assure you that our current cash and cash equivalents or cash flows from Vancocin and Cinryze sales will be sufficient to fund all of our ongoing development and operational costs, as well as the interest payable on our outstanding senior convertible notes, over the next several years, that planned clinical trials can be initiated, or that planned or ongoing clinical trials can be successfully concluded or concluded in accordance with our anticipated schedule and costs. Moreover, the results of our business development efforts could require considerable investments.

Our actual results could differ materially from those results expressed in, or implied by, our expectations and assumption described in this Quarterly Report on Form 10-Q. The risks described in this report, our Form 10-Q for the quarter ended September 30, 2009 are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Please also see our discussion of the Risk Factors as described in our Form 10-K for the year ended December 31, 2008 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 in Item 1A, which describe other important matters relating our business.

Results of Operations

Three and Nine Months Ended September 30, 2009 and 2008

(in thousands, except per share data)	For the three months ended September 30, 2009	2008	For the nine months ended September 30, 2009	2008
Net product sales	$ 80,551	$ 65,913	$ 222,614	$ 182,287
Cost of sales (excluding amortization of product rights)	$ 10,216	$ 2,460	$ 28,266	$ 6,764
Operating income (loss)	$ 32,425	$ 32,835	$ (3,481)	$ 82,069
Net income (loss)	$ 20,072	$ 27,106	$ (23,091)	$ 66,275
Net income (loss) per share:				
Basic	$ 0.26	$ 0.39	$ (0.30)	$ 0.95
Diluted	$ 0.24	$ 0.33	$ (0.30)	$ 0.82

The $32.4 million in operating income for the three month period ended September 30, 2009 decreased $0.4 million as compared to the same period in 2008 resulted primarily from the decrease in Vancocin sales, the increased cost of sales associated with Cinryze, increased Selling, General and Administrative (SG&A) costs related to the launch of Cinryze and increased amortization, offset by an increase in net sales from Cinryze. The $3.5 million in operating loss for the nine months ended September 30, 2009 as compared to the same period in 2008 resulted from the impairment of goodwill in the first quarter of 2009 and increased costs associated with our acquisition of Lev including cost of sales, intangible amortization and increased SG&A costs related to the launch of Cinryze, partially offset by net sales of Vancocin and Cinryze.

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Revenues

Revenues consisted of the following:

(in thousands)	For the three months ended September 30, 2009	2008	For the nine months ended September 30, 2009	2008
Net product sales				
Vancocin	$ 51,441	$ 65,913	$ 161,277	$ 182,287
Cinryze	29,110		61,337	
Total revenues	$ 80,551	$ 65,913	$ 222,614	$ 182,287

Revenue Vancocin and Cinryze product sales

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

We sell Cinryze to specialty pharmacy/specialty distributors (SP/SD s) who then sell and distribute to physicians, hospitals and patients, among others. Beginning in the second quarter of 2009, we recognized revenue based upon shipments of Cinryze to SP/SD s due to our ability to meet the revenue recognition criteria under ASC Topic 605, specifically our ability to estimate our payor mix. We previously recognized revenue upon shipment of Cinryze from SP/SD s to patients. We are temporarily managing the rate at which additional patients are started on drug to ensure that those already receiving commercial drug, and those new patients who start their routine prophylaxis will continue with a reliable uninterrupted supply of Cinryze. Our team is working with Sanquin to complete a two tiered scale up process that will significantly increase available supply in the second quarter of 2010 and beyond. When the additional supply enters the market, we will then return to adding new patients at a normal rate.

During the three and nine months ended September 30, 2009, net sales of Vancocin decreased 22.0% and 11.5%, respectively, compared to the same periods in 2008. The decreased for the three and nine months ended September 30, 2009 is primarily due to lower sales volumes driven by lower rates of severe disease, as compared to last year at this time, and a suspected increase in compounding seen both in the hospital and long-term care marketplace, partially offset by the price increase in January 2009. Based upon data reported by IMS Health Incorporated, prescriptions during the three and nine months ended September 30, 2009 decreased from the same period in 2008 period by 11.6% and 7.9%, respectively. The units sold for the three and nine months ended September 30, 2009 decreased by 25.3% and 15.7%, respectively, compared to the same period in 2008.

Vancocin and Cinryze product sales are influenced by prescriptions and wholesaler forecasts of prescription demand, which could be at different levels from period to period. In the third quarter of 2009, we began to manage patients added to Cinryze therapy to ensure patients on drug will continue to receive Cinryze in future periods. We receive inventory data from our three largest wholesalers through our fee for service agreements and our two SP/SD s through service agreements. We do not independently verify this data. Based on this inventory data and our estimates, we believe that as of September 30, 2009, the wholesalers and SP/SD s did not have excess channel inventory.

Cost of sales (excluding amortization of product rights)

Cost of sales increased for the three and nine months ended September 30, 2009 by $7.8 million and $21.5 million, respectively, as compared to the same period in the prior year due to the launch of Cinryze. Included in the Cost of sales for the nine months ended September 30, 2008 was $1.8 million that was previously deferred. Cost of sales during the three and nine months ended September 30, 2008 did not include Cinryze as we acquired Lev Pharmaceuticals in October 2008. Vancocin and Cinryze cost of sales includes the cost of materials and distribution costs and excludes amortization of product rights. As part of our October 2008 purchase of Lev, we acquired Cinryze inventory which was recorded at fair value in purchase accounting. This step-up of inventory value increased the cost of sales during the three and nine months ended September 30, 2009 by $0.7 million and $6.9 million, respectively.

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

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Research and development expenses

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts, and preclinical and development costs. Indirect expenses include personnel, facility, stock compensation and other overhead costs. Due to advancements in our NTCD preclinical program, the start of our Phase 4 commitment for Cinryze, we expect costs in these programs to exceed current costs. We are evaluating our maribavir program and will continue to incur additional costs necessary to complete certain activities related to the Phase 3 studies which were discontinued in February 2009.

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

(in thousands)	For the three months ended September 30, 2009	2008	For the nine months ended September 30, 2009	2008
Direct Core programs				
CMV	$ 1,862	$ 8,232	$ 15,008	$ 27,108
Cinryze	1,364		5,339	
Non-toxigenic strains of C. difficile (NTCD)	2,753	1,003	7,207	2,875
Vancocin	161	223	582	232
HCV		1	8	751
Indirect				
Development	4,866	5,392	15,014	12,880
Total	$ 11,006	$ 14,851	$ 43,158	$ 43,846

Direct Expenses Core Development Programs

Our direct expenses related to our CMV program decreased during the three and nine months ended September 30, 2009 as we wind-down our stem cell and liver transplant studies. Costs incurred during 2009 include enrollment in our solid organ (liver) study through February 2009, conducting follow-up visits and continuing to evaluate the results of our Phase 3 programs. In February 2009, based upon preliminary analysis of the data, we announced that our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell, or bone, marrow, transplant patients did not achieve its primary endpoints. In the primary analysis, there was no statistically significant difference between maribavir and placebo in reducing the rate of CMV disease. In addition, the study failed to meet its key secondary endpoints. We are continuing to analyze the study results. Additionally, we announced that our Phase 3 trial evaluating maribavir in liver transplant patients was discontinued and that all patients on study drug were moved to the current standard of care. This decision was made based on the results of the Phase 3 study of maribavir in stem cell transplant patients, and the recommendation from our independent Data Monitoring Committee who considered the rate of viremia in both arms of the study. During 2008, we continued recruitment and site initiations into ongoing phase 3 studies of maribavir in patients undergoing allogeneic stem cell transplant at transplant centers in the U.S., Canada and several European Countries and patients undergoing liver transplantation in the U.S. and Europe. Additionally, we began executing on our pre-launch plans for our clinical, regulatory and commercial activities for maribavir in the U.S. and Europe.

In April 2008, we announced that ViroPharma and Wyeth have jointly discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. We also announced that ViroPharma and Wyeth do not expect to continue to collaborate on future development of hepatitis C treatment candidates and the agreement expired in accordance with its terms during the third quarter of 2009.

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

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

Vancocin costs in the first nine months of 2009 and 2008 related to additional research activities.

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

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Indirect Expenses

These costs primarily relate to the compensation of and overhead attributable to our development team, the increase primarily relates to the year over year headcount increase from the first nine months of 2008. During the second half of 2009, our development team has shifted its focus from our CMV program to our Cinryze and NTCD programs.

Selling, general and administrative expenses

Selling, general and administrative expenses (SG&A) increased for the three and nine months ended September 30, 2009, $5.9 million and $23.8 million, respectively, compared to the same periods in 2008. For the nine month period, the largest contributors to this increase over the nine month period in 2008 were increased compensation costs resulting primarily from the expansion of our Cinryze field force ($11.0 million), increased marketing efforts ($3.3 million), increased professional fees ($2.8 million), and increased medical education activities ($0.4 million). Included in SG&A are legal and consulting costs incurred related to our opposition to the attempt by the OGD regarding the conditions that must be met in order for a generic drug application to request a waiver of in-vivo bioequivalence testing for copies of Vancocin, which were $3.3 million and $2.8 million for the first nine months of 2009 and 2008, respectively. We anticipate that these additional legal and consulting costs will gradually dimish in future periods. We anticipate continued increased spending in selling, general and administrative expenses in future periods as we continue the commercial launch of Cinryze.

Intangible amortization and acquisition of technology rights

Intangible amortization is the result of the Vancocin product rights acquisition in the fourth quarter of 2004 as well as the acquisition of Cinryze product rights in October 2008. Additionally, as described in our agreement with Lilly, to the extent that we incur an obligation to Lilly for additional payments on Vancocin sales, we have contingent consideration. We record the obligation as an adjustment to the carrying amount of the related intangible asset and a cumulative adjustment to the intangible amortization upon achievement of the related sales milestones. Contingent consideration and Lilly related additional payments are more fully described in Note 4 of the Unaudited Consolidated Financial Statements.

Intangible amortization for the three and nine months ended September 30, 2009 were $6.8 million and $21.4 million, respectively, as compared to $1.5 million and $5.3 million, respectively in 2008. Amortization is higher in 2009 as compared to 2008 due to the intangible asset acquired in our acquisition of Lev Pharmaceuticals.

On an ongoing periodic basis, we evaluate the useful life of our intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives. This evaluation did not result in a change in the life of the intangible assets during the quarter ended September 30, 2009. We will continue to monitor the actions of the FDA and OGD surrounding the bioequivalence recommendation for Vancocin and consider the effects of our opposition efforts, the announcements by generic competitors or other adverse events for additional impairment indicators. We will reevaluate the expected cash flows and fair value of our Vancocin-related assets, as well as estimated useful lives, at such time.

Other Income (Expense)

Interest Income

Interest income for three and nine months ended September 30, 2009 was $0.1 million and $0.3 million, respectively, as compared to $3.1 million and $13.5 million, in the respective periods in 2008. Interest income for both periods in 2009 as compared to 2008 decreased due to lower amounts of cash on hand and lower interest rates.

Interest Expense

(in thousands)	For the three months ended September 30, 2009	2008	For the nine months ended September 30, 2009	2008
Interest expense on senior convertible notes	$ 1,069	$ 1,250	$ 3,317	$ 3,730
Amortization of debt discount	1,651	1,781	5,171	5,256

Amortization of finance costs	97	201	315	590
Total interest expense	$ 2,817	$ 3,232	$ 8,803	$ 9,576

Interest expense and amortization of finance costs in 2009 and 2008 relates entirely to the senior convertible notes issued on March 26, 2007, as described in Note 7 to the Unaudited Consolidated Financial Statements.

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Income Tax Expense

Our income tax expense was $9.6 million and $5.6 million for the three months ended September 30, 2009 and 2008, respectively, which represents effective tax rates of 32.7% and 17.1%, respectively. Our income tax expense was $20.2 million and $19.7 million for the nine months ended September 30, 2009 and 2008, respectively. Our income tax expense includes federal, state and foreign income taxes at statutory rates and the effects of various permanent differences. The income tax expense in the first nine months of 2009 reflects the full impact of our gain on the repurchase of a portion of our convertible notes. In addition, our tax expense for the year includes our current estimate of the impact of the orphan drug credit for maribavir. The increase in the 2009 expense as compared to 2008 is primarily due to the decrease in our orphan drug qualified expenses, offset by the decrease in our taxable income from 2008. We continue to evaluate our orphan drug qualified expenses and, to the extent that actual qualified expenses vary significantly from our estimates; our tax expense will be impacted accordingly.

During the nine months ended September 30, 2009, we paid approximately $1.2 million as a result of the IRS audit of our 2006 federal income tax return and results in a reduction of our taxes payable liability. We also have various state returns currently under examination. The final outcome of these reviews are not yet determinable.

Liquidity

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

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

While we anticipate that cash flows from Vancocin and Cinryze, as well as our current cash and cash equivalents, should allow us to fund substantially all of our ongoing development and other operating costs for the foreseeable future, as well as the interest payable on our senior convertible notes, we may need additional financing in order to expand our product portfolio. At September 30, 2009, we had cash and cash equivalents of $288.9 million.

Overall Cash Flows

During the nine months ended September 30, 2009, we were provided with $41.6 million of net cash from operating activities, primarily from our net loss offset for non-cash items such as our goodwill impairment and depreciation and amortization expense, and our changes in working capital, specifically increases in accounts receivable, inventory and accrued expenses and other current liabilities. We used $8.3 million of cash from investing activities and our net cash used in financing activities for the nine months ended September 30, 2009 was $20.7 million, mainly in the repurchase of a portion of our senior convertible notes.

Operating Cash Inflows

We began to receive cash inflows from the sale of Vancocin in January 2005 and Cinryze in 2009. We cannot reasonably estimate the period in which we will begin to receive material net cash inflows from Cinryze that could cover our operating expenses, should Vancocin face generic competition. Cash inflows from pharmaceutical products are dependent on achievement of regulatory approvals. We may not receive revenues if a pharmaceutical product fails to obtain regulatory approvals.

Operating Cash Outflows

The cash flows we have used in operations historically have been applied to research and development activities, marketing and business development efforts, general and administrative expenses, servicing our debt, and income tax payments. Bringing drugs from the preclinical research and development stage through phase 1, phase 2, and phase 3 clinical trials and FDA approval is a time consuming and expensive process. Because our product candidates are currently in the clinical stage of development, there are a variety of events that could occur during the development process that will dictate the course we must take with our drug development efforts and the cost of these efforts. As a result, we cannot reasonably estimate the costs that we will incur through the commercialization of any product candidate. However, we anticipate we will continue to invest in our pipeline on our initiative to develop non-toxigenic strains of C. *difficile*, our phase 4 program for Cinryze, evaluating additional indications and territories for

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Cinryze and our maribavir program, future costs may exceed current costs. Additionally, our operating expenses will not decrease significantly due to the introduction of copies of generic Vancocin. We are also required to pay contingent consideration to Lev shareholders upon certain regulatory and commercial milestones. The most significant of our near-term operating development cash outflows are as described under ***Development Programs*** as set forth below.

Direct Expenses Development Programs

For each of our development programs, we incur both direct and indirect expenses. Direct expenses include third party costs related to these programs such as contract research, consulting, cost sharing payments or receipts, and preclinical and clinical development costs. Indirect expenses include personnel, facility and other overhead costs. Additionally, for some of our development programs, we have cash inflows and outflows upon achieving certain milestones.

Core Development Programs

Cinryze We acquired Cinryze in October 2008 and through September 30, 2009 have spent approximately $10.6 million in direct research and development costs related to Cinryze since acquisition. During the remainder of 2009, we continue to expect research and development costs related to Cinryze as we complete our Phase 4 commitment. Additionally, we will incur costs related to evaluating additional indications, formulations and territories as we develop our life cycle program related to Cinryze. We are solely responsible for the costs of Cinryze development.

NTCD We acquired NTCD in February 2006 and through September 30, 2009 have spent approximately $13.7 million in direct research and development costs. During the remainder of 2009, we expect our research and development activities related to NTCD to increase significantly as we commenced clinical studies with NTCD during the third quarter of 2009.

CMV program From the date we in-licensed maribavir through September 30, 2009, we paid $97.8 million of direct costs in connection with this program, including the acquisition fee of $3.5 million paid to GSK for the rights to maribavir in September 2003 and a $3.0 million milestone payment in February 2007.

During the remainder of 2009, we will continue to analyze the study results for the Phase 3 trial evaluating maribavir used as prophylaxis stem cell transplant patients that did not achieve its primary endpoint. In the remainder of 2009, we will continue to incur costs related to analyzing our Phase 3 results, patient monitoring and study wind down costs. We are solely responsible for the cost of developing our CMV product candidate.

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

Vancocin We acquired Vancocin in November 2004 and through September 30, 2009, we have spent approximately $1.6 million in direct research and development costs related to Vancocin activities since acquisition.

HCV program In April 2008 we, along with Wyeth, discontinued the development of HCV-796 due to the previously announced safety issue that emerged in the ongoing Phase 2 trial in patients with hepatitis C. Additionally, we announced that ViroPharma and Wyeth do not expect to continue to collaborate on future development of hepatitis C treatment candidates and the agreement expired in accordance with its terms during the third quarter of 2009.

Business development activities

On October 21, 2008, we completed our acquisition under which ViroPharma acquired Lev Pharmaceuticals, Inc. (Lev). Lev is a biopharmaceutical company focused on developing and commercializing therapeutic products for the treatment of inflammatory diseases. The terms of the merger agreement provided for the conversion of each share of Lev common stock into upfront consideration of $453.1 million, or $2.75 per Lev share, comprised of $2.25 per share in cash and $0.50 per share in ViroPharma common stock, and contingent consideration of up to $1.00 per share which may be paid on achievement of certain regulatory and commercial milestones. The Company used approximately $385 million of existing cash and cash equivalents to fund the acquisition, including deal related expenses, and issued 7,359,667 shares in conjunction with the merger.

We intend to seek to acquire additional products or product candidates. The costs associated with evaluating or acquiring any additional product or product candidate can vary substantially based upon market size of the product, the commercial effort required for the product, the product s current stage of development, and actual and potential generic and non-generic competition for the product, among other factors. Due to the

variability of the cost of evaluating or acquiring business development candidates, it is not feasible to predict what our actual evaluation or acquisition costs would be, if any, however, the costs could be substantial.

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Senior Convertible Notes

On March 26, 2007, we issued $250.0 million of 2% senior convertible notes due March 2017 (the senior convertible notes) in a public offering. Net proceeds from the issuance of the senior convertible notes were $241.8 million. The senior convertible notes are unsecured unsubordinated obligations and rank equally with any other unsecured and unsubordinated indebtedness. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007.

We adopted the requirements of ASC Topic 470-20 as of January 1, 2009 and retrospectively applied this change in accounting to all prior periods presented for which we had outstanding convertible debt, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities are bifurcated and accounted for separately. Under this new method of accounting, the convertible debt securities will recognize interest expense at effective rates of 8.0% as they are accreted to par value. See Note 2 for further explanation.

On March 24, 2009 we repurchased, in a privately negotiated transaction, $45.0 million in principal amount of our senior convertible notes due March 2017 for total consideration of approximately $21.2 million. The repurchase represented 18% of our then outstanding debt and was executed at a price equal to 47% of par value. Following these repurchases, senior convertible notes representing $205.0 million of principal debt are outstanding with a carrying value of $ 136.9 million as of September 30, 2009. Additionally, in negotiated transactions, we sold approximately 2.38 million call options for approximately $1.8 million and repurchased approximately 2.38 million warrants for approximately $1.5 million which terminated the call options and warrants that were previously entered into by us in March 2007. We recognized a $9.1 million gain in the first quarter of 2009 as a result of this debt extinguishment. For tax purposes, the gain qualifies for deferral until 2014 in accordance with the provisions of the American Recovery and Reinvestment Act.

As of September 30, 2009, we have accrued $0.2 million in interest payable to holders of the senior convertible notes. Debt issuance costs of $4.8 million have been capitalized and are being amortized over the term of the senior convertible notes, with the balance to be amortized as of September 30, 2009 being $2.9 million.

The senior convertible notes are convertible into shares of our common stock at an initial conversion price of $18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the measurement period) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to our option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of September 30, 2009, the fair value of the principal of the $205.0 million convertible senior notes outstanding was approximately $156.8 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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

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

The purchased call options are expected to reduce the potential dilution upon conversion of the senior convertible notes in the event that the market value per share of our common stock at the time of exercise is greater than $18.87, which corresponds to the initial conversion price of the senior convertible notes, but less than $24.92 (the warrant exercise price). The warrant exercise price is 75.0% higher than the price per share of $14.24 of the our on the pricing date. If the market price per share of our common stock at the time of conversion of any senior convertible

notes is above the strike price of the purchased call options ($18.87), the purchased call options will entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted senior convertible notes. Additionally, if the market price of our common

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stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants ($24.92), we will owe the counterparties an aggregate of approximately 13.25 million shares of our common stock. If we have insufficient shares of common stock available for settlement of the warrants, we may issue shares of a newly created series of preferred stock in lieu of our obligation to deliver common stock. Any such preferred stock would be convertible into 10% more shares of our common stock than the amount of common stock we would otherwise have been obligated to deliver under the warrants. We are entitled to receive approximately 10.87 million shares of its common stock at $18.87 from the call option holders and if the market price of our common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants ($24.92), will owe the counterparties an aggregate of approximately 10.87 million shares of our common stock.

The purchased call options and sold warrants are separate transactions entered into by us with the counterparties, are not part of the terms of the senior convertible notes, and will not affect the holders rights under the senior convertible notes. Holders of the senior convertible notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options and sold warrants meet the definition of derivatives. These instruments have been determined to be indexed to our own stock and have been recorded in stockholders equity in our Consolidated Balance Sheet. As long as the instruments are classified in stockholders equity they are not subject to the mark to market requirements of US GAAP.

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

Capital Resources

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

Financing

If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of existing stockholders.

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

Additional equity or debt financing, however, may not be available on acceptable terms from any source as a result of, among other factors, our operating results, our inability to achieve regulatory approval of any of our product candidates, our inability to generate revenue through our existing collaborative agreements, and our inability to file, prosecute, defend and enforce patent claims and or other intellectual property rights. If sufficient additional financing is not available, we may need to delay, reduce or eliminate current development programs, or reduce or eliminate other aspects of our business.

Critical Accounting Policies

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Preparing consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and contingent assets and liabilities. Actual results could differ from such estimates. These estimates and assumptions are affected by the application of our accounting policies. Critical policies and practices are both most important to the portrayal of a company s financial condition and results of operations, and require management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Our summary of significant accounting policies is described in Note 2 to our Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended December 31, 2008. However, we consider the following policies and estimates to be the most critical in understanding the more complex judgments that are involved in preparing our consolidated financial statements and that could impact our results of operations, financial position, and cash flows:

Product Sales Our net sales consist of revenue from sales of our products, Vancocin and Cinryze, less estimates for chargebacks, rebates, distribution service fees, returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, distribution service fees, returns and losses are reasonably determinable, and when collectability is reasonably assured. Revenue from the launch of a new or significantly unique product may be deferred until estimates can

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be made for chargebacks, rebates and losses and all of the above conditions are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

At the end of each reporting period, as part of an analysis of returns, we analyze our estimated channel inventory and we would defer recognition of revenue on product that has been delivered if we believe that channel inventory at a period end is in excess of ordinary business needs. Further, in connection with our analysis of returns, if we believe channel inventory levels are increasing without a reasonably correlating increase in prescription demand, we proactively delay the processing of wholesaler orders until these levels are reduced.

We establish accruals for chargebacks and rebates, sales discounts and product returns. These accruals are primarily based upon the history of Vancocin and for Cinryze they are based on information on payee s obtained from our SP/SD s and CinryzeSolutions. We also consider the volume and price of our products in the channel, trends in wholesaler inventory, conditions that might impact patient demand for our product (such as incidence of disease and the threat of generics) and other factors.

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

Chargebacks and rebates are the most subjective sales related accruals. While we currently have no contracts with private third party payors, such as HMO s, we do have contractual arrangements with governmental agencies, including Medicaid. We establish accruals for chargebacks and rebates related to these contracts in the period in which we record the sale as revenue. These accruals are based upon historical experience of government agencies market share, governmental contractual prices, our current pricing and then-current laws, regulations and interpretations. We analyze the accrual at least quarterly and adjust the balance as needed. We believe that if our estimates of the rate of chargebacks and rebates as a percentage of annual gross sales were incorrect by 5%, our operating income and accruals would be impacted by approximately $1.5 million in the period of correction, which we believe is immaterial.

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

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

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

Impairment of Long-lived Assets We review our fixed and intangible assets for possible impairment annually and whenever events occur or circumstances indicate that the carrying amount of an asset may not be recoverable. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include, for example, projections of future cash flows and the timing and number of generic/competitive entries into the market, in determining the undiscounted cash flows, and if necessary, the fair value of the asset and whether an impairment exists. These assumptions are subjective and could result in a material impact on operating results in the period of impairment. While we reviewed our intangible assets in March 2006 and December 2008 in light of the actions taken by the OGD, we did not recognize any impairment charges. See Note 4 of the Consolidated Financial Statements for further information.

On an ongoing periodic basis, we evaluate the useful life of intangible assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives. While we reviewed the useful life of our intangible assets in March 2006 and December 2008 in light of the actions taken by the OGD, we did not change the useful life of our intangible assets. See Note 4 of the Consolidated Financial Statements for further information.

On August 4, 2009 the FDA s Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted in favor of the OGD s 2008 draft guidelines on bioequivalence for Vancocin. If FDA s proposed bioequivalence method for Vancocin

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becomes effective, the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market, which would materially impact our operating results, cash flows and possibly intangible asset valuations. This could also result in a reduction to the useful life of the Vancocin-related intangible assets. Management currently believes there are no indicators that would require a change in useful life as management believes that Vancocin will continue to be utilized along with generics that may enter the market, and the number of generics and the timing of their market entry is unknown.

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

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

During the first quarter of 2009, our market cap dropped below the carrying value of our net assets due to the results of our Phase 3 trial evaluating maribavir used as prophylaxis in allogeneic stem cell or bone marrow transplant patients. We concluded that the drop in our market cap was a triggering event which required us to perform an impairment test of our intangible assets and a step 2 test for goodwill impairment. As part of this process, we also assessed our intangible and fixed assets for impairment. Based on the analysis performed under step two, there was no remaining implied value attributable to goodwill and accordingly, we wrote off the entire goodwill balance and recognized a goodwill impairment charge in the first quarter of 2009.

Short-term Investments We review our short-term investments on a periodic basis for other-than-temporary impairments. This review considers credit worthiness and our intent and ability to hold debt securities until maturity and is subjective as it requires management to evaluate whether an event or change in circumstances has occurred in that period that may have a significant adverse effect on the fair value of the investment.

Share-Based Employee Compensation The calculation of this expense includes judgment related to the period of time used in calculating the volatility of our common stock, the amount of forfeitures and an estimate of the exercising habits of our employees, which is also influenced by our Insider Trading Policy. Changes in the volatility of our common stock or the habits of our employees could result in variability in the fair value of awards granted.

Income Taxes Our annual effective tax rate is based on expected pre-tax earnings, existing statutory tax rates, limitations on the use of tax credits and net operating loss carryforwards, evaluation of qualified expenses related to the orphan drug credit and tax planning opportunities available in the jurisdictions in which we operate. Significant judgment is required in determining our annual effective tax rate.

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

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences becomes deductible or the NOLs and credit carryforwards can be utilized. When considering the reversal of the valuation allowance, we consider the level of past and future taxable income, the reversal of deferred tax liabilities, the utilization of the carryforwards and other factors. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Acquisition Accounting Businesses acquired before December 31, 2008 are accounted for in accordance with SFAS No. 141, *Business Combinations* and the total purchase price was allocated to Lev s net tangible assets or identifiable intangible assets based on their fair values as of the date of the acquisition. The application of the purchase accounting requires certain estimates and assumptions especially concerning the determination of the fair values of the acquired intangible assets and property, plant and equipment as well as the liabilities assumed at the date of the acquisition. Moreover, the useful lives of the acquired intangible assets, property, plant and equipment have to be determined.

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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.

Legal During the second quarter, we began recording an allowance for rebates related to the Department of Defense s (DoD s) TRICARE Retail Pharmacy program pursuant to a final regulation that became effective on May 26, 2009. This regulation would require manufacturers to pay rebates to DoD on product distributed to TRICARE beneficiaries through retail pharmacies retroactive to January 28, 2008. The final regulation implements section 703 of the National Defense Authorization Act of 2008, or NDAA. The final regulation requires that pharmaceuticals paid for by the DoD through the TRICARE Retail Pharmacy program be subject to the Federal Ceiling Price program, which will require manufacturers to provide DoD with a refund on pharmaceuticals utilized through the TRICARE Retail Pharmacy program. As permitted by the regulations, we have requested a waiver of the retroactive rebate for TRICARE Retail Pharmacy utilization for the period from January 28, 2008 to May 26, 2009. In addition, the regulation is currently the subject to litigation and it is our belief that the retroactive application of the regulation is contrary to established case law. We have determined that payment of the retroactive rebate created by the regulation is not probable as of September 30, 2009. Although the ultimate disposition of this matter is uncertain, we have estimated that our maximum exposure of the retroactive rebate due to the DoD is $2.9 million.

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

Recently Issued Accounting Pronouncements

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

Off-Balance Sheet Arrangements

In conjunction with our acquisition of Lev, we acquired purchase obligations related to the supply and manufacturing of Cinryze. We have committed to purchase a minimum number of liters of plasma per year through 2013 from our supplier. Additionally, we are required to purchase a minimum number of units from our third party toll manufacturer. In October 2009, we terminated our agreement with Plasma Centers of America (PCA) and our obligation to purchase plasma collected from centers own by PCA. The total minimum purchase commitments for these continuing arrangements as of September 30, 2009 are approximately $139.2 million.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Our holdings of financial instruments are primarily comprised of money mark funds holding only U.S. government securities. All such instruments are classified as securities available for sale. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. Our primary investment objective is the preservation of principal, while at the same time optimizing the generation of investment income. We seek reasonable assuredness of the safety of principal and market liquidity by investing in cash equivalents (such as Treasury bills and money market funds) and fixed income securities (such as U.S. government and agency securities, municipal securities, taxable municipals, and corporate notes) while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. Historically, we have typically

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invested in financial instruments with maturities of less than one year. The carrying amount, which approximates fair value, and the annualized weighted average nominal interest rate of our investment portfolio at September 30, 2009, was approximately $246.2 million and 0.1%, respectively. A one percent change in the interest rate would have resulted in a $0.6 million impact to interest income for the quarter ended September 30, 2009.

At September 30, 2009, we had principal outstanding of $205.0 million of our senior convertible notes. The senior convertible notes bear interest at a rate of 2% per annum, payable semi-annually in arrears on March 15 and September 15 of each year commencing on September 15, 2007. The senior convertible notes are convertible into shares of our common stock at an initial conversion price of $18.87 per share. The senior convertible notes may only be converted: (i) anytime after December 15, 2016; (ii) during the five business-day period after any five consecutive trading day period (the measurement period) in which the price per note for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (iii) during any calendar quarter (and only during such quarter) after the calendar quarter ending June 30, 2007, if the last reported sale price of our common stock for 20 or more trading days in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the applicable conversion price in effect on the last trading day of the immediately preceding calendar quarter; or (iv) upon the occurrence of specified corporate events. Upon conversion, holders of the senior convertible notes will receive shares of common stock, subject to our option to irrevocably elect to settle all future conversions in cash up to the principal amount of the senior convertible notes, and shares for any excess. We can irrevocably elect this option at any time on or prior to the 35th scheduled trading day prior to the maturity date of the senior convertible notes. The senior convertible notes may be required to be repaid on the occurrence of certain fundamental changes, as defined in the senior convertible notes. As of September 30, 2009, the fair value of the principal of the $205.0 million convertible senior notes outstanding was approximately $156.8 million, based on the level 2 valuation hierarchy of the fair value measurements standard.

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

ITEM 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 September 30, 2009. Based on that evaluation, our management, including our CEO and CFO, concluded that as of September 30, 2009 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the third quarter of 2009 there were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that 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 1A. Risk Factors

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

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

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

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

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

the time required to develop appropriate manufacturing procedures.

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

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

In December 2008, the FDA changed OGD s 2006 bioequivalence recommendation by issuing draft guidance for establishing bioequivalence to Vancocin which would require generic products that have the same inactive ingredients in the same quantities as Vancocin, or Q1 and Q2 the same, to demonstrate bioequivalence through comparative dissolution testing. Under this latest proposed method, any generic product that is not Q1 and Q2 the same as Vancocin would need to conduct an in vivo study with clinical endpoints to demonstrate bioequivalence with Vancocin.

The FDA convened a meeting of its Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products on August 4, 2009. The Advisory Committee was asked if the proposed guidelines are sufficient for establishing bioequivalence for generic vancomycin oral capsules. The Advisory Committee voted unanimously in favor of the component of the proposed OGD recommendation that requires bioequivalence to be demonstrated through comparable dissolution in media of pH 1.2, 4.5 and 6.8 for potential vancomycin HCl

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

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

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

The Orphan Drug Act was created to encourage companies to develop therapies for rare diseases by providing incentives for drug development and commercialization. One of the incentives provided by the act is seven years of market exclusivity for the first product in a class licensed for the treatment of a rare disease. HAE is considered to be a rare disease under the Orphan Drug Act, and companies may obtain orphan drug status for therapies that are developed for this indication. The FDA granted Cinryze seven years of marketing exclusivity to Cinryze C1 inhibitor (human) for routine prophylaxis of HAE pursuant to the Orphan Drug Act. The FDA has granted marketing approval of CSL Behring s product, Berinert® C1-Esterase Inhibitor, Human, for the treatment of acute abdominal or facial attacks of hereditary angioedema and we expect that Berinert will receive exclusivity pursuant to the Orphan Drug Act.

While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication unless the subsequent sponsors could demonstrate clinical superiority or a market shortage occurs, it would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. In the event we are unable to fill demand for Cinryze, it is possible that the FDA may view such unmet demand as a market shortage which could impact the market exclusivity provided by the Orphan Drug Act. The U.S. Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug and, thus, we cannot be sure that the benefits of the existing statute will remain in effect.

Acute treatment of HAE is an indication that fits within the definition of the Orphan Drug Act, and therefore any company that develops a therapy for this indication could, upon licensure, obtain a seven year marketing exclusivity in the United States for the licensed indication. The approval of Cinryze for the routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE would not prevent another company from gaining licensure related to the acute treatment of HAE. The FDA has granted marketing approval of CSL Behring s product, Berinert® C1-Esterase Inhibitor, Human, for the treatment of acute abdominal or facial attacks of hereditary angioedema and we expect that Berinert will receive exclusivity pursuant to the Orphan Drug Act. As a result we would be prevented from obtaining FDA licensure and marketing our C1-INH product for the acute treatment of HAE for up to seven years which could reduce our potential future revenues from sales of Cinryze.

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

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

There are a limited number of manufacturers that operate under cGMPs that are capable of manufacturing our products and product candidates. As such, if we are unable to enter into supply and processing contracts with any of these manufacturers or processors for our development stage product candidates, there may be additional costs and delays in the development and commercialization of these product candidates. For example, Cinryze is a biologic which requires processing steps that are more difficult than those required for most chemical pharmaceuticals and therefore the third party contracts must have additional technical skills and multiple steps to attempt to control the manufacturing processes.

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

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If we are required to find an additional or alternative source of supply, there may be additional costs and delays in the development or commercialization of our product candidates. Additionally, the FDA and other regulatory agencies routinely inspect manufacturing facilities before approving a new drug application, or NDA, or biologic application, or BLA, for a drug or biologic manufactured at those sites. If any of our manufacturers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our products and product candidates may be delayed.

In addition, regulatory agencies subject a marketed therapy, its manufacturer and the manufacturer s facilities to continual review and periodic inspections. The discovery of previously unknown problems with a therapy or the facility or process used to produce the therapy could prompt a regulatory authority to impose restrictions on us or delay approvals for new products or could cause us to voluntarily adopt restrictions, including withdrawal of one or more of our products or services from the market. The FDA recently inspected two sites maintained by our contract manufacturer for Cinryze and issued a notice of observations at the close of the inspection on FDA Form 483 for each site. The observations at one site were subsequently remedied and a notice to this effect was issued by the FDA. Responses to the observations made at the second site have been provided to the FDA. If any of our manufacturers or processors fails to satisfy regulatory requirements, operations at such facility may be halted which could result in our inability to supply product to patients and reduce our revenues.

All of our contract manufacturers must comply with the applicable cGMPs, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. If our contract manufacturers do not comply with the applicable cGMPs and other FDA regulatory requirements, we may be subject to product liability claims, the availability of marketed products for sale could be reduced, our product commercialization could be delayed or subject to restrictions, we may be unable to meet demand for our products and may lose potential revenue and we could suffer delays in the progress of clinical trials for products under development. We do not have control over our third-party manufacturers compliance with these regulations and standards. Moreover, while we may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the product, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

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

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

We rely on a single manufacturer of Cinryze. Pursuant to our distribution agreement, Sanquin Blood Supply Foundation will supply us with certain annual minimum and maximum amounts of C1 INH. In the event demand for C-1NH is greater than the amount supplied by Sanquin, we would have to find alternative suppliers of C1 INH. Currently, to our knowledge, there is only one other commercial supplier of C1 esterase inhibitor and that supplier has recently received marketing approval for their product in the U.S. Accordingly, we cannot be certain that we would be able to locate another willing supplier for our product on the terms we require.

The risks associated with the numerous factors that could cause interruptions in the supply of our products, including manufacturing capacity limitations, regulatory reviews, changes in our sources for manufacturing, disputes with a manufacturer, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials, are magnified when the suppliers are limited in number. Any interruption in the supply of finished products could hinder our ability to timely distribute our products and satisfy customer demand. If we are unable to obtain adequate product supplies to satisfy our customers orders, we may lose those orders, our customers may cancel other orders, and they may choose instead to stock and purchase competing products. This in turn could cause a loss of our market share and negatively affect our revenues. Supply interruptions may occur and our inventory may not always be adequate.

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

Pursuant to our distribution agreement, Sanquin Blood Supply Foundation supplies us with certain annual minimum and maximum amounts of C1 INH. We and Sanquin are undertaking process improvements and facility expansions to increase the capacity of the facilities involved in manufacturing Cinryze. Our manufacturing scale up effort is a two-tiered approach including a parallel chromatography process, which we anticipate will be completed in the first quarter of 2010, with the additional product becoming

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available for commercial sale in the second quarter of 2010. The second phase of our scale up plan involves a larger scale construction project to significantly increase the production facilities of Sanquin. Pursuant to an agreement with Sanquin we have financed a portion of the costs of the project to increase the manufacturing capacity of its facilities. Following the completion of construction, Sanquin would need to obtain the requisite regulatory approvals for the facility on a timely basis in order to manufacture Cinryze for us at an increased capacity. We anticipate that the approvals could be received by the end of 2010.

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

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ITEM 6. Exhibits

10.1	First Amendment to the Agreement for the Purchase and Sale of Blood Plasma, dated as of July 9, 2009 by and between ViroPharma Biologics, Inc., a wholly owned subsidiary of ViroPharma Incorporated, and DCI Management Group LLC.*
31.1	Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith
Portions of this exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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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

Date: October 28, 2009

By: /s/ VINCENT J. MILANO
Vincent J. Milano

President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ CHARLES A. ROWLAND, JR.
Charles A. Rowland, Jr.

Vice President, Chief Financial Officer

(Principal Financial Officer)

By: /s/ RICHARD S. MORRIS
Richard S. Morris

Chief Accounting Officer and Controller

(Principal Accounting Officer)