CORNERSTONE THERAPEUTICS INC
Form 10-Q
November 07, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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, 2013

or

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

For the Transition Period From to

Commission File Number: 000-50767

CORNERSTONE THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1255 Crescent Green Drive, Suite 250	
Cary, North Carolina	**27518**
(Address of Principal Executive Offices)	**(Zip Code)**

(919) 678-6611

(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 x No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	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

As of October 31, 2013, the registrant had 26,902,898 shares of Common Stock, $0.001 par value per share, outstanding.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Cautionary Statement Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management s prospects, plans and objectives; and any other statements about management s future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, ex intend, may, plan, project, should, target, will, would or other words that convey uncertainty of future e outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates ; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; patient, physician and third-party payer acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products; our ability to obtain U.S. Food and Drug Administration, or FDA, approval to manufacture, market and sell our products and product candidates, including RETAVASE® (reteplase, recombinant) and RETAFLO® (reteplase, recombinant); our ability to successfully and effectively launch BETHKIS® (tobramycin inhalation solution) and manage the recent launch of our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product; our ability to enter into additional strategic licensing, product acquisition, collaboration or co-promotion transactions on favorable terms, if at all; our ability to manage and control unknown liabilities in connection with any acquisitions; our ability to successfully manage growth or integrate acquired businesses and operations; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to develop and commercialize our product candidates before our competitors develop and commercialize competing products; our ability to satisfy FDA and other regulatory requirements; our substantial indebtedness and debt covenants; our entry into the Agreement and Plan of Merger, or the Merger Agreement, with Chiesi Farmaceutici S.p.A., or Chiesi, and Chiesi U.S. Corporation, or Merger Sub, pursuant to which we have agreed to merge with Merger Sub and become a wholly owned subsidiary of Chiesi, which we refer to as the Chiesi Merger, including our ability to consummate the Chiesi Merger, uncertainties associated with the Chiesi Merger, the impact of the Chiesi Merger on our ability to attract and retain personnel, and the effect of contractual restrictions on the conduct of our business prior to the completion of the Chiesi Merger and on our ability to make certain business decisions; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail in Item 1A. Risk Factors of our annual report on Form 10-K for the year ended December 31, 2012 filed with the Securities and Exchange Commission, or SEC, on March 14, 2013. Any material changes to the risk factors disclosed in the annual report are discussed below in Part II Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this quarterly report on Form 10-Q represent our views only as of the date of this quarterly report on Form 10-Q and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking

statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as may be required by law. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make, except that in particular circumstances as specifically indicated we may address the potential impact of the Chiesi Merger.

Table of Contents

ITEM 1. ***FINANCIAL STATEMENTS***

CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	September 30, 2013 (Unaudited)	December 31, 2012 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 69,612	$ 56,250
Accounts receivable, net	29,804	14,368
Inventories, net	14,459	11,384
Prepaid expenses	6,771	3,343
Income tax receivable		4,094
Deferred tax asset	3,079	1,614
Acquisition-related current assets	1,578	11,134
Other current assets	783	379
Total current assets	126,086	102,566
Property and equipment, net	1,548	1,310
Product rights, net	229,248	232,111
Goodwill	33,151	33,356
Other assets	32	32
Total assets	$ 390,065	$ 369,375
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 7,534	$ 12,439
Accrued expenses	48,129	37,379
Acquisition-related contingent payments	8,511	6,846
Acquisition-related current liabilities	1,587	9,636
Income tax payable	2,683	
Other current liabilities	777	525
Total current liabilities	69,221	66,825
Acquisition-related contingent payments, less current portion	25,935	26,362
Long-term debt	89,618	89,540
Deferred tax liability	14,274	15,683
Other long-term liabilities	4,306	4,792

Total liabilities	203,354	203,202
Commitments and contingencies, Note 11		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock $0.001 par value, 90,000,000 shares authorized; 26,544,266 and 26,348,470 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	27	26
Additional paid-in capital	170,243	167,461
Retained earnings (accumulated deficit)	16,441	(1,314)
Total stockholders equity	186,711	166,173
Total liabilities and stockholders equity	$ 390,065	$ 369,375

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net revenues	$ 53,697	$ 37,525	$ 132,083	$ 81,157
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	12,642	14,397	34,904	31,984
Selling, general and administrative	16,371	12,933	43,288	32,745
Research and development	594	1,998	2,036	3,729
Amortization of product rights	4,408	5,284	12,863	13,774
Change in acquisition-related contingent payments	2,298	(1,574)	6,080	(1,574)
Transaction-related expenses	1,458	1,764	2,595	7,944
Other operating expenses, net	(113)		(1,101)	(1,492)
Total costs and expenses	37,658	34,802	100,665	87,110
Income (loss) from operations	16,039	2,723	31,418	(5,953)
Other expenses, net:				
Interest expense, net	(1,683)	(1,684)	(5,007)	(1,799)
Other income, net	(103)	(215)	426	(215)
Total other expenses	(1,786)	(1,899)	(4,581)	(2,014)
Income (loss) before income taxes	14,253	824	26,837	(7,967)
(Provision for) benefit from income taxes	(4,676)	425	(9,082)	3,038
Net income (loss)	$ 9,577	$ 1,249	$ 17,755	$ (4,929)
Comprehensive income (loss)	$ 9,577	$ 1,249	$ 17,755	$ (4,929)
Net income (loss) per share, basic	$ 0.36	$ 0.05	$ 0.67	$ (0.19)
Net income (loss) per share, diluted	$ 0.31	$ 0.05	$ 0.60	$ (0.19)
Weighted-average common shares, basic	26,515,190	26,245,765	26,446,783	26,040,695
Weighted-average common shares, diluted	31,495,632	26,603,258	31,274,715	26,040,695

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Nine Months Ended September 30,	
	2013	**2012**
Cash flows from operating activities		
Net income (loss)	$ 17,755	$ (4,929)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Amortization and depreciation	13,416	14,267
Amortization of debt costs	78	26
Provision for prompt payment discounts	3,777	2,390
Provision for other receivables	83	
Provision for inventory allowances	1,373	847
Acquisition accounting adjustment on inventory sold	98	3,061
Gain on sale of product rights		(1,492)
Loss on disposal of property and equipment	53	215
Change in acquisition-related contingent payments	6,080	(1,574)
Stock-based compensation	2,005	2,027
Deferred revenue		(1,428)
Deferred income taxes	884	177
Changes in operating assets and liabilities:		
Accounts receivable	(19,167)	(7,654)
Inventories	(4,546)	(1,001)
Prepaid expenses and other assets	(4,050)	(356)
Accounts payable, accrued expenses, and other liabilities	5,753	(5,543)
Acquisition-related current assets and liabilities	1,514	(1,477)
Income taxes	3,293	(2,341)
Net cash provided by (used in) operating activities	28,399	(4,785)
Cash flows from investing activities		
Acquisition of businesses, net of cash acquired	13	(126,921)
Purchase of product rights	(10,000)	
Purchase of property and equipment	(844)	(265)
Proceeds from sale of product rights		3,000
Net cash used in investing activities	(10,831)	(124,186)
Cash flows from financing activities		
Proceeds from term loans		90,000

Proceeds of debt financing costs		(511)
Proceeds from exercise of common stock options	773	1,157
Excess tax benefit from stock-based compensation	12	284
Payments related to net settlement of restricted stock	(7)	(122)
Acquisition-related contingent payments	(4,909)	(1,603)
Principal payments on capital lease obligation	(75)	(23)
Net cash (used in) provided by financing activities	(4,206)	89,182
Net increase (decrease) in cash and cash equivalents	13,362	(39,789)
Cash and cash equivalents as of beginning of period	56,250	73,968
Cash and cash equivalents as of end of period	$ 69,612	$ 34,179

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION

Nature of Operations

Cornerstone Therapeutics Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on commercializing products for the hospital and adjacent specialty markets. Key elements of the Company s strategy are to focus its commercial and development efforts in the hospital and adjacent specialty markets within the U.S. pharmaceutical marketplace; continue to seek out opportunities to acquire companies, marketed or registration-stage products and late-stage development products that fit within the Company s focus areas; and generate revenues by marketing approved generic products through the Company s wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

Principles of Consolidation

The Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc. and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Reclassifications

The gain on divestiture of product rights previously classified separately is included in other operating expenses, net in the accompanying consolidated statements of comprehensive income (loss). This reclassification had no effect on net loss as previously reported.

Chiesi Merger

On February 18, 2013, the Company s Board of Directors received a proposal from Chiesi Farmaceutici S.p.A., the owner of approximately 58% of the outstanding shares of the Company s common stock (Chiesi), to acquire the shares of the Company s common stock that it does not already own for a cash purchase price of between $6.40 and $6.70 per share. Following its receipt of Chiesi s proposal, the Company s Board of Directors formed a special committee comprised of five independent and disinterested directors (the Special Committee). The Board of Directors granted the Special Committee the authority to, among other things, review, evaluate, reject or negotiate the terms of Chiesi s proposal (including any revised proposal Chiesi might make) and to consider and explore alternatives.

Following negotiations between Chiesi and the Special Committee, on September 15, 2013, the Company entered into an agreement and plan of merger (the Chiesi Merger Agreement) with Chiesi and Chiesi U.S. Corporation (Merger Sub), a Delaware corporation that is a wholly owned subsidiary of Chiesi. The Chiesi Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Chiesi Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving the merger as a direct wholly owned subsidiary of Chiesi (the Chiesi Merger). In the Chiesi Merger, each share of the Company s common stock that is issued and outstanding as of the effective time of the Chiesi Merger, except for treasury stock, dissenting shares and shares held by Chiesi or its subsidiaries, will be converted into the right to receive $9.50 in cash, without interest and subject to deduction for any required withholding taxes. The Chiesi Merger Agreement also provides that all outstanding unvested options and shares of restricted stock will become fully vested upon completion of the Chiesi Merger. Before the Company entered into the Chiesi Merger Agreement, the Special Committee unanimously determined that the Chiesi Merger Agreement and the transactions contemplated thereby, including the Chiesi Merger, were fair to, and in

the best interests of, the stockholders of the Company other than Chiesi and its affiliates, and that it was advisable for the Company to enter into the Chiesi Merger Agreement. Based on the Special Committee s recommendation, the Board of Directors (i) determined that the Chiesi Merger Agreement and the transactions contemplated thereby, including the Chiesi Merger, are fair to, and in the best interests of, the Company s stockholders, (ii) approved and declared advisable the Chiesi Merger Agreement and the transactions contemplated thereby, including the Chiesi Merger, and (iii) resolved to recommend that the Company s stockholders vote to adopt the Chiesi Merger Agreement.

At the same time that the Company entered into the Chiesi Merger Agreement, Craig A. Collard, the Company s Chairman, Chief Executive Officer and beneficial owner of 8.1% of the Company s shares, and Cornerstone Biopharma Holdings, Ltd., an entity controlled by him, entered into a voting agreement with the Company, Chiesi and Merger Sub under which Mr. Collard and Cornerstone Biopharma Holdings, Ltd. agreed to vote their shares of the Company s common stock in favor of the Chiesi Merger.

Consummation of the Chiesi Merger will require approval by the holders of (i) at least a majority of all shares of the Company s common stock outstanding and entitled to vote on the matter and (ii) a majority of the Company s outstanding shares of common stock that are not owned, directly or indirectly, by Chiesi, Merger Sub or any of their affiliates, by any officer or director of the Company or by any other person or entity having any equity interest in, or any right to acquire any equity interest in, Merger Sub or any person or entity of which Merger Sub is a direct or indirect subsidiary.

The Chiesi Merger Agreement places limitations on the Company s ability to engage in certain types of transactions without Chiesi s consent during the period between the signing of the Chiesi Merger Agreement and the effective time of the Chiesi Merger. During this period, with limited exceptions and among other things, the Company may not (i) issue, sell, pledge, grant, transfer,

Table of Contents

encumber or otherwise dispose of any shares of capital stock of the Company or any of its subsidiaries; (ii) declare, set aside or pay any dividend or other distribution payable in cash, stock or property with respect to its capital stock; (iii) purchase, redeem or otherwise acquire any shares of its capital stock; (iv) make any acquisition (by merger, consolidation or acquisition of stock or assets) of any interest in any company or any division or assets thereof with a value or purchase price in the aggregate in excess of $5.0 million for all such acquisitions; or (v) incur or assume any indebtedness.

The Company expects the Chiesi Merger will be completed during the first quarter of 2014, subject to receipt of the requisite stockholder approvals described above and to the satisfaction of the other conditions specified in the Chiesi Merger Agreement.

Other than expenses associated with the Chiesi Merger, which include fees for advisors and other transaction costs, the terms of the Chiesi Merger Agreement did not impact the Company s consolidated financial statements as of and for the nine months ended September 30, 2013. The transaction-related expenses related to costs associated with the Chiesi Merger during the three and nine months ended September 30, 2013 were $1.5 million and $2.5 million, respectively.

Since the announcement of the execution of the Chiesi Merger Agreement, four lawsuits challenging the Chiesi Merger have been filed in the Delaware Court of Chancery. Each of the Delaware lawsuits is a putative class action filed on behalf of the stockholders of the Company other than the defendants and their affiliates. In each case the complaint names as defendants the Company, its directors, Chiesi and Chiesi US and alleges that the Cornerstone directors and Chiesi breached their fiduciary duties in connection with their approval of the Merger Agreement and that either the Company, Chiesi or Chiesi US aided and abetted those breaches. Each complaint seeks, among other relief, declaratory and injunctive relief enjoining the Merger and/or compensatory damages in an unspecified amount. The four complaints have been consolidated into a single action by court order, but the plaintiffs have not yet filed a consolidated amended complaint.

The outcome of these lawsuits is uncertain. An adverse judgment for money damages against the Company could have an adverse effect on the operations and liquidity of the Company. A preliminary injunction could delay or jeopardize the completion of the Merger, and an adverse judgment granting permanent injunctive relief could indefinitely enjoin completion of the Chiesi Merger. The Company and its directors believe that the claims asserted against them in the lawsuits are without merit.

Interim Financial Statements

The accompanying unaudited consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of these financial statements. The consolidated balance sheet at December 31, 2012 has been derived from the Company s audited consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2012. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP) have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2012.

Operating results for the three and nine month periods ended September 30, 2013 are not necessarily indicative of the results for the full year.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company s consolidated financial statements include certain judgments regarding revenue recognition and related accruals, goodwill and intangible assets, inventory, stock-based compensation and income taxes. Actual results could differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company maintains its cash deposits with federally insured banks, however, as of September 30, 2013, the majority of the Company s cash deposits were not federally insured.

Table of Contents

Accounts Receivable

The Company typically requires its customers to remit payments within the first 30 to 80 days after the invoice date, depending on the customer and the products purchased. In addition, the Company offers wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2% to 3%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company s wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. The allowance for prompt payment discounts was $626,000 and $320,000 as of September 30, 2013 and December 31, 2012, respectively.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of September 30, 2013 or December 31, 2012. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write-offs during the three or nine months ended September 30, 2013 or 2012.

Inventories

Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method and consist of raw materials, work in process and finished goods. Raw materials include the active pharmaceutical ingredient (API) for a product to be manufactured, work in process includes the bulk inventory of tablets or liquids that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples.

Pre-approval inventory is expensed until it is probable that the inventory will be saleable. The Company capitalizes inventory costs associated with marketed products prior to product launch and certain products prior to regulatory approval, based on management s judgment of probable future commercial use and net realizable value. Capitalization of pre-approval inventory does not begin until the product candidate is considered to have a high probability of regulatory approval, which is generally after the Company has submitted a filing with the U.S. Food and Drug Administration (the FDA). If the Company is aware of any specific risks or contingencies that are likely to impact the expected regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling of the product candidate, the Company does not capitalize the related inventory. Once the Company capitalizes inventory for a product candidate that is not yet approved, the Company monitors, on a quarterly basis, the status of this candidate within the regulatory approval process, its projected sales volume and estimated selling price. The Company could be required to expense previously capitalized costs related to pre-approval inventory upon a change in its judgment of future commercial use and net realizable value, including due to a denial or delay of approval by regulatory bodies, a delay in the timeline for commercialization or other potential factors. At September 30, 2013, inventories included $3.5 million of costs capitalized as raw materials prior to regulatory approval of the Supplemental Biologics License Application (sBLA) for RETAVASE® (reteplase, recombinant). This inventory will be used in manufacturing saleable product after approval and will not be used in the remaining testing required for the sBLA approval. The sBLA is intended to qualify SCIL Proteins Production in Germany as a new supplier of reteplase, the API for RETAVASE, and to modify the existing approved Biologics License Application to include an intermediate step between the API and finished good manufacturing processes.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales.

Goodwill and Intangible Assets

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Other intangibles including product rights and acquired in-process research and development (IPR&D) are capitalized and recorded at fair value. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized.

Product rights are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins, which the Company targets launching shortly following regulatory approval. The Company evaluates its product rights on an ongoing basis to determine whether a revision to their useful lives should be made. This evaluation is based on management s projection of the future cash flows associated with the products.

Table of Contents

Acquired IPR&D resulting from a business combination is initially characterized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized. Acquired IPR&D is classified as product rights on the accompanying consolidated balance sheets.

The Company evaluates the recoverability of its long-lived assets, including property and equipment and identifiable intangible assets on an exception basis whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. The Company measures the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any write-downs are recorded as permanent reductions in the carrying amount of the assets.

Goodwill and indefinite-lived intangible assets including acquired IPR&D are reviewed for impairment on an annual basis or more frequently if events or circumstances indicate that goodwill or indefinite-lived intangible assets may be impaired. The Company s goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company assesses qualitative factors to determine if its sole reporting unit s fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit s fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the carrying value. If the implied fair value of goodwill is less than the carrying value, then an impairment charge would be recorded. The Company performs its annual evaluation of goodwill as of October 1 of each fiscal year.

Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability test.

Revenue Recognition

The Company s consolidated net revenues represent the Company s net product sales and other revenues. The following table sets forth the categories of the Company s net revenues (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Gross product sales	$ 76,255	$ 57,793	$ 191,567	$ 122,267
Sales allowances	(23,092)	(20,268)	(60,196)	(41,114)
Net product sales	53,163	37,525	131,371	81,153
Other revenues	534		712	4
Net revenues	$ 53,697	$ 37,525	$ 132,083	$ 81,157

The Company records all of its revenue from product sales and other revenues when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an

arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

Net Product Sales

Product Sales. The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers and specialty pharmacies, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated.

Product Returns. Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the majority of its products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company s products have an 18- to 24-month expiration period from the date of manufacture. The

Table of Contents

Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include actual and historical return rates for expired lots, historical and forecasted product sales and consumer consumption data reported by external information management companies, estimated expiration dates or remaining shelf life of inventory in the distribution channel, estimates of inventory levels of its products in the distribution channel and any significant changes to these levels, and competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve through charges to income in the period in which the information that gives rise to the adjustment becomes known.

Rebates. The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

Price Adjustments and Chargebacks. The Company s estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company s listed prices of its products. These estimates are also based on the contract fees the Company pays to certain group purchasing organizations (GPOs). In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from the Company s estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for ZYFLO CR® (zileuton) and PERTZYE® (pancrelipase) whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. In addition, the Company offers a customer loyalty program for CARDENE® I.V. (nicardipine hydrochloride). The Company estimates its liability for this program based on historical participation and redemption rates as well as projected sales for individual customers during the program evaluation period. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt Payment Discounts. The Company typically offers its wholesale customers a prompt payment discount of 2% to 3% as an incentive to remit payments within the first 30 to 80 days after the invoice date depending on the customer and the products purchased.

Other Revenues

Other revenues include revenues from copromotion, license and royalty agreements. We record copromotion, license and royalty revenues from third parties based on the nature of the agreement (including its contractual terms), the nature of the payments and applicable accounting guidance. Copromotion and royalty revenues are typically based on net sales, as defined in the respective agreements, which may include estimates of sales discounts and other deductions. Any adjustments related to estimated sales discounts and other deductions are recognized in the period the third-party partner reports the amounts to the Company, which is typically the following quarter. Historically, these adjustments have not been significant. Other revenues for the three and nine months ended September 30, 2013 consisted solely of copromotion revenue related to PERTZYE, which the Company began actively marketing in July 2013.

Non-refundable fees where the Company has no continuing performance obligations are recognized as revenue when there is persuasive evidence of an arrangement and collection is reasonably assured. If the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the estimated performance period. At-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company s licensees, are recognized as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

Table of Contents

Stock-Based Compensation

The Company measures compensation cost for share-based payment awards granted, including grants of stock options and restricted stock, to employees and non-employee directors at fair value. The fair value of stock options is determined by using the Black-Scholes-Merton option-pricing model. The Company determines the fair value of restricted stock based on the market price of its common stock on the date of grant. Compensation expense is recognized on a straight-line basis over the service period for awards expected to vest. Stock-based compensation cost related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of the Company s stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and the tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse.

Net deferred tax assets are recognized to the extent the Company s management believes these assets will more likely than not be realized. In making such determination, management considers all positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is recorded to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management periodically reviews its deferred tax assets for recoverability and its estimates and judgments in assessing the need for a valuation allowance.

The Company recognizes a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during each period. Diluted net income (loss) per share is computed by dividing net income (loss) by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. In periods for which the convertible term loan is determined to be dilutive to earnings per share, net income is adjusted for interest expense related to the convertible term loan, net of tax effects. Dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants, the impact of non-vested restricted stock and the impact of the convertible debt.

Fair Value Measurements

The carrying amounts of the Company s cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximated their fair values as of September 30, 2013 and December 31, 2012 due to the short-term nature of these financial items.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The fair value for contingent consideration potentially payable related to the acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc. (collectively EKR), at June 26, 2012 was $37.8 million, of which $23.9 million related to a contingent consideration arrangement that existed prior to the acquisition date. The fair value of these liabilities is a Level 3 measurement in the fair value hierarchy which is defined as one with unobservable inputs. The Company uses a discounted cash flow analysis incorporating the probability of estimated future cash flows from potential milestones and royalty payments using risk-adjusted discount rates. Changes to the discount rate would have an inverse effect on the liability s fair value. Contingent consideration includes the following potential payments for RETAVASE: (1) $4.0 million payable after relaunch approval, (2) $2.0 million payable on or before the first anniversary of the relaunch approval, and (3) three years of annual royalty payments based on a percentage of revenue. Contingent consideration also includes quarterly payments for CARDENE I.V. that are based on a percentage of CARDENE I.V. net revenue through July 2017. The liabilities are evaluated for remeasurement at the end of each reporting period and any changes are recorded in the Company s consolidated statements of comprehensive income (loss). The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

Table of Contents

The following table presents a reconciliation of contingent consideration obligations measured on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2013 (in thousands):

	December 31, 2012	Issuances	Payments (1)	Adjustments (2)	September 30, 2013
Acquisition-related contingent consideration (3)	$ 33,208	$	$ (4,908)	$ 6,146	$ 34,446

(1) Relates to payments of acquisition-related contingent consideration with respect to CARDENE I.V.
(2) This amount includes fair value adjustments to the acquisition-related contingent consideration for CARDENE I.V. and RETAVASE. The adjustment is recognized as change in acquisition-related contingent payments in the consolidated statements of comprehensive income (loss).
(3) Acquisition-related contingent consideration is classified as acquisition-related contingent payments in the accompanying consolidated balance sheets.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

There were no significant assets or liabilities that were re-measured at fair value on a non-recurring basis in the nine month period ended September 30, 2013.

NOTE 3: BUSINESS COMBINATIONS

Acquisition of EKR

Description of Transaction

On June 26, 2012, the Company completed its acquisition of EKR, a specialty pharmaceutical company focused on serving the acute-care hospital setting, for an estimated consideration of approximately $164.2 million. As part of the transaction, the Company acquired the product rights to the cardiovascular products CARDENE I.V. and RETAVASE. The Company made an upfront payment of $126.4 million and may pay a series of contingent consideration payments related to CARDENE I.V. and RETAVASE if certain milestones are achieved. The fair value for contingent consideration was determined to be $37.8 million.

Basis of Presentation

The transaction has been accounted for as a business combination under the acquisition method of accounting, which requires, among other things, that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The results of operations of EKR were consolidated beginning on the date of the merger. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred. Any changes within the measurement period resulting from facts and circumstances that existed as of the acquisition date may result in retrospective adjustments to the provisional amounts recorded at the acquisition date.

Fair Value of Consideration Transferred

A summary of the purchase price is as follows (in thousands):

Cash paid for EKR s outstanding shares	$ 126,424
Acquisition-related contingent consideration	37,788
Total fair value of consideration	$ 164,212

Assets Acquired and Liabilities Assumed

The total purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of EKR based on their estimated fair values as of June 26, 2012. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill.

Table of Contents

The following table presents the preliminary allocation of the total fair value of consideration transferred to the acquired tangible and intangible assets and assumed liabilities of EKR based on their estimated fair values as of the closing date of the transaction, measurement period adjustments recorded during the first six months of 2013, in which our measurement period concluded, and the as adjusted allocations of the total fair value of consideration transferred, as shown above (in thousands):

	June 26, 2012(1)	Measurement Period Adjustments (2)	June 26, 2012 (As adjusted)
Cash	$ 516	$	$ 516
Accounts receivable, net	7,401	46	7,447
Inventory, net	32,226		32,226
Prepaid expenses and other assets	14,682	(121)	14,561
Identifiable intangibles	154,123		154,123
Deferred tax assets	35,079	274	35,353
Accounts payable	(2,690)		(2,690)
Accrued liabilities	(29,515)	(7)	(29,522)
Deferred tax liability related to intangibles acquired	(65,735)		(65,735)
Total identifiable net assets	$ 146,087	$ 192	$ 146,279
Goodwill	18,138	(205)	17,933
Total fair value of consideration	$ 164,225	$ (13)	$ 164,212

(1) As reported previously in the Company s annual report on Form 10-K for the year ended December 31, 2012.

(2) The measurement period adjustments during the first six months of 2013, in which our measurement period concluded, primarily reflect changes in accounts receivables, net, indemnified assets and liabilities and the related impact on deferred taxes. The measurement period adjustments were made to reflect facts and circumstances existing as of the acquisition date, and did not result from intervening events subsequent to the acquisition date. These measurement period adjustments did not have a material impact on the Company s December 31, 2012 consolidated financial statements. Accordingly, the Company has not retrospectively adjusted those financial statements.

The Company recorded $154.1 million in identifiable intangibles at fair value, consisting of $158.4 million in acquired product rights, partially offset by $4.3 million related to an unfavorable contract liability. The fair value of the product rights was allocated as $131.6 million for CARDENE I.V. and $26.9 million for RETAVASE. CARDENE I.V. product rights are being amortized over 15 years. RETAVASE product rights will be amortized over approximately 12 years beginning upon commercial launch. The unfavorable contract liability resulted from an existing supply contract that was determined to have terms that were less favorable than market. The liability was recorded at fair value based on the discounted cash flows resulting from the Company s estimated loss that will be incurred on the manufacturing of RETAVASE inventory for the provider of RETAVASE in the European market. The fair value of the unfavorable contract liability as of June 30, 2012 was $4.3 million and is classified in other long-term liabilities on the consolidated balance sheet as of September 30, 2013. The value of the contract will be amortized and recorded as an offset to cost of product sales based on inventory movement over the life of the contract.

Acquired inventory was recorded at fair value and includes an acquisition accounting adjustment of approximately $19.4 million to increase inventory to its fair value.

The Company recorded indemnification assets of $4.5 million and indemnification liabilities of $8.8 million, which are offset by corresponding liabilities and assets, respectively. The indemnification balances relate to (i) certain litigation and contractual liabilities included in accrued expenses and (ii) anticipated income tax refunds related to federal net operating loss (NOL) carryback claims and EKR s 2012 short period tax return. EKR s former shareholders are responsible for specified litigation and contractual liabilities included in acquisition-related current liabilities and for tax liabilities related to pre-closing periods and are obligated to fully indemnify the Company against losses related to these matters. EKR s former shareholders are also generally entitled to the benefit of tax refunds associated with pre-closing periods. These indemnification assets and liabilities are classified in acquisition-related current assets and liabilities. The remaining balances are reflected on the accompanying consolidated balance sheet as of September 30, 2013. The Company expects the full amount of the indemnification assets and liabilities related to these matters to be realized or covered by the EKR shareholders.

At the closing of the acquisition, the fair value for contingent consideration potentially payable was $37.8 million, of which $23.9 million related to a contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V. that existed prior to the acquisition date. The fair value of these liabilities was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments. The liabilities were evaluated as of September 30, 2013 as discussed above in Note 2. The Company will continue to evaluate these liabilities for remeasurement at the end of each reporting period and any change will be recorded in the Company s consolidated statement of comprehensive income (loss). The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

Table of Contents

Goodwill was calculated as the difference between the fair value of the consideration and the values assigned to the assets acquired and liabilities assumed. None of the goodwill will be deductible for tax purposes.

In connection with the acquisition, during the nine months ended September 30, 2013 and 2012, the Company incurred $35,000 and $7.3 million, respectively, of transaction-related costs, which include severance expenses and the costs of advisory, legal, valuation and accounting services. These costs were expensed as incurred and are included in transaction-related expenses on the accompanying consolidated statements of comprehensive income (loss).

During the second quarter of 2013, the Company settled certain liabilities acquired in connection with the EKR acquisition resulting in a gain of approximately $700,000, which is included in other operating expenses, net on the accompanying consolidated statements of comprehensive income (loss) for the nine months ended September 30, 2013.

Net revenues and net income for EKR of $13.5 million and $2.1 million, respectively, are included in the Company s consolidated statements of comprehensive income (loss) from the acquisition date, June 26, 2012, through September 30, 2012.

Pro Forma Impact of the Acquisition of EKR (Unaudited)

The following table presents pro forma results of operations and gives effect to the transaction as if the transaction had been consummated on January 1, 2011. The unaudited pro forma results of operations have been prepared for comparative purposes only and are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from combining the two companies (in thousands, except per share data).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net revenues	$ 37,525	$ 40,645	$ 107,428	$ 125,434
Net income (loss)	$ 2,068	$ (3,628)	$ (4,048)	$ (2,648)
Basic income (loss) per share	$ 0.08	$ (0.14)	$ (0.16)	$ (0.10)
Diluted income (loss) per share	$ 0.08	$ (0.14)	$ (0.16)	$ (0.10)

The unaudited pro forma consolidated results were prepared using the acquisition method of accounting and are based on the historical financial information of the Company and EKR, reflecting the Company s and EKR s results of operations for the three and nine month periods ending September 30, 2012 and 2011. The historical financial information has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition, (ii) factually supportable and (iii) expected to have a continuing impact on the combined results. The unaudited pro forma consolidated results reflect primarily the following pro forma adjustments:

Additional interest expense related to the Company s long-term debt used to fund the acquisition;

Additional amortization expense related to the fair value of identifiable intangible assets acquired; and

Removal of acquisition-related transaction costs.

NOTE 4: INVENTORY

The following table represents inventories, net as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	$ 6,580	$ 3,561
Work in process	3,029	2,920
Finished goods	7,386	7,016
Total	16,995	13,497
Inventory allowances	(2,536)	(2,113)
Inventories, net	$ 14,459	$ 11,384

Table of Contents

NOTE 5: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance was $33.2 million and $33.4 million as of September 30, 2013 and December 31, 2012, respectively. The change in goodwill is described in Note 3. No amount of the goodwill balance at September 30, 2013 will be deductible for income tax purposes.

Product Rights

The following tables represent product rights, net as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
CUROSURF®	$ 107,606	$ 39,424	$ 68,182	15.0
ZYFLO®	11,500	7,890	3,610	7.1
CARDENE I.V.	131,556	11,061	120,495	15.0
PERTZYE	10,000	395	9,605	10.0
RETAVASE	26,858		26,858	n/a
Other	575	77	498	5.0
Total	$ 288,095	$ 58,847	$ 229,248	14.4

	December 31, 2012			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 34,740	$ 72,866	15.0
ZYFLO	11,500	6,686	4,814	7.1
CARDENE I.V.	131,556	4,483	127,073	15.0
RETAVASE	26,858		26,858	n/a
Other	575	75	500	n/a
Total	$ 278,095	$ 45,984	$ 232,111	14.6

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which range from five to fifteen years. As of September 30, 2013, the Company had $26.9 million of product rights related to RETAVASE, which is expected to be launched in the future. The Company expects to begin amortization upon the commercial launch of the product. The rights will be amortized over the product candidate s estimated useful life.

On May 9, 2013, the Company entered into a license and distribution agreement with Digestive Care, Inc. (DCI) pursuant to which it acquired exclusive U.S. rights to market DCI s PERTZYE for the treatment of Exocrine Pancreatic Insufficiency due to cystic fibrosis. PERTZYE is an FDA approved unique pancreatic enzyme replacement therapy drug product containing bicarbonate-buffered, enteric-coated microspheres. In consideration for marketing rights, the Company made an initial payment of $10 million. The Company is required to make certain minimum investments in promotion and make payments based on a percentage of net sales. In addition, the Company is required to make certain milestone payments upon achievement of net sales targets. The initial payment was, and potential future payments of milestones met will be, capitalized and amortized over the remaining useful life of the asset, which is currently estimated to be ten years. The initial term of the agreement is ten years with an automatic renewal provision for successive two-year terms unless either party provides written notice six months before the end of the current term.

Table of Contents

Aggregate annual amortization expense of product rights (excluding the rights related to products expected to be launched) for each of the five succeeding fiscal years is estimated as follows (in thousands):

2013	$ 17,293
2014	17,721
2015	17,721
2016	16,116
2017	16,116
Thereafter	130,287
	$ 215,254

Divestiture of Anti-infective Product Rights

In March 2012, the Company entered into asset purchase agreements with each of Merus Labs International Inc. (Merus) and Vansen Pharma Inc. (Vansen) pursuant to which the Company sold all of its rights to the anti-infective drugs Factive (gemifloxacin mesylate) and Spectracef (cefditoren pivoxil). In connection with the transaction, the Company divested approximately $3.8 million in product rights, net of accumulated amortization, $2.5 million in inventory and product samples, and other assets of $1.4 million. In addition, Merus and Vansen assumed product-related liabilities of approximately $4.1 million. Total cash consideration for the divestiture was $6.2 million, of which $1.2 million was recorded as a receivable from the buyers. Under the asset purchase agreement for Factive, the Company retained certain royalty obligations to LG Life Sciences, Ltd. and Oscient Pharmaceuticals Corporation through the end of September 30, 2014. The Company calculated the fair value of the expected royalty payments and recorded a contingent liability of $1.1 million, which is included in other current and other long-term liabilities. The Company also recognized a gain on the divestiture of $1.5 million which is included in other operating expenses, net in the accompanying consolidated statements of comprehensive income (loss).

NOTE 6: ACCRUED EXPENSES

The components of accrued expenses are as follows (in thousands):

	September 30, 2013	December 31, 2012
Accrued product returns	$ 15,373	$ 13,629
Accrued rebates	2,325	1,766
Accrued price adjustments and chargebacks	14,699	9,651
Accrued compensation and benefits	3,264	3,022
Accrued royalties	3,560	3,487
Accrued research and development	1,899	1,300
Accrued co-promotion	2,244	2,330
Accrued expenses, other	4,765	2,194
Total accrued expenses	$ 48,129	$ 37,379

NOTE 7: LONG TERM DEBT

On June 21, 2012, the Company entered into a credit agreement with Chiesi (the Credit Agreement) in order to finance a portion of the costs of its acquisition of EKR. Pursuant to the Credit Agreement, Chiesi made two loans to the Company: (i) a loan of $60.0 million (Term Loan A), and (ii) a loan of $30.0 million (Term Loan B, and together with Term Loan A, the Term Loans). All of the obligations owed by the Company under the Credit Agreement are guaranteed by the Company s domestic subsidiaries and are secured by a security interest in substantially all of the assets of the Company and its domestic subsidiaries. Chiesi is the administrative agent and collateral agent under the Credit Agreement.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears. Term Loan A requires quarterly principal payments of $3.5 million commencing in the fiscal quarter ending December 31, 2014 with any remaining balance being due at maturity. The Term Loans are due and payable in full on June 23, 2017, unless previously prepaid or, in the case of Term Loan B, unless previously converted into shares of common stock pursuant to the conversion right described below.

Table of Contents

The Company has the right to prepay the Term Loans, in whole or in part, without any premium or penalty. Any partial prepayment must be in the amount of $5.0 million or, if more than $5.0 million, in whole multiples of $1.0 million, in each case plus any accrued and unpaid interest.

The Company is required to prepay all or a portion of the Term Loans (i) if the Company s ratio of consolidated secured debt to Consolidated EBITDA (as defined in the Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013, by using 50% of the Company s Consolidated Excess Cash (as defined in the Credit Agreement), or (ii) if the Company undertakes certain asset sales or sales of capital stock and does not reinvest the proceeds according to the terms of the Credit Agreement. The Company will evaluate its compliance with the ratio of consolidated secured debt to Consolidated EBITDA as of and for the year ending on December 31, 2013 and does not anticipate any prepayment for 2013.

Until June 21, 2014, Chiesi has the option to convert all or a portion of the Term Loan B principal balance into shares of common stock at a conversion price of $7.098 per share, subject to adjustment under certain conditions. Any such conversion must be in a minimum amount of $5.0 million unless the outstanding balance is less than $5.0 million. At September 30, 2013, the outstanding balance of Term Loan B was $30.0 million, which was convertible into 4,226,542 shares of common stock.

The Credit Agreement contains customary representations, covenants and events of default. Upon an Event of Default (as defined in the Credit Agreement), (i) the interest rates for Term Loan A and Term Loan B will each increase by 2% and (ii) Chiesi may declare all outstanding principal and accrued but unpaid interest under the Credit Agreement to be immediately due and payable. In addition, the Company is subject to covenants prohibiting the payment of any dividends (other than stock dividends) and restricting or limiting other restricted payments, certain corporate activities, transactions with affiliates, incurrence of debt (which debt limit expressly permits, among other things, a secured working capital facility of up to $25 million), liens on properties and asset dispositions. The Company is not subject to any financial covenants other than the mandatory prepayment provisions discussed above.

In connection with the Term Loans, the Company incurred an estimated $511,000 of debt financing costs, which primarily consisted of legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through the maturity of the loans.

The following table summarizes information on the Term Loans as of September 30, 2013 (in thousands):

	Maturity Date	September 30, 2013
Term Loan A (7.5% interest payable quarterly and principal payable in quarterly installments of $3.5 million starting on December 31, 2014)	June 2017	
Principal amount		$ 60,000
Unamortized debt financing costs		(249)
Net carrying amount		59,751
Term Loan B (6.5% interest payable quarterly and principal payable upon maturity, with conversion option through	June 2017	

June 21, 2014)		
Principal amount		30,000
Unamortized debt financing costs		(133)
Net carrying amount		29,867
Total debt, carrying amount		89,618
Less: current portion		
Total long-term debt, carrying amount	$	89,618

NOTE 8: STOCK-BASED COMPENSATION

Stock Options

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the Company s expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

Table of Contents

There were 145,000 and 136,773 stock options granted and exercised, respectively, during the nine months ended September 30, 2013.

The following table shows the assumptions used to value stock options on the date of grant, as follows:

	Nine Months Ended September 30, 2013
Estimated dividend yield	0.0%
Expected stock price volatility	74-77%
Risk-free interest rate	0.97-1.71%
Expected life of option (in years)	5.82-5.84
Weighted-average grant date fair value per share of options granted	$5.45

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%. The expected stock price volatility was based on the Company s historical volatility for the approximate five year period preceding September 30, 2013. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

As of September 30, 2013, the aggregate intrinsic value of options outstanding and exercisable was $9.4 million and $7.6 million, respectively.

As of September 30, 2013, there was $2.0 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.71 years.

Restricted Stock

During the nine months ended September 30, 2013, 289,672 shares of restricted stock were issued and 60,240 shares vested. As of September 30, 2013, there were 338,197 restricted common shares outstanding and approximately $2.0 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 2.92 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately $615,000 and $684,000 for the three months ended September 30, 2013 and 2012, respectively, and $2.0 million for both of the nine months ended September 30, 2013 and 2012.

NOTE 9: INCOME TAXES

The Company computes an estimated annual effective tax rate for interim financial reporting purposes. The estimated annual effective tax rate is used to compute the tax expense or benefit related to ordinary income or loss. Tax expense or benefit related to all other items is individually computed and recognized when the items occur. The Company s effective tax rate for the three and nine months ended September 30, 2013 was 32.8% and 33.8%, respectively. The

Company s effective tax rate for the three and nine months ended September 30, 2012 was (51.6)% and (38.1)%, respectively. The change in the effective tax rate for the three and nine months ended September 30, 2013 compared to the three and nine months ended September 30, 2012 was due primarily to the tax impact of projected income for 2013 as compared to losses for 2012.

As of September 30, 2013 and December 31, 2012, the Company had provided a valuation allowance related to federal NOLs and federal tax credits due to uncertainty regarding the Company s ability to fully realize these assets. This determination considered the limitations on the utilization of NOLs and tax credits imposed by Section 382 and 383, respectively, of the Internal Revenue Code. The Company has reassessed its need for a valuation allowance related to its charitable contribution carryforwards. The Company believes the valuation allowance recorded at December 31, 2012 for charitable contributions carryforward is no longer required as of September 30, 2013. Accordingly, the Company has recorded a tax benefit of $656,000 as a result of this change. The Company has not established any other valuation allowances and it will continue to assess the realizability of its deferred tax assets and the corresponding impact on the valuation allowance.

The 2010 through 2012 tax years of the Company are open to examination by federal and state tax authorities. Currently EKR is under audit by the federal authorities and in the state of New Jersey. The Company is fully indemnified by the former shareholders and participating equityholders of EKR for any losses related to audits by federal and state tax authorities for pre-acquisition periods.

Table of Contents

There were no changes in unrecognized tax positions for the nine months ended September 30, 2013. As of September 30, 2013, the Company has no unrecognized tax benefits. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next 12 months.

NOTE 10: NET INCOME (LOSS) PER SHARE

The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Numerator:				
Net income (loss)	$ 9,577	$ 1,249	$ 17,755	$ (4,929)
Interest on convertible debt, net of tax effects	340		993	
Net income (loss) used to calculate diluted earnings per share	$ 9,917	$ 1,249	$ 18,748	$ (4,929)
Denominator:				
Weighted-average common shares, basic	26,515,190	26,245,765	26,446,783	26,040,695
Dilutive effect of stock options and restricted stock	753,900	357,493	601,390	
Dilutive effect of convertible debt	4,226,542		4,226,542	
Weighted-average common shares, diluted	31,495,632	26,603,258	31,274,715	26,040,695
Net income (loss) per share, basic	$ 0.36	$ 0.05	$ 0.67	$ (0.19)
Net income (loss) per share, diluted	$ 0.31	$ 0.05	$ 0.60	$ (0.19)
Anti-dilutive weighted-average shares	419,691	1,520,234	558,762	2,845,845

As of September 30, 2013 and 2012, there were 338,197 and 135,810 shares of unvested restricted stock outstanding that contain non-forfeitable rights to dividends. These securities are considered to be participating securities under the two-class method for determining basic and fully diluted net income (loss) per share. Because the treasury stock method and the two-class method yield the same result for both basic and diluted net income (loss) in each of the periods presented, only the treasury stock method has been disclosed.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases its facilities, certain equipment and automobiles under non-cancelable operating leases expiring at various dates through 2016. The Company recognizes lease expense on a straight-line basis over the term of the lease, excluding renewal periods, unless renewal of the lease is reasonably assured. Lease expense was approximately $134,000 and $894,000 for the three months ended September 30, 2013 and 2012, respectively, and approximately $421,000 and $1.3 million for the nine months ended September 30, 2013 and 2012, respectively.

In connection with the acquisition of EKR in June 2012, the Company assumed the lease for office space in Bedminster, New Jersey that was scheduled to extend through December 15, 2015. The lease was subsequently terminated in August 2012, effective September 30, 2012. The Company paid lease termination fees, of which $541,000 was recorded as lease expense during the third quarter of 2012.

Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $52.0 million as of September 30, 2013, which includes any minimum amounts payable and penalties for failure to satisfy purchase commitments that the Company has determined to be probable and that are reasonably estimable. Since many of these commitment amounts are dependent on variable components of the agreements, actual payments and the timing of those payments may differ from management s estimates. As of September 30, 2013, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $21.2 million.

Table of Contents

Royalty Agreements

The Company has contractual obligations to pay royalties to the former owners or current licensors of certain product rights that have been acquired by or licensed to the Company. These royalties are typically based on a percentage of net sales of the particular licensed product and are included in cost of product sales in the consolidated statements of comprehensive income (loss). For the three months ended September 30, 2013 and 2012, total royalty expenses were $2.4 million and $684,000, respectively, and for the nine months ended September 30, 2013 and 2012, total royalty expenses were $4.9 million and $3.5 million, respectively.

Other Licensing Agreements

The Company is committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. The Company may be required to make $30.9 million in additional payments to various parties if all milestones under the agreements are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on the accompanying consolidated balance sheets. The Company is also obligated to pay royalties on net sales or gross profit, if any, of certain products and product candidates currently in its portfolio following their commercialization.

As of September 30, 2013, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately $769,000.

Additional Consideration for the Cardiokine, Inc. (Cardiokine) Merger

In addition, in connection with its acquisition of Cardiokine in December 2011, the Company recorded an $8.8 million contingent liability for additional consideration potentially payable under the merger agreement. The Company agreed to pay potential consideration consisting of each of the following: (i) either $7.0 million or $8.5 million if Cardiokine s pending new drug application for its lixivaptan compound, LIXAR® (lixivaptan), is approved for sale by the FDA; (ii) up to $147.5 million based on the achievement of certain sales related milestones ($7.5 million at $75 million, $15 million at $150 million, $25 million at $250 million and $100 million at $500 million, each payable at the first time the annual sales reach the relevant milestone); (iii) quarterly earnout payments of 8% or 12% of net sales of the approved product, with such rate being dependent upon the scope of the labeling which the FDA may approve for the product; and (iv) one-half of any proceeds realized from the license of the approved product outside the United States (collectively, the Purchase Consideration). The Purchase Consideration will be paid first to a subsidiary of Pfizer Inc. (Pfizer), the licensor of certain rights to the lixivaptan compound, in satisfaction of Cardiokine s payment obligations to Pfizer, until Pfizer has been paid a total of $20 million. Thereafter, any further Purchase Consideration will be paid in accordance with the merger agreement to certain other parties for which obligations existed and then directly to Cardiokine s former stockholders.

The initial fair value of this liability is a level 3 measurement and was determined using a probability-weighted discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments discounted to present value using a discount rate of 21.5%. The liability will be periodically assessed based on events and circumstances related to the underlying milestones, and any change in fair value will be recorded in the Company s consolidated statement of comprehensive income (loss). The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability. At December 31, 2012, the Company determined the fair value of the contingent liability was zero. During the nine months ended September 30, 2013, there were no events or circumstances that would have required a revaluation of

the liability.

Co-Promotion and Marketing Services Agreements

The Company entered into, but has now terminated, a co-promotion agreement that granted a third party the exclusive right to promote and sell ZYFLO CR and ZYFLO (zileuton) in conjunction with the Company. Under this agreement, the Company pays the third party co-promotion fees equal to the ratio of total prescriptions written by pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of the products covered by the agreement, after third-party royalties. Under this agreement, the Company is obligated to make these payments for a sunset period that lasts until the fourth quarter of 2013.

The Company also entered into a license and distribution agreement with DCI, as discussed above in Note 5. Under this agreement, each of the Company and DCI is required to make payments to the other party based on a percentage of such party s net sales of PERTZYE attributable to the cystic fibrosis market in the territory covered by the agreement.

As of September 30, 2013, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $4.5 million.

Table of Contents

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments of up to two times base salary, bonuses and benefits upon termination, depending on the reasons for the termination. These executives would also be required to execute a release and settlement agreement. As of September 30, 2013, the Company had no amounts recorded as accrued severance for executives under such agreements.

Legal Proceedings

The Company is involved in lawsuits, claims, investigations and proceedings related to its business. There are no matters pending that the Company currently believes are reasonably possible of having a material impact to its business, consolidated financial condition, results of operations or cash flows except as described above in Note 1 and as discussed below.

Louisiana Litigation

On September 11, 2013, the State of Louisiana (the State) filed suit against the Company and 53 other defendants (the Louisiana Litigation), alleging that the defendants submitted incorrect data and other information to the federal Medicaid program s electronic product database. The State s petition alleges that this conduct caused the Louisiana Medicaid program to pay for products that were not covered by the program. The State alleges that this conduct resulted in violations of the State s Unfair Trade Practices and Consumer Protection Law and Medical Assistance Program Integrity Law; constituted actionable fraud, negligent misrepresentation, and redhibition; and resulted in unjust enrichment.

The Louisiana Litigation was originally filed in Louisiana s 19th Judicial District; the defendants on October 15, 2013, removed the case to the United States District Court for the Middle District of Louisiana, where it is currently pending. It is not possible at this time to predict the schedule, jurisdiction, or procedural context in which the Louisiana Litigation will ultimately be resolved. As the case is at an early stage, the Company cannot at this time estimate its ultimate exposure to loss or liability, if any, related to this lawsuit.

NOTE 12: RELATED PARTY TRANSACTIONS

Chiesi, the Company s majority stockholder, manufactures all of the Company s requirements for CUROSURF (poractant alfa) pursuant to a license and distribution agreement that became effective on July 28, 2009, as amended on September 28, 2010 and December 14, 2012. The Company began promoting and selling CUROSURF in September 2009. Inventory purchases from Chiesi aggregated $6.3 million and $20.1 million for the three and nine months ended September 30, 2013, respectively, compared to $6.4 million and $18.5 million for the three and nine months ended September 30, 2012, respectively. As of September 30, 2013, the Company had accounts payable of $2.8 million due to Chiesi.

As discussed in Note 7, on June 21, 2012, the Company entered into the Credit Agreement with Chiesi in connection with its acquisition of EKR. The Credit Agreement includes a Term Loan A of $60.0 million and Term Loan B of $30.0 million. The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. As of September 30, 2013, the net carrying value of the Term Loans was $89.6 million, net of capitalized unamortized debt financing costs. During the three and nine months ended September 30, 2013, the Company paid $1.5 million and $4.4 million, respectively, of interest expense less withholding tax to Chiesi related to the Term Loans. There was no accrued interest payable due to Chiesi as of September 30, 2013.

On November 6, 2012, the Company and Chiesi entered into a License and Distribution Agreement pursuant to which Chiesi granted the Company an exclusive license to market and sell Chiesi s BETHKIS® (tobramycin inhalation solution) product in the United States. BETHKIS is an FDA-approved, inhaled, aminoglycoside antibacterial product indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in less than one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with *Burkholderia cepacia*. In consideration for the grant of the license, the Company made an initial payment of $1.0 million and will make a milestone payment of $2.5 million upon the first commercial sale of the product in the United States. The Company will also be required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.

The BETHKIS license transfer between the Company and Chiesi was recorded by the Company as an equity transaction between entities under common control. As such, the Company did not record an asset for the license acquired, since there were no historical carrying amounts recorded by Chiesi. No liabilities were transferred.

On September 15, 2013, the Company entered into the Chiesi Merger Agreement with Chiesi and the Merger Sub. The Chiesi Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Chiesi Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving the merger as a direct wholly owned subsidiary of Chiesi. At the same time that the Company entered into the Chiesi Merger Agreement, Craig A. Collard, the Company s Chairman, Chief Executive Officer and beneficial owner of 8.1% of the Company s shares, and an entity controlled by him, entered into a voting agreement with the Company, Chiesi and Merger Sub under which Mr. Collard and Cornerstone Biopharma Holdings, Ltd. agreed to vote their shares of the Company s common stock in favor of the Chiesi Merger.

Table of Contents

NOTE 13: SUBSEQUENT EVENTS

The Company has evaluated all events and transactions that occurred after September 30, 2013. The Company did not have any material subsequent events that require adjustment or disclosure in these financial statements.

NOTE 14: RECENT ACCOUNTING PRONOUNCEMENTS

There were no recent accounting pronouncements that have not yet been adopted by the Company that are expected to have a material impact on the Company s consolidated financial statements.

Table of Contents

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

The following discussion is designed to provide a better understanding of our unaudited consolidated financial statements, including a brief discussion of our business and products, key factors that impact our performance and a summary of our operating results. You should read the following discussion and analysis of financial condition and results of operations together with our unaudited consolidated financial statements and the related notes included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q and the consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our annual report on Form 10-K for the year ended December 31, 2012. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth under Part I Item 1A. Risk Factors of our annual report on Form 10-K for the year ended December 31, 2012 and any material changes to those risk factors discussed below in Part II Item 1A. Risk Factors.

Executive Overview

Strategy

We are a specialty pharmaceutical company focused on commercializing products for the hospital and adjacent specialty markets. We are actively seeking to expand our portfolio of products for these markets through the acquisition of companies and products and through internal development.

Our strategy is to:

- Focus our commercial and development efforts in the hospital and adjacent specialty markets within the U.S. pharmaceutical marketplace;
- Acquire companies, marketed or registration-stage products, and late-stage development products that fit within our focus areas; and
- Market approved generic products through our wholly owned subsidiary, Aristos Pharmaceuticals, Inc., or Aristos.

We believe this strategy will allow us to increase our revenues, improve our margins and profitability and enhance stockholder value.

Third Quarter 2013 Highlights

The following summarizes certain key financial measures for the three months ended September 30, 2013:

- Net revenues were $53.7 million for the third quarter of 2013 compared to $37.5 million for the three months ended September 30, 2012, representing 43% year-over-year growth;

Gross margin was 76% for the third quarter of 2013 compared to 62% for the three months ended September 30, 2012, representing a 14 percentage point increase year-over-year;

When calculated in accordance with accounting principles generally accepted in the United States, or GAAP, income from operations was $16.0 million for the three months ended September 30, 2013 compared to $2.7 million for the three months ended September 30, 2012 and net income was $9.6 million for the three months ended September 30, 2013 compared to $1.2 million for the three months ended September 30, 2012;

On a non-GAAP basis, income from operations increased $13.1 million to $24.8 million and net income increased $8.7 million to $14.3 million for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012; and

Cash and cash equivalents were $69.6 million at September 30, 2013, representing an increase of $14.1 million from June 30, 2013 and $13.4 million from December 31, 2012.

On July 29, 2013, we began actively marketing PERTZYE® (pancrelipase) in the United States. PERTZYE is a combination of porcine-derived lipases, proteases and amylases indicated for the treatment of Exocrine Pancreatic Insufficiency, or EPI, due to cystic fibrosis or other conditions. PERTZYE is an FDA-approved, pancreatic enzyme replacement therapy drug product containing bicarbonate buffered, enteric coated microspheres. We acquired the exclusive U.S. rights to market PERTZYE for EPI due to cystic fibrosis in May 2013 when we entered into a License and Distribution Agreement with Digestive Care, Inc., or DCI. In consideration for marketing rights, we made an initial payment of $10 million, a portion of which is earmarked to satisfy certain outstanding obligations of DCI. We are required to make certain minimum investments in promotion and make payments based on a percentage of net sales. In addition, we are required to make certain milestone payments upon achievement of net sales targets. The initial term of the agreement is ten years with an automatic renewal provision for successive two-year terms unless either party provides written notice six months before the end of the current term. The agreement also includes the right of first refusal to negotiate a license to any alternative, substitute, successor or improvement to PERTZYE that DCI may develop.

Table of Contents

On September 23, 2013, we launched our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product, or HP/CP ER Suspension product, which is being distributed by Aristos. HP/CP ER Suspension is an antitussive/antihistamine combination product that is a generic equivalent for the product currently sold under the Tussionex brand name. HP/CP ER Suspension is indicated for the relief of cough and upper respiratory symptoms associated with an allergy or a cold in adults and children six years of age and older. The FDA approved HP/CP ER Suspension in June 2012. This launch should allow our product to compete with other available generic products. We expect the majority of our product sales will occur between September and March which aligns with the cough/cold season.

On July 24, 2013, in response to a Paragraph IV Notice Letter received on June 11, 2013, or the Exela Notice Letter, from Exela Pharma Sciences, LLC, or Exela, we filed a complaint against Exela in the United States District Court for the District of Delaware alleging that Exela infringed our CARDENE® I.V. (nicardipine hydrochloride) U.S. Patent Nos. 7,612,102 and 7,659,291. The Exela Notice Letter advised us of Exela s filing of a supplemental New Drug Application, or sNDA, seeking approval for a ready to use injectable formulation of 0.1 mg/mL and 0.2 mg/mL nicardipine hydrochloride in 0.9% sodium chloride. We market a ready to use injectable formulation of 0.1 mg/mL and 0.2 mg/mL nicardipine hydrochloride in 0.86% and 0.83% sodium chloride, respectively, under the name CARDENE I.V. The Exela Notice Letter also alleged that Exela s generic product will not infringe the claims of U.S. Patent No. 7,612,102 and U.S. Patent No. 7,659,291, and/or that the claims of those patents are invalid.

On July 12, 2013, we received a second Paragraph IV Notice Letter from Exela alleging that Exela s generic product will not infringe the claims of our recently-issued U.S. Patent No. 8,455,524, and/or that the claims of that patent are invalid. On August 19, 2013, we filed an amended complaint in the United States District Court for the District of Delaware alleging that Exela infringed our U.S. Patent No. 8,455,524 and our U.S Patent No. 7,659,290.

Exela filed a motion to transfer venue from the United States District Court for the District of Delaware to the United States District Court for the Western District of North Carolina and filed a Complaint in the Western District of North Carolina seeking a declaration of noninfringement and invalidity of the U.S. patent No. 7,659,290. We opposed Exela s transfer motion in the Delaware action and moved to dismiss or transfer the Western District of North Carolina action. Both motions are fully briefed and awaiting decision.

On September 25, 2013, in response to a Paragraph IV Notice Letter received on August 15, 2013, or the Sandoz Notice Letter, from Sandoz Inc., or Sandoz, we filed a complaint against Sandoz in the United States District Court for the District of New Jersey alleging that Sandoz s proposed generic product will infringe our U.S. Patent Nos. 7,612,102, 7,659,291, 8,455,524 and 7,659,290. The Sandoz Notice Letter advised us of Sandoz s filing of an Abbreviated New Drug Application, or ANDA, containing a Paragraph IV patent certification with the FDA seeking approval to market a generic version of CARDENE I.V. The Sandoz Notice Letter states that the Paragraph IV certification was made with respect to our three CARDENE I.V. patents listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluation, commonly known as the Orange Book. Our three Orange Book patents U.S. Patent Nos. 7,612,102, 7,659,291 and 8,455,524 have expiration dates ranging from April 18, 2027 to December 26, 2027. The Sandoz Notice Letter was the first Paragraph IV notice letter received from an ANDA filer for CARDENE I.V.

By filing suit to enforce our patents within 45 days from our receipt of the Exela Notice Letter and the Sandoz Notice Letter, under the Hatch-Waxman Act, the FDA may not approve Exela s or Sandoz s generic applications for a period of 30 months from our receipt of the corresponding notice letter, or until an earlier court decision adverse to our patents. We cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Opportunities and Trends

We are currently promoting CARDENE I.V., CUROSURF® (poractant alfa) and PERTZYE with our hospital-based sales force and are managing the life cycle of ZYFLO CR® (zileuton). We have established a network of specialty pharmacies and a customer service hub in connection with our marketing efforts for PERTZYE that we believe will also support our launch of BETHKIS, which is planned for later this year. In addition, we believe that RETAVASE, if approved, will give us the opportunity to further strengthen our existing relationships within the cardiology community and aid in our long-term growth in the hospital and adjacent specialty markets.

In September 2013, we submitted our meeting request for a meeting with the Division of Cardiovascular and Renal Drug Products of the FDA to discuss the contents of the Complete Response Letter received on October 31, 2012 for our new drug application for LIXAR® (lixivaptan) and additional statistical analyses of the existing data. Our meeting is scheduled for December 5, 2013; following such meeting, we plan to determine appropriate action regarding our LIXAR development program, which may result in abandonment of the development program.

As we focus on the growth of our existing products and other product candidates, we also continue to position ourselves to execute upon the licensing and acquisition opportunities that will drive our next phase of growth. Our organization is fully committed to this effort, and we believe we will be successful in executing upon our corporate strategy in ways that will drive this future growth.

Table of Contents

In order to do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships. We believe these actions, combined with the experience and expertise of our management team, position us well to drive the future growth of our revenue and income.

We are currently focused on the following priorities:

- growing revenue from our existing product portfolio;
- launching BETHKIS pursuant to our license agreement with Chiesi Farmaceutici S.p.A., or Chiesi;
- progressing toward validation of a new active pharmaceutical ingredient, or API, supplier and certain manufacturing process changes to allow for FDA approval and re-launch of RETAVASE; and
- acquiring products and companies in the hospital and adjacent specialty markets.

Chiesi Merger

On February 18, 2013, our Board of Directors received a proposal from Chiesi to acquire the shares of our common stock that it does not already own for a cash purchase price of between $6.40 and $6.70 per share. Following its receipt of Chiesi s proposal, our Board of Directors formed a special committee comprised of five independent and disinterested directors, or the Special Committee. Our Board of Directors granted to the Special Committee the authority to, among other things, review, evaluate, reject or negotiate the terms of Chiesi s proposal (including any revised proposal Chiesi might make) and to consider and explore alternatives.

Following negotiations between Chiesi and the Special Committee, on September 15, 2013, we entered into an agreement and plan of merger, or the Chiesi Merger Agreement, with Chiesi and the Merger Sub. The Chiesi Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Chiesi Merger Agreement, Merger Sub will merge with and into our company, with our company surviving the merger as a direct wholly owned subsidiary of Chiesi, referred to as the Chiesi Merger. In the Chiesi Merger, each share of our common stock that is issued and outstanding as of the effective time of the Chiesi Merger, except for treasury stock, dissenting shares and shares held by Chiesi or its subsidiaries, will be converted into the right to receive $9.50 in cash, without interest and subject to deduction for any required withholding taxes. The Chiesi Merger Agreement also provides that all outstanding unvested options and shares of restricted stock will become fully vested upon completion of the Chiesi Merger. Before we entered into the Chiesi Merger Agreement, the Special Committee unanimously determined that the Chiesi Merger Agreement and the transactions contemplated thereby, including the Chiesi Merger, were fair to and in the best interests of the stockholders of our company other than Chiesi and its affiliates, and that it was advisable for us to enter into the Chiesi Merger Agreement. Based on the Special Committee s recommendation, the Board of Directors (i) determined that the Chiesi Merger Agreement and the transactions contemplated thereby, including the Chiesi Merger, are fair to, and in the best interests of, our stockholders, (ii) approved and declared advisable the Chiesi Merger Agreement and the transactions contemplated thereby, including the Chiesi Merger, and (iii) resolved to recommend that our stockholders vote to adopt the Chiesi Merger Agreement.

At the same time that we entered into the Chiesi Merger Agreement, Craig A. Collard, our Chairman, Chief Executive Officer and beneficial owner of 8.1% of the our shares, and Cornerstone Biopharma Holdings, Ltd., an entity controlled by him, entered into a voting agreement with us, Chiesi and Merger Sub under which Mr. Collard and Cornerstone Biopharma Holdings, Ltd. agreed to vote their shares of our common stock in favor of the Chiesi Merger.

Consummation of the Chiesi Merger will require approval by the holders of (i) at least a majority of all shares of our common stock outstanding and entitled to vote on the matter and (ii) a majority of our outstanding shares of common stock that are not owned, directly or indirectly, by Chiesi, Merger Sub or any of their affiliates, by any of our officers or directors or by any other person or entity having any equity interest in, or any right to acquire any equity interest in, Merger Sub or any person or entity of which Merger Sub is a direct or indirect subsidiary.

The Chiesi Merger Agreement places limitations on our ability to engage in certain types of transactions without Chiesi s consent during the period between the signing of the Chiesi Merger Agreement and the effective time of the Chiesi Merger. During this period, with limited exceptions and among other things, we may not (i) issue, sell, pledge, grant, transfer, encumber or otherwise dispose of any shares of our capital stock or the capital stock of any of our subsidiaries; (ii) declare, set aside or pay any dividend or other distribution payable in cash, stock or property with respect to our capital stock; (iii) purchase, redeem or otherwise acquire any shares of our capital stock; (iv) make any acquisition (by merger, consolidation or acquisition of stock or assets) of any interest in any company or any division or assets thereof with a value or purchase price in the aggregate in excess of $5.0 million for all such acquisitions; or (v) incur or assume any indebtedness.

We expect the Chiesi Merger will be completed during the first quarter of 2014, subject to receipt of the requisite stockholder approvals described above and to the satisfaction of the other conditions specified in the Chiesi Merger Agreement.

Table of Contents

Other than expenses associated with the Chiesi Merger, which include fees for advisors and other transaction costs, the terms of the Chiesi Merger Agreement did not impact our consolidated financial statements as of and for the nine months ended September 30, 2013. The transaction-related expenses related to costs associated with the Chiesi Merger during the three and nine months ended September 30, 2013 were $1.5 million and $2.5 million, respectively.

Since the announcement of the execution of the Chiesi Merger Agreement, four lawsuits challenging the Chiesi Merger have been filed in the Delaware Court of Chancery. Each of the Delaware lawsuits is a putative class action filed on behalf of our stockholders other than the defendants and their affiliates. In each case the complaint names as defendants us, our directors, Chiesi and Chiesi US and alleges that our directors and Chiesi breached their fiduciary duties in connection with their approval of the Merger Agreement and that either we, Chiesi or Chiesi US aided and abetted those breaches. Each complaint seeks, among other relief, declaratory and injunctive relief enjoining the Merger and/or compensatory damages in an unspecified amount. The four complaints have been consolidated into a single action by court order, but the plaintiffs have not yet filed a consolidated amended complaint.

The outcome of these lawsuits is uncertain. An adverse judgment for money damages against us could have an adverse effect on our operations and liquidity. A preliminary injunction could delay or jeopardize the completion of the Merger, and an adverse judgment granting permanent injunctive relief could indefinitely enjoin completion of the Chiesi Merger. We and our directors believe that the claims asserted against us in the lawsuits are without merit.

Table of Contents

Results of Operations

Comparison of the Three Months Ended September 30, 2013 and 2012

The following table sets forth certain consolidated statement of comprehensive income (loss) data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Three Months Ended September 30,		Change	
	2013	2012	$	%
Net product sales				
CARDENE I.V. product family	$ 20,729	$ 12,778	$ 7,951	62%
CUROSURF	11,222	9,963	1,259	13
ZYFLO® product family	19,780	14,495	5,285	36
PERTZYE	86		86	NM
HP/CP ER Suspension product	246		246	NM
Other products	1,100	289	811	281
Total net product sales	53,163	37,525	15,638	42
Other revenues	534		534	NM
Net revenues	53,697	37,525	16,172	43
Cost of product sales (exclusive of amortization of product rights)	12,642	14,397	(1,755)	(12)
Selling, general and administrative	16,371	12,933	3,438	27
Research and development	594	1,998	(1,404)	(70)
Amortization of product rights	4,408	5,284	(876)	(17)
Change in acquisition-related contingent payments	2,298	(1,574)	3,872	NM
Transaction-related expenses	1,458	1,764	(306)	(17)
Other operating expenses, net	(113)		(113)	NM
Income (loss) from operations	16,039	2,723	13,316	489
Total other expenses, net	(1,786)	(1,899)	113	NM
Income (loss) before income taxes	14,253	824	13,429	1,630
(Provision for) benefit from income taxes	(4,676)	425	(5,101)	NM
Net income (loss)	$ 9,577	$ 1,249	$ 8,328	667
Net income (loss) per share, diluted	$ 0.31	$ 0.05	$ 0.26	520
Non-GAAP income from operations (1)	$ 24,841	$ 11,783	$ 13,058	111
Non-GAAP net income (1)	$ 14,317	$ 5,636	$ 8,681	154
Non-GAAP net income per share, diluted (1)	$ 0.46	$ 0.19	$ 0.27	142

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.
NM Not meaningful.

Net Revenues

Net Product Sales.

CARDENE I.V. net product sales increased $8.0 million, or 62%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012, primarily due to increased unit volume largely due to a shortage of product from generic manufacturers, a reduction in our estimated rate of chargebacks and an adjustment to reduce our estimate of product returns, partially offset by increases in our estimated rates for price adjustments.

CUROSURF net product sales increased $1.3 million, or 13%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012, primarily due to increased unit volume, coupled with decreases in our estimated rates for price adjustments and chargebacks due to an increase in contract prices.

Table of Contents

ZYFLO CR and ZYFLO (zileuton) net product sales increased $5.3 million, or 36%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012, primarily driven by price increases, partially offset by a decline in unit volume.

PERTZYE net product sales were $86,000 during the three months ended September 30, 2013. PERTZYE sales reflect product sales made directly by us to specialty pharmacies within our network. We began actively marketing PERTZYE on July 29, 2013.

HP/CP ER Suspension net product sales were $246,000 during the three months ended September 30, 2013. We launched our HP/CP ER Suspension product on September 23, 2013.

Net product sales from other products increased $811,000 during the three months ended September 30, 2013 compared to the three months ended September 30, 2012, primarily due to a reduction of our estimate of product returns relating to HyoMax (hyoscamine sulfate).

Other Revenues.

Other revenues were $534,000 during the three months ended September 30, 2013. Other revenues consisted of PERTZYE copromotion revenue, which is recorded based on our contractual agreement with DCI.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $4.4 million and $5.3 million for the three months ended September 30, 2013 and 2012, respectively) decreased $1.8 million, or 12%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012 primarily due to a reduction of acquisition-related CARDENE I.V. inventory charges, partially offset by an increase in ZYFLO royalty expense, as a result of increased sales. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

Gross profit (exclusive of other revenues and amortization of product rights) was as follows (dollars in thousands):

	Three Months Ended September 30,		Change	
	2013	2012	$	%
Net product sales	$ 53,163	$ 37,525	$ 15,638	42%
Cost of product sales (exclusive of amortization of product rights)	12,642	14,397	(1,755)	(12)
Gross profit	$ 40,521	$ 23,128	$ 17,393	75%
Gross margin	76%	62%		

Gross margin of net product sales for the three months ended September 30, 2013 increased 14.0 percentage points compared to the three months ended September 30, 2012. This increase was primarily impacted by sales growth in CARDENE I.V., due to a shortage of product from generic manufacturers. In addition, we have experienced growth in our net product sales due to price increases, certain adjustments for product returns that were less than estimated and lower estimated rates for other sales allowances.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $3.4 million, or 27%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012. This increase was primarily due to increases in legal fees related to ongoing patent litigation; compensation, travel and other related employee benefits due to the continued growth of our products and related sales force; advertising and promotional expenses related to the addition of PERTZYE and our anticipated launch of BETHKIS, and marketed product stability expenses.

Research and Development Expenses. Research and development expenses decreased $1.4 million, or 70%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012. The research and development expenses in the third quarter of 2013 primarily resulted from the development costs we incurred related to RETAVASE. The research and development costs we incurred during the third quarter of 2012 primarily related to LIXAR. Our product development expenses for particular product candidates vary significantly from period to period depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given reporting period.

Amortization of Product Rights. Amortization of product rights decreased $876,000, or 17%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012. This decrease was primarily driven by change in estimated life of CUROSURF from 10 to 15 years during the fourth quarter of 2012, partially offset by amortization of product rights related to PERTZYE beginning in May 2013.

Table of Contents

Change in Acquisition-related Contingent Payments. The change in acquisition-related contingent payments was $2.3 million during the three months ended September 30, 2013 due to changes in the fair value measurements of CARDENE I.V. and RETAVASE contingent consideration, which products were acquired in June 2012 as part of our acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc., or EKR. For additional information regarding the change in acquisition-related contingent payments, refer to Note 2 to our consolidated financial statements included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q.

Transaction- related Expenses. Transaction-related expenses decreased $306,000, or 17%, during the three months ended September 30, 2013 compared to the three months ended September 30, 2012. The transaction-related expenses in the third quarter of 2013 primarily related to costs associated with the Chiesi Merger. The transaction-related expenses in the third quarter of 2012 primarily related to our acquisition of EKR.

Provision for (Benefit from) Income Taxes. The provision for income taxes was $4.7 million for the three months ended September 30, 2013 compared to a benefit from income taxes of $425,000 for the three months ended September 30, 2012. Our effective tax rates for the three months ended September 30, 2013 and 2012 were 32.8% and (51.6)%, respectively. The change in the effective tax rate was due primarily to the tax impact of projected income for 2013 as compared to losses for 2012.

Comparison of the Nine Months Ended September 30, 2013 and 2012

The following table sets forth certain consolidated statement of comprehensive income (loss) data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Nine Months Ended September 30,		Change	
	2013	2012	$	%
Net product sales				
CARDENE I.V. product family	$ 48,787	$ 13,514	35,273	261%
CUROSURF	32,000	26,845	5,155	19
ZYFLO product family	49,159	37,731	11,428	30
PERTZYE	86		86	NM
HP/CP ER Suspension product	246		246	NM
Other products	1,093	3,063	(1,970)	(64)
Total net product sales	131,371	81,153	50,218	62
Other revenues	712	4	708	17,700
Net revenues	132,083	81,157	50,926	63
Cost of product sales (exclusive of amortization of product rights)	34,904	31,984	2,920	9
Selling, general and administrative	43,288	32,745	10,543	32
Research and development	2,036	3,729	(1,693)	(45)
Amortization of product rights	12,863	13,774	(911)	(7)
Change in acquisition-related contingent payments	6,080	(1,574)	7,654	NM
Transaction-related expenses	2,595	7,944	(5,349)	(67)
Other operating expenses, net	(1,101)	(1,492)	391	26

Income (loss) from operations	31,418	(5,953)	37,371	NM
Total other expenses, net	(4,581)	(2,014)	(2,567)	(127)
Income (loss) before income taxes	26,837	(7,967)	34,804	NM
(Provision for) benefit from income taxes	(9,082)	3,038	(12,120)	NM
Net income (loss)	$ 17,755	$ (4,929)	$ 22,684	NM
Net income (loss) per share, diluted	$ 0.60	$ (0.19)	$ 0.79	NM
Non-GAAP income from operations (1)	$ 55,059	$ 17,787	$ 37,272	210
Non-GAAP net income (1)	$ 31,347	$ 9,758	$ 21,589	221
Non-GAAP net income per share, diluted (1)	$ 1.03	$ 0.36	$ 0.67	186

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.
NM Not meaningful.

Table of Contents

Net Revenues

Net Product Sales.

CARDENE I.V. net product sales increased $35.3 million, or 261%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 primarily due to our acquisition of the CARDENE I.V. product rights on June 26, 2012 as part of our acquisition of EKR; hence, approximately six additional months of CARDENE I.V. net product sales are included in net product sales for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012. Also driving the increase in net product sales during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was increased unit volume during the three months ended September 30, 2013 largely due to a shortage of product from generic manufacturers. We also experienced a reduction in our estimated rate of chargebacks and an adjustment to reduce our estimate of product returns, partially offset by increases in our estimated rates for price adjustments.

CUROSURF net product sales increased $5.2 million, or 19%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, primarily due to increased unit volume, coupled with decreases in our estimated rates for price adjustments and chargebacks due to increases in contract prices.

ZYFLO CR and ZYFLO net product sales increased $11.4 million, or 30%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, primarily driven by price increases, partially offset by a decline in unit volume.

PERTZYE net product sales were $86,000 during the nine months ended September 30, 2013. PERTZYE sales reflect product sales made directly by us to specialty pharmacies within our network. We began actively marketing PERTZYE on July 29, 2013.

HP/CP ER Suspension net product sales were $246,000 during the nine months ended September 30, 2013. We launched our HP/CP ER Suspension product on September 23, 2013.

Net product sales from other products decreased $2.0 million during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, primarily due to our divestiture of our anti-infective product rights and certain related assets and liabilities in early March 2012.

Other Revenues.

Other revenues were $712,000 during the nine months ended September 30, 2013. Other revenues consisted of PERTZYE copromotion revenue, which is recorded based on our contractual agreement with DCI.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $12.9 million and $13.8 million for the nine months ended September 30, 2013 and 2012, respectively) increased $2.9 million, or 9%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 primarily due to the addition of CARDENE I.V. to our product portfolio, coupled with inventory obsolescence charges related to ZYFLO, partially offset by a reduction of acquisition-related CARDENE I.V. inventory charges. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

Gross profit (exclusive of other revenues and amortization of product rights) was as follows (dollars in thousands):

	Nine Months Ended September 30,		Change	
	2013	2012	$	%
Net product sales	$ 131,371	$ 81,153	$ 50,218	62%
Cost of product sales (exclusive of amortization of product rights)	34,904	31,984	2,920	9
Gross profit	$ 96,467	$ 49,169	$ 47,298	96%
Gross margin	73%	61%		

Gross margin of net product sales for the nine months ended September 30, 2013 increased 12.0 percentage points compared to the nine months ended September 30, 2012. This increase was primarily impacted by the June 2012 addition of CARDENE I.V. to our product mix coupled with increased unit volume of CARDENE I.V., due to a shortage of product from generic manufacturers.

Table of Contents

Additionally, gross margin was impacted by growth in our net product sales due to price increases, certain adjustments for product returns that were less than estimated and lower estimated rates for other sales allowances.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $10.5 million, or 32%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. This increase was primarily due to increases in compensation, travel and other related employee benefits due to the continued growth of our products and related sales force; advertising and promotional expenses related to the addition of CARDENE I.V. and PERTZYE and our anticipated launch of BETHKIS; and legal fees related to ongoing patent litigation. These increases were partially offset by a reduction in copromotion expenses related to ZYFLO. Our copromotion liability to Dey, L.P. related to ZYFLO ends on December 31, 2013.

Research and Development Expenses. Research and development expenses decreased $1.7 million, or 45%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. The research and development expenses in the first nine months of 2013 primarily resulted from the development costs we incurred related to RETAVASE. The research and development costs we incurred during the first nine months of 2012 primarily related to LIXAR. Our product development expenses for particular product candidates vary significantly from period to period depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given reporting period.

Amortization of Product Rights. Amortization of product rights decreased $911,000, or 7%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. The addition of CARDENE I.V. product rights in June 2012 increased amortization of product rights in the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, which were partially offset by a reduction of amortization of product rights due to the divestiture of our anti-infective product rights in March 2012 of approximately $2.2 million, coupled with the fourth quarter 2012 change in estimated life of CUROSURF from 10 to 15 years.

Change in Acquisition-related Contingent Payments. The change in acquisition-related contingent payments was $6.1 million during the nine months ended September 30, 2013 due to changes in the fair value measurements of CARDENE I.V. and RETAVASE contingent consideration, which products were acquired in June 2012 as part of our acquisition of EKR. For additional information regarding the change in acquisition-related contingent payments, refer to Note 2 to our consolidated financial statements included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q.

Transaction- related Expenses. Transaction-related expenses decreased $5.3 million, or 67%, during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. The transaction-related expenses in the nine months ended September 30, 2013 primarily related to costs associated with the Chiesi Merger. The transaction-related expenses in the nine months ended September 30, 2012 primarily related to our acquisition of EKR.

Other operating expenses, net. The $391,000 change in other operating expenses, net during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, was due to the March 2012 gain on our divestiture of our anti-infective product rights compared to the 2013 settlement of certain liabilities acquired in connection with our acquisition with EKR.

Total other expenses, net. Total other expenses, net increased by $2.6 million during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012, primarily due to interest expense related to the credit agreement we entered into in June 2012 with Chiesi, or the Credit Agreement, partially offset by a receipt of cash consideration from the demutualization of a former mutual insurance provider.

Provision for (Benefit from) Income Taxes. The provision for income taxes was $9.1 million for the nine months ended September 30, 2013 compared to a benefit from income taxes of $3.0 million for the nine months ended September 30, 2012. Our effective tax rates for the nine months ended September 30, 2013 and 2012 were 33.8% and (38.1)%, respectively. The change in the effective tax rate was due primarily to the tax impact of projected income for 2013 as compared to losses for 2012.

Reconciliation of Non-GAAP Financial Measures

To supplement the consolidated financial statements presented in accordance with GAAP, we use non-GAAP measures of certain components of financial performance. These non-GAAP measures include non-GAAP operating income, non-GAAP net income and non-GAAP net income per diluted share. Our management regularly uses supplemental non-GAAP financial measures to understand, manage and evaluate our business and make operating and compensation decisions. These non-GAAP measures are among the primary factors management uses in planning for and forecasting future periods.

These non-GAAP measures are not in accordance with, or an alternative to, measures prepared in accordance with GAAP and may be different from similarly titled non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. The additional non-GAAP financial information presented herein

Table of Contents

should be considered in conjunction with, and not as a substitute for, or superior to, the financial information presented in accordance with GAAP (such as operating income (loss), net income (loss) and earnings (loss) per share) and should not be considered measures of our liquidity. These non-GAAP measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP measures.

The non-GAAP financial measures reflect adjustments for stock-based compensation expense, amortization of product rights, transaction-related expenses, acquisition adjustments related to inventory sold, changes in acquisition-related contingent payments and the gain on the divestiture of certain product rights. Transaction-related expenses consist of (1) costs incurred to complete product or company acquisitions or other strategic transactions, including due diligence and legal, consulting and other related fees; (2) integration costs related to our completed transactions; and (3) transaction-related fees associated with transactions that are not consummated. We exclude these expenses from our non-GAAP measures because we believe that their exclusion provides an additional means to assess the extent to which our efforts and execution of our strategy are reflected in our operating results. In particular, stock-based compensation expense is excluded primarily because it is a non-cash expense that is determined based on subjective assumptions, amortization of product rights is excluded because it is not reflective of the cash-settled expenses incurred related to product sales; and the transaction-related expenses, acquisition adjustments related to inventory sold, changes in acquisition contingent payments, and our gain on the divestiture of certain product rights are excluded because management believes they have no direct correlation to current operating results. Our management believes that these non-GAAP measures, when shown in conjunction with the corresponding GAAP measures, enhance investors and management s overall understanding of our current financial performance and our prospects for the future.

The non-GAAP measures are subject to inherent limitations because (1) they do not reflect all of the expenses associated with the results of operations as determined in accordance with GAAP and (2) the exclusion of these expenses involves the exercise of judgment by management. Even though we have excluded stock-based compensation expense, amortization of product rights, transaction-related expenses, acquisition adjustments related to inventory sold, changes in acquisition-related contingent payments, and the gain from the divestiture of product rights from the non-GAAP financial measures, stock-based compensation is an integral part of our compensation structure, the acquisition of additional companies and/or product rights and the divestiture of our anti-infective product rights are an important part of our business strategy, and transaction-related expenses, whether or not the transaction is successfully closed, may be significant cash expenses.

Table of Contents

The following tables reconcile our non-GAAP measures to the most directly comparable GAAP financial measures (in thousands, except share and per share amounts):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2013	2012	2013	2012
GAAP income (loss) from operations	$ 16,039	$ 2,723	$ 31,418	$ (5,953)
Add: stock-based compensation	615	684	2,005	2,027
Add: amortization of product rights	4,408	5,284	12,863	13,774
Add: transaction-related expenses	1,458	1,764	2,595	7,944
Add: acquisition adjustments related to inventory sold	23	2,902	98	3,061
Less: change in acquisition-related contingent payments	2,298	(1,574)	6,080	(1,574)
Less: gain on divestiture of product rights				(1,492)
Non-GAAP income from operations	$ 24,841	$ 11,783	$ 55,059	$ 17,787
GAAP net income (loss)	$ 9,577	$ 1,249	$ 17,755	$ (4,929)
Add: stock-based compensation	615	684	2,005	2,027
Add: amortization of product rights	4,408	5,284	12,863	13,774
Add: transaction-related expenses	1,458	1,764	2,595	7,944
Add: acquisition adjustments related to inventory sold	23	2,902	98	3,061
Less: change in acquisition-related contingent payments	2,298	(1,574)	6,080	(1,574)
Less: gain on divestiture of product rights				(1,492)
Less: tax effects related to above items[1]	(4,062)	(4,673)	(10,049)	(9,053)
Non-GAAP net income	$ 14,317	$ 5,636	$ 31,347	$ 9,758
GAAP net income (loss) per share, diluted	$ 0.31	$ 0.05	$ 0.60	$ (0.19)
Non-GAAP net income per share, diluted[2]	$ 0.46	$ 0.19	$ 1.03	$ 0.36
Shares used in diluted net income (loss) per share calculation:				

GAAP net income (loss)	31,495,632	26,603,258	31,274,715	26,040,695
Non-GAAP net income	31,495,632	30,829,800	31,274,715	27,948,621

(1) Income taxes typically represent a complex element of our consolidated statement of comprehensive income (loss) and effective tax rates can vary widely between different periods. As such, for the three and nine months ended September 30, 2013, we calculated non-GAAP net income by applying our statutory tax rate of 37.9% to non-GAAP income before taxes of $23.1 million and $50.5 million, respectively. The tax effects for the three and nine months ended September 30, 2013 represent the difference between our GAAP tax provision of $4.7 million and $9.1 million, respectively, and our calculated non-GAAP tax expense of $8.7 million and $19.1 million, respectively. Tax effects for the three and nine months ended September 30, 2012 were calculated using the effective tax rates of 51.6% and 38.1%, respectively.

Table of Contents

(2) For the three and nine months ended September 30, 2013 and 2012, the convertible term loan was determined to be dilutive to non-GAAP net income per share, diluted. For the three and nine months ended September 30, 2013, non-GAAP net income was adjusted for $314,000 and $933,000, respectively, of interest expense related to the convertible term loan, net of tax effects. For the three and nine months ended September 30, 2012, non-GAAP net income was adjusted for $245,000 and $330,000, respectively, of interest expense related to the convertible term loan, net of tax effects. Non-GAAP net income adjusted for the related interest expense, net of tax effects, was divided by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period, as adjusted for the impact of the shares related to the convertible debt of approximately 4.2 million shares for both the three and nine months ended September 30, 2013 and approximately 4.2 million and 1.5 million shares for the three and nine months ended September 30, 2012, respectively.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and in-licenses of rights to products. To date, we have funded our operations primarily from product sales, royalty agreement revenues, and an investment from Chiesi. In June 2012, we entered into the term loans with Chiesi with proceeds of $90.0 million, or the Term Loans, which are described below. We used the proceeds from the Term Loans, together with $36.4 million of cash on hand, to fund our acquisition of EKR. As of September 30, 2013, we had $69.6 million in cash and cash equivalents on hand. As discussed more fully above, the Chiesi Merger Agreement places certain limitations on our ability to raise and use funds in connection with our business, including by limiting our ability to issue shares of capital stock, incur indebtedness, pay dividends, repurchase our existing capital stock and pursue certain acquisitions.

Cash Flows

The following table provides information regarding our cash flows (in thousands):

	Nine Months Ended September 30,	
	2013	**2012**
Cash provided by (used in):		
Operating activities	$ 28,399	$ (4,785)
Investing activities	(10,831)	(124,186)
Financing activities	(4,206)	89,182
Net increase (decrease) in cash and cash equivalents	$ 13,362	$ (39,789)

Net Cash Provided By (Used In) Operating Activities

Our primary sources of operating cash flows are product sales. Our primary uses of cash in our operations are for funding working capital, selling, general and administrative expenses and royalties.

Net cash provided by operating activities for the nine months ended September 30, 2013 reflected our net income of $17.8 million, adjusted by non-cash expenses totaling $27.8 million and changes in operating assets and liabilities from December 31, 2012 to September 30, 2013 totaling $17.2 million. Non-cash items consisted primarily of

amortization and depreciation of $13.4 million, provision increases for prompt payment discounts and inventory allowances of $5.2 million, stock-based compensation of $2.0 million, fair value adjustments to acquisition-related contingent payments of $6.1 million and changes of deferred income taxes of $884,000. Changes in operating assets and liabilities were primarily affected by increases in accounts receivable, inventories and prepaid expenses combined with decreases in accounts payable, accrued expenses and other liabilities, partially offset by a $1.5 million change in acquisition-related assets and liabilities and a $3.3 million change in income taxes.

Table of Contents

Net cash used in operating activities for the nine months ended September 30, 2012 reflected our net loss of $4.9 million, adjusted by non-cash expenses totaling $18.5 million and changes in operating assets and liabilities from December 31, 2011 to September 30, 2012 totaling $18.4 million.

Net Cash Used in Investing Activities

Our primary uses of cash in investing activities are the purchase of property and equipment and the acquisition and licensing of product rights.

Net cash used in investing activities for the nine months ended September 30, 2013 reflected the purchase of product rights for PERTZYE for $10 million and the purchase of property and equipment for $844,000.

Net cash used in investing activities for the nine months ended September 30, 2012 reflected the $126.9 million of cash paid for our acquisition of Cardiokine, Inc., or Cardiokine, and EKR, net of cash acquired, $3.0 million cash proceeds allocated to the divested anti-infective product rights and purchase of property and equipment for $265,000.

Net Cash (Used in) Provided by Financing Activities

Our primary sources of historical cash flows from financing activities are the investment by Chiesi and the Credit Agreement. Going forward, we expect our primary sources of cash flows from financing activities to be equity or debt issuances or arrangements we may make or enter into. Our primary uses of cash in financing activities are to acquire companies, and marketed, registration-stage, or late-stage development products that fit within our focus areas.

Net cash used in financing activities for the nine months ended September 30, 2013 reflected contingent payments relating to CARDENE I.V. acquisition-related contingent consideration of $4.9 million and principal payments on capital leases of $74,000, partially offset by proceeds from common stock option exercises of $773,000.

Net cash provided by financing activities for the nine months ended September 30, 2012 reflected proceeds from our long-term debt of $90.0 million, proceeds from common stock option exercises of $1.2 million and an excess tax benefit from stock compensation of $284,000, partially offset by contingent payments relating to CARDENE I.V. acquisition-related contingent consideration of $1.6 million, debt financing costs of $511,000, principal payments on capital leases and purchases of treasury stock.

Funding Requirements

Our future capital requirements will depend on many factors, including:

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the cost and timing of completion of the Chiesi Merger and related litigation challenging the Chiesi Merger;
- the scope, progress, results and costs of development activities for our product candidates;

the costs, timing and outcome of regulatory review of our product candidates;

the number of, and development requirements for, additional product candidates that we pursue;

the extent to which we acquire or invest in products, businesses and technologies;

the costs of commercialization activities, including product marketing, sales and distribution;

the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

the extent to which we are required to make certain contingent payments in connection with our acquisitions;

the extent to which we may be required to prepay our indebtedness under the Credit Agreement;

the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

Table of Contents

As of September 30, 2013, we had $69.6 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for at least the next 12 months.

Chiesi Credit Agreement

On June 21, 2012, we entered into the Credit Agreement in order to finance a portion of the costs of our acquisition of EKR. Pursuant to the Credit Agreement, Chiesi made two loans to the Company: (i) a loan of $60.0 million, or Term Loan A, and (ii) a loan of $30.0 million, or Term Loan B, which we collectively refer to as the Term Loans. All of the obligations owed by us under the Credit Agreement are guaranteed by our domestic subsidiaries, and are secured by a security interest in substantially all of our assets and our domestic subsidiaries assets. Chiesi is the administrative agent and collateral agent under the Credit Agreement.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears. Term Loan A requires quarterly principal payments of $3.5 million commencing in the fiscal quarter ending December 31, 2014 with any remaining balance being due at maturity. The Term Loans are due and payable in full on June 23, 2017, unless previously prepaid or, in the case of Term Loan B, unless previously converted into shares of common stock pursuant to the conversion right described below.

We have the right to prepay the Term Loans, in whole or in part without any premium or penalty. Any partial prepayment must be in the amount of $5.0 million or, if more than $5.0 million, in whole multiples of $1.0 million, in each case plus any accrued and unpaid interest.

We are required to prepay all or a portion of the Term Loans: (i) if our ratio of consolidated secured debt to Consolidated EBITDA (as defined in the Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013, by using 50% of our Consolidated Excess Cash (as defined in the Credit Agreement), or (ii) if we undertake certain asset sales or sales of capital stock and do not reinvest the proceeds according to the terms of the Credit Agreement. We will evaluate our compliance with the ratio of consolidated secured debt to Consolidated EBITDA as of and for the year ending December 31, 2013 and do not anticipate any prepayment for 2013.

Until June 21, 2014, Chiesi has the option to convert all or a portion of the Term Loan B principal loan balance into shares of common stock at a conversion price of $7.098 per share, subject to adjustment under certain conditions. Any such conversion must be in a minimum amount of $5.0 million unless the outstanding principal balance is less than $5.0 million. At September 30, 2013, the outstanding balance of Term Loan B was $30.0 million, which was convertible into 4,226,542 shares of common stock.

The Term Loans are collateralized by substantially all of our assets, including the assets of our subsidiaries that are guarantors of the Term Loans. The Credit Agreement contains customary representations, covenants and events of default. Upon an Event of Default (as defined in the Credit Agreement), (i) the interest rates for Term Loan A and Term Loan B will each increase by 2% and (ii) Chiesi may declare all outstanding principal and accrued but unpaid interest under the Credit Agreement to be immediately due and payable. In addition, we are subject to covenants prohibiting the payment of any dividends (other than stock dividends) and restricting or limiting other restricted payments, certain corporate activities, transactions with affiliates, incurrence of debt (which debt limit expressly permits, among other things, a secured working capital facility of up to $25 million), liens on properties and asset dispositions. We are not subject to any financial covenants other than the mandatory prepayment provisions discussed above.

In connection with the Term Loans, we incurred $511,000 of debt financing costs, which primarily consisted of legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through the maturity of the loans.

Table of Contents

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of September 30, 2013 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt obligations (1)	$ 110,816	$ 1,648	$ 29,911	$ 79,257	$
Capital lease obligations	49	10	39		
Operating leases(2)	1,582	156	1,252	174	
Purchase obligations(3)	78,958	16,546	25,873	20,639	15,900
Total(4)	$ 191,405	$ 18,360	$ 57,075	$ 100,070	$ 15,900

(1) Long-term debt obligations represent future minimum principal and interest payments due under both our Term Loan A and Term Loan B assuming that the loans remain outstanding until maturity, the conversion option for Term Loan B is not exercised and the default rate of interest is not triggered.

(2) Operating leases include minimum payments under leases for our facilities and automobiles. Our total minimum lease payments for the corporate headquarters are $536,000 in 2013 (of which we paid $393,000 during the first nine months of 2013), $584,000 in 2014, $599,000 in 2015, $152,000 in 2016 and $0 thereafter.

(3) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of $52.0 million; clinical trial and research agreements with contract research organizations and consultants of $769,000; agreements with providers of marketing analytical services of $4.5 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $21.6 million.

(4) Excluded from the contractual obligations table are (i) potential payments of up to $167.5 million for contingent consideration that we may be required to pay in connection with our acquisitions of Cardiokine and EKR; (ii) $20 million for potential milestone payments in connection with our licensing and distribution agreement with DCI; (iii) $10.9 million in potential future milestone payments as part of our other licensing, distribution and development agreements; (iv) a contingent liability of $750,000 related to our divestiture of Factive (gemifloxacin mesylate); (v) anticipated payments under the assumed contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V., which is based on a percentage of net sales; and (vi) anticipated losses related to a RETAVASE supply contract, which we acquired as part of our acquisition of EKR, that was determined to have terms that were less favorable than market. We have excluded these potential liabilities and milestone payments from the contractual obligations table because we are unable to precisely predict the timing or ultimate cash settlement amounts of these payments. See Note 11 to our consolidated financial statements included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q for more information regarding the potential payments related to our acquisition of Cardiokine and milestone payments related to our licensing, distribution and development agreements.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with GAAP. For information regarding our critical accounting policies and estimates, please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates contained in our annual report on Form 10-K for the year ended December 31, 2012 and Note 2 to our consolidated financial statements contained therein. There have been no material changes to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

As discussed in Note 14 to our consolidated financial statements included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q, there are no recent accounting pronouncements that we have not yet adopted that are expected to have a material impact on our consolidated financial statements.

Table of Contents

Iran Threat Reduction and Syria Human Rights Act of 2012

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 added Section 13(r) to the Exchange Act. Section 13(r) requires an issuer to disclose in its annual or quarterly reports, as applicable, whether it or any of its affiliates knowingly engaged in certain activities, transactions or dealings relating to Iran or with designated natural persons or entities involved in terrorism or the proliferation of weapons of mass destruction. Disclosure is required even where the activities, transactions or dealings are conducted outside the U.S. by non-U.S. affiliates in compliance with applicable law, and whether or not the activities are sanctionable under U.S. law.

Chiesi, which owns a majority of our common stock, is considered to be an affiliate of ours under Section 13(r) of the Exchange Act. During the quarter ended September 30, 2013, Chiesi was a party to distribution agreements pursuant to which the applicable distributor sold CUROSURF to hospitals in Iran, which may include hospitals owned by the Government of Iran. We believe Chiesi s gross revenue attributable to such sales during the quarter ended September 30, 2013 was approximately $1.1 million, while net profit generated from such sales was approximately $339,000.

We are committed to fully complying with all U.S. economic sanctions. However, because Chiesi, as our majority shareholder, has the ability to act independently of us, we have no ability to control whether it will sell CUROSURF or other products to distributors that may sell such products to hospitals in Iran. As a result, we cannot disclose with certainty whether Chiesi intends to continue distributing CUROSURF to Iranian hospitals.

As of the date of this quarterly report on Form 10-Q, we are not aware of any other activity, transaction or dealing by us or any of our affiliates during the quarter ended September 30, 2013, that requires disclosure in this quarterly report under Section 13(r) of the Exchange Act. For affiliates that we do not control and that are our affiliates solely due to their common control by Chiesi, we have relied upon Chiesi for information regarding their activities, transactions and dealings.

Table of Contents

ITEM 3. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Interest Rate Risk

Our exposure to market risk is confined to our cash equivalents, all of which have maturities of less than three months and bear and pay interest in U.S. dollars. Since we invest in highly liquid, relatively low yield investments, we do not believe interest rate changes would have a material impact on us.

Our risk associated with fluctuating interest expense is limited to future capital leases and other short-term debt obligations we may incur in our normal operations. The impact of fluctuations in interest expense related to future capital leases is expected to be immaterial to our consolidated financial statements. The interest rates on our existing long-term debt borrowings are fixed and as a result, interest due on borrowings are not impacted by changes in market-based interest rates. We do not have any other instruments with interest rate exposure.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have one supply contract denominated in Euros and two development agreements denominated in foreign currencies, Euros and Swiss francs. Unfavorable fluctuations in these exchange rates could have a negative impact on our consolidated financial statements. The impact of changes in the exchange rates related to these contracts was immaterial to our consolidated financial statements for the three and nine months ended September 30, 2013 and 2012. We do not believe a fluctuation in these exchange rates would have a material impact on us. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

ITEM 4. *CONTROLS AND PROCEDURES*

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of September 30, 2013, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Exchange Act. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2013, our disclosure controls and procedures were effective in ensuring that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. ***LEGAL PROCEEDINGS***

Please see Part I Item 3. Legal Proceedings of our annual report on Form 10-K for the year ended December 31, 2012 for a description of certain pending legal proceedings to which we are a party. There have been no material developments in these legal proceedings since the filing of the Form 10-K on March 14, 2013 except as disclosed below.

Propoxyphene Litigation

Since January 11, 2012, we have been served with 38 complaints involving 1,458 plaintiffs in which plaintiffs allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the API propoxyphene marketed and sold as generic and/or brand-name drugs under various names by the numerous defendant companies. The suits name numerous pharmaceutical companies, including Cornerstone BioPharma, Inc., Cornerstone BioPharma Holdings, LLC, and Aristos and do not specify which company s product each plaintiff allegedly ingested. The damages plaintiffs seek include compensatory and exemplary damages.

These cases were initially filed in various jurisdictions. Of the cases filed and served to date, four were originally filed in Federal Courts and 34 were originally filed in State Courts. The four originally filed in federal court were transferred to the pending MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division) and were dismissed on the basis that

Table of Contents

Federal food and drug laws preempted the plaintiffs claims. The dismissal rulings in two of the dismissed cases, together with other cases in which we have not been named as defendants, have been appealed to the United States Court of Appeals for the Sixth Circuit. Appellants Principal Brief was filed October 9, 2013, while Appellees Opposition Brief is due November 12, 2013. Appellants Reply Brief is due seventeen days after filing of the Opposition.

The 34 State Court cases were initially removed to Federal Court. Thirty-three of the cases have been remanded to California State Courts, one is pending in the United States District Court for the Northern District of California, and none currently remain in the MDL proceedings. California state court propoxyphene cases were consolidated in a coordinated proceeding (JCCP No. 4741) and the first hearing in these cases took place in Los Angeles Superior Court on July 15, 2013. The next Status Conference is set for December 9, 2013. Certain defendants have also requested that the Ninth Circuit Court of Appeals perform an en banc review of the Ninth Circuit s previous decision affirming remand of certain propoxyphene cases to California State Court.

We expect additional cases to be filed but it is not possible at this time to predict the schedule, jurisdiction, or procedural context in which the propoxyphene litigation will ultimately be resolved.

Paragraph IV Litigation

On July 24, 2013, in response to the Exela Notice Letter, we filed a complaint against Exela in the United States District Court for the District of Delaware alleging that Exela infringed our CARDENE® I.V. U.S. Patent Nos. 7,612,102 and 7,659,291. The Exela Notice Letter advised us of Exela s filing of an sNDA seeking approval for a ready to use injectable formulation of 0.1 mg/mL and 0.2 mg/mL nicardipine hydrochloride in 0.9% sodium chloride. We market a ready to use injectable formulation of 0.1 mg/mL and 0.2 mg/mL nicardipine hydrochloride in 0.86% and 0.83% sodium chloride, respectively, under the name CARDENE I.V. The Exela Notice Letter also alleged that Exela s generic product will not infringe the claims of U.S. Patent No. 7,612,102 and U.S. Patent No. 7,659,291, and/or that the claims of those patents are invalid.

On July 12, 2013, we received a second Paragraph IV Notice Letter from Exela alleging that Exela s generic product will not infringe the claims of our recently-issued U.S. Patent No. 8,455,524, and/or that the claims of that patent are invalid. On August 19, 2013, we filed an amended complaint in the United States District Court for the District of Delaware alleging that Exela infringed our U.S. Patent No. 8,455,524 and our U.S Patent No. 7,659,290.

Exela filed a motion to transfer venue from the United States District Court for the District of Delaware to the United States District Court for the Western District of North Carolina and filed a Complaint in the Western District of North Carolina seeking a declaration of noninfringement and invalidity of the U.S. patent No. 7,659,290. We opposed Exela s transfer motion in the Delaware action and moved to dismiss or transfer the Western District of North Carolina action. Both motions are fully briefed and awaiting decision.

On September 25, 2013, in response to the Sandoz Notice Letter, we filed a complaint against Sandoz in the United States District Court for the District of New Jersey alleging that Sandoz s proposed generic product will infringe our U.S. Patent Nos. 7,612,102, 7,659,291, 8,455,524 and 7,659,290. The Sandoz Notice Letter advised us of Sandoz s filing of an ANDA containing a Paragraph IV patent certification with the FDA seeking approval to market a generic version of CARDENE I.V. The Sandoz Notice Letter states that the Paragraph IV certification was made with respect to our three CARDENE I.V. patents listed in the Orange Book. Our three Orange Book patents U.S. Patent Nos. 7,612,102, 7,659,291 and 8,455,524 have expiration dates ranging from April 18, 2027 to December 26, 2027. The Sandoz Notice Letter was the first Paragraph IV notice letter received from an ANDA filer for CARDENE I.V.

By filing suit to enforce our patents within 45 days from our receipt of the Exela Notice Letter and the Sandoz Notice Letter, under the Hatch-Waxman Act, the FDA may not approve Exela s or Sandoz s generic applications for a period of 30 months from our receipt of the corresponding notice letter, or until an earlier court decision adverse to our patents. We cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Merger-Related Litigation

Since the announcement of the execution of the Chiesi Merger Agreement, four lawsuits challenging the Chiesi Merger have been filed in the Delaware Court of Chancery. Each of the Delaware lawsuits is a putative class action filed on behalf of our stockholders other than the defendants and their affiliates. In each case the complaint names as defendants us, our directors, Chiesi and Chiesi US and alleges that our directors and Chiesi breached their fiduciary duties in connection with their approval of the Merger Agreement and that either we, Chiesi or Chiesi US aided and abetted those breaches. Each complaint seeks, among other relief, declaratory and injunctive relief enjoining the Merger and/or compensatory damages in an unspecified amount. The four complaints have been consolidated into a single action by court order, but the plaintiffs have not yet filed a consolidated amended complaint.

The outcome of these lawsuits is uncertain. An adverse judgment for money damages against us could have an adverse effect on our operations and liquidity. A preliminary injunction could delay or jeopardize the completion of the Merger, and an adverse judgment granting permanent injunctive relief could indefinitely enjoin completion of the Chiesi Merger. We and our directors believe that the claims asserted against us in the lawsuits are without merit.

Table of Contents

ITEM 1A.*RISK FACTORS*

We operate in a rapidly changing environment that involves a number of risks that could materially and adversely affect our business, financial condition, prospects, operating results or cash flows. For a detailed discussion of the risk factors that should be understood by any investor contemplating an investment in our stock, please refer to Item 1A of our annual report on Form 10-K for the year ended December 31, 2012, which was filed with the SEC on March 14, 2013. There have been no material changes from the risk factors previously disclosed in that annual report on Form 10-K, other than as described below.

Our announcement of, and compliance with, the Chiesi Merger Agreement could adversely affect us.

The Chiesi Merger may not be completed in a timely manner or at all. Our entry into the Chiesi Merger Agreement, including uncertainties regarding whether or when the Chiesi Merger will occur and the effect of the completion of or failure to complete the Chiesi Merger, may negatively impact:

our business and prospects by causing management to devote attention to completing the Chiesi Merger instead of focusing on our day-to-day operations and implementing our short- and long-term growth strategies;

our ability to pursue certain business opportunities or take other actions that otherwise could be beneficial to us because of the significant restrictions imposed under the Chiesi Merger Agreement on the conduct of our business prior to the completion of the Chiesi Merger;

our results of operations and financial condition due to the substantial expenses that we have incurred and will continue to incur in connection with the Chiesi Merger, most of which are payable regardless of whether the Chiesi Merger is completed; and

our ability to retain existing, or attract new personnel.

ITEM 6. *EXHIBITS*

The exhibits listed in the accompanying exhibit index are filed as part of this quarterly report on Form 10-Q, and such exhibit index is incorporated by reference herein.

Table of Contents

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.

CORNERSTONE THERAPEUTICS INC.

Date: November 7, 2013

/s/ Craig Collard
Craig Collard
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2013

/s/ Alastair McEwan
Alastair McEwan
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

Date: November 7, 2013

/s/ Ira Duarte
Ira Duarte
Senior Director, Accounting and Financial Planning and Analysis
(Principal Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger among Chiesi Farmaceutici S.p.A, Chiesi U.S. Corporation and the Registrant dated September 15, 2013 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated September 15, 2013).
3.1	Fifth Amended and Restated Bylaws of the Registrant dated September 15, 2013 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated September 15, 2013).
10.1	Voting Agreement between Chiesi Farmaceutici S.p.A, Chiesi U.S. Corporation, the Registrant, Craig A. Collard and Cornerstone Biopharma Holdings, Ltd. dated September 15, 2013.
10.2	Description of Special Committee Compensation.
10.3	Form of Restricted Stock Agreement granted under the 2004 Stock Incentive Plan (for awards granted on or after September 15, 2013).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant s quarterly report on Form 10-Q for the quarter ended September 30, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Consolidated Balance Sheets, (ii) the Unaudited Consolidated Statements of Comprehensive Income (Loss), (iii) the Unaudited Consolidated Statements of Cash Flows, and (iv) Notes to Unaudited Consolidated Financial Statements.