

CORNERSTONE THERAPEUTICS INC

Form 10-Q

May 09, 2013

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**Form 10-Q**

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

For the Quarterly Period Ended March 31, 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)

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<b>Delaware</b> (State or Other Jurisdiction of Incorporation or Organization)	<b>04-3523569</b> (I.R.S. Employer Identification No.)
<b>1255 Crescent Green Drive, Suite 250</b>  <b>Cary, North Carolina</b> (Address of Principal Executive Offices)	<b>27518</b> (Zip Code)
<b>(919) 678-6611</b> (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  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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  (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

As of May 2, 2013, the registrant had 26,802,150 shares of Common Stock, \$0.001 par value per share, outstanding.

**Table of Contents**

**CORNERSTONE THERAPEUTICS INC.**

**FORM 10-Q**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	<b>3</b>
<b><u>Cautionary Statement Regarding Forward-Looking Statements</u></b>	<b>3</b>
Item 1. <b><u>Financial Statements</u></b>	<b>4</b>
<b><u>Consolidated Balance Sheets as of March 31, 2013 (Unaudited) and December 31, 2012</u></b>	<b>4</b>
<b><u>Consolidated Statements of Comprehensive Income (Loss) for the Three Months Ended March 31, 2013 and 2012 (Unaudited)</u></b>	<b>5</b>
<b><u>Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2013 and 2012 (Unaudited)</u></b>	<b>6</b>
<b><u>Notes to Consolidated Financial Statements (Unaudited)</u></b>	<b>7</b>
Item 2. <b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>21</b>
Item 3. <b><u>Quantitative and Qualitative Disclosures about Market Risk</u></b>	<b>31</b>
Item 4. <b><u>Controls and Procedures</u></b>	<b>31</b>
<b><u>PART II OTHER INFORMATION</u></b>	<b>31</b>
Item 1. <b><u>Legal Proceedings</u></b>	<b>31</b>
Item 1A. <b><u>Risk Factors</u></b>	<b>32</b>
Item 2. <b><u>Unregistered Sales of Securities and Use of Proceeds</u></b>	<b>33</b>
Item 6. <b><u>Exhibits</u></b>	<b>33</b>
<b><u>SIGNATURES</u></b>	<b>34</b>
<b><u>EXHIBIT INDEX</u></b>	<b>35</b>

---

**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, expect, intend, may, plan, project, should, target, will, or would to convey uncertainty of future events or 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; our ability to replace the revenues from products we no longer market; 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 LIXAR® and RETAVASE®; our ability to successfully and effectively launch our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product and BETHKIS®; 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; 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.

**Table of Contents****ITEM 1. FINANCIAL STATEMENTS****CORNERSTONE THERAPEUTICS INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share data)**

	<b>March 31, 2013 (Unaudited)</b>	<b>December 31, 2012 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 63,392	\$ 56,250
Accounts receivable, net	16,672	14,368
Inventories, net	9,808	11,384
Prepaid expenses	4,374	3,343
Income tax receivable	450	4,094
Deferred tax asset	2,593	1,614
Acquisition-related current assets	9,655	11,134
Other current assets	221	379
<b>Total current assets</b>	<b>107,165</b>	<b>102,566</b>
Property and equipment, net	1,489	1,310
Product rights, net	227,956	232,111
Goodwill	33,180	33,356
Other assets	32	32
<b>Total assets</b>	<b>\$ 369,822</b>	<b>\$ 369,375</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 11,904	\$ 12,439
Accrued expenses	36,920	37,379
Acquisition-related contingent payments	7,156	6,846
Acquisition-related current liabilities	8,053	9,636
Other current liabilities	641	525
<b>Total current liabilities</b>	<b>64,674</b>	<b>66,825</b>
Acquisition-related contingent payments, less current portion	27,288	26,362
Long-term debt	89,566	89,540
Deferred tax liability	14,110	15,683
Other long-term liabilities	4,553	4,792
<b>Total liabilities</b>	<b>200,191</b>	<b>203,202</b>
Commitments and contingencies, Note 11		
Stockholders equity		
Preferred stock \$0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
	26	26

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Common stock \$0.001 par value, 90,000,000 shares authorized; 26,426,811 and 26,348,470 shares issued and outstanding as of March 31, 2013 and December 31, 2012, respectively		
Additional paid-in capital	168,504	167,461
Retained earnings (accumulated deficit)	1,101	(1,314)
Total stockholders' equity	169,631	166,173
Total liabilities and stockholders' equity	\$ 369,822	\$ 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)**

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Net revenues	\$ 37,980	\$ 22,161
Costs and expenses:		
Cost of product sales (exclusive of amortization of product rights)	12,157	8,686
Selling, general and administrative	13,117	10,922
Research and development	827	1,045
Amortization of product rights	4,155	5,301
Change in acquisition-related contingent payments	2,398	
Transaction-related expenses	683	742
Other operating expenses, net		(1,492)
Total costs and expenses	33,337	25,204
Income (loss) from operations	4,643	(3,043)
Other expenses, net:		
Interest expense, net	(1,663)	(2)
Other income (expense), net	529	
Total other expenses	(1,134)	(2)
Income (loss) before income taxes	3,509	(3,045)
(Provision for) benefit from income taxes	(1,094)	1,220
Net income (loss)	\$ 2,415	\$ (1,825)
Comprehensive income (loss)	\$ 2,415	\$ (1,825)
Net income (loss) per share, basic	\$ 0.09	\$ (0.07)
Net income (loss) per share, diluted	\$ 0.09	\$ (0.07)
Weighted-average common shares, basic	26,364,035	25,817,185
Weighted-average common shares, diluted	30,972,585	25,817,185

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)**

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 2,415	\$ (1,825)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Amortization and depreciation	4,340	5,455
Amortization of debt costs	26	
Provision for prompt payment discounts	1,110	664
Provision for other receivables	23	
Provision for inventory allowances	1,572	12
Acquisition accounting adjustment on inventory sold	29	
Gain on sale of product rights		(1,492)
Change in acquisition-related contingent payments	2,398	
Stock-based compensation	668	675
Deferred revenue		(608)
Deferred income taxes	932	(1,222)
Changes in operating assets and liabilities:		
Accounts receivable	(3,368)	(2,770)
Inventories	(25)	(325)
Prepaid expenses and other assets	(1,031)	1,424
Accounts payable, accrued expenses, and other liabilities	(891)	(2,796)
Acquisition-related current assets and liabilities	31	(1,000)
Income taxes receivable	160	1,099
Net cash provided by (used in) operating activities	8,389	(2,709)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(364)	(80)
Proceeds from sale of product rights		3,000
Net cash (used in) provided by investing activities	(364)	2,920
<b>Cash flows from financing activities</b>		
Proceeds from exercise of common stock options	382	23
Excess tax benefit from stock-based compensation		38
Payments related to net settlement of restricted stock	(7)	(24)
Acquisition-related contingent payments	(1,229)	
Principal payments on capital lease obligation	(29)	(17)
Net cash (used in) provided by financing activities	(883)	20
Net increase in cash and cash equivalents	7,142	231
<b>Cash and cash equivalents as of beginning of period</b>	<b>56,250</b>	<b>73,968</b>



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<b>Cash and cash equivalents as of end of period</b>	\$ 63,392	\$ 74,199
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The accompanying notes are an integral part of the consolidated financial statements.

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**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**

Transaction-related expenses previously included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive income (loss) are separately disclosed. Transaction-related expenses consist of (i) costs incurred to complete product or company acquisitions or other strategic transactions, including due diligence and legal, consulting and other related fees; (ii) integration costs related to completed transactions; and (iii) transaction-related fees associated with transactions that are not consummated. 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). These reclassifications had no effect on net loss as previously reported.

**Going-Private Proposal**

On February 18, 2013, the Company's Board of Directors received a proposal from Chiesi Farmaceutici S.p.A., the owner of approximately 60% 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. The Company's Board of Directors has formed a Special Committee comprised of five independent directors to coordinate the Company's response to this proposal.

**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-month period ended March 31, 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, 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 March 31, 2013, the majority of the Company's cash deposits were not federally insured.

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## **Table of Contents**

### **Accounts Receivable**

The Company typically requires its customers to remit payments within the first 30 to 35 days, 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%, 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 \$360,000 and \$320,000 as of March 31, 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 March 31, 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 months ended March 31, 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 and certain products prior to regulatory approval and product launch, based on management's judgment of probable future commercial use and net realizable value. Capitalization of this 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 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 March 31, 2013, inventories included \$773,000 of costs capitalized as raw materials prior to regulatory approval of the Supplemental Biologics License Application ( sBLA ) for RETAVASE. 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. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. Other intangibles including product rights and acquired in-process research and development ( IPR&D ) are capitalized and recorded at fair value.

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 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. The Company's 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 license and royalty agreement revenues. The following table sets forth the categories of the Company's net revenues (in thousands):

	Three Months Ended March 31,	
	2013	2012
Gross product sales	\$ 56,554	\$ 34,186
Sales allowances	(18,574)	(12,029)
Net product sales	37,980	22,157
License and royalty agreement revenues		4
Net revenues	\$ 37,980	\$ 22,161

The Company records all of its revenue from product sales, license agreements and royalty agreements 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, 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.

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*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® 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. 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% as an incentive to remit payments within the first 30 to 35 days after the invoice date depending on the customer and the products purchased.

## ***License and Royalty Agreement Revenues***

Payments from the Company's licensees are recognized as revenue based on the nature of the arrangement (including its contractual terms), the nature of the payments and applicable accounting guidance. Non-refundable fees where the Company has no continuing performance obligations are recognized as revenues 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.

## **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.





**Table of Contents**

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 March 31, 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.

The following table presents a reconciliation of contingent consideration obligations measured on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2013 (in thousands):

	December 31, 2012	Issuances	Payments (1)	Adjustments (2)	March 31, 2013
Acquisition-related contingent consideration (3)	\$ 33,208	\$	\$ (1,229)	\$ 2,465	\$ 34,444

- (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.



**Table of Contents*****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 three months ended March 31, 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, subject to customary post-closing adjustments, 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	\$ 126,437
Acquisition-related contingent consideration	37,788
<b>Total fair value of consideration</b>	<b>\$ 164,225</b>

**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, as shown above, 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 quarter of 2013 and the as adjusted allocations of the total fair value (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		14,682
Identifiable intangibles	154,123		154,123
Deferred tax assets	35,079		35,079
Accounts payable	(2,690)		(2,690)
Accrued liabilities	(29,515)	130	(29,385)
Deferred tax liability related to intangibles acquired	(65,735)		(65,735)
Total identifiable net assets	\$ 146,087	\$ 176	\$ 146,263
Goodwill	18,138	(176)	17,962
Total fair value of consideration	\$ 164,225	\$	\$ 164,225

- (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 quarter of 2013 primarily reflect changes in accounts receivables, net and accrued liabilities. 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 believes that the above information provides a reasonable basis for estimating the fair values but is waiting for additional information necessary to finalize the amount of goodwill, including potential post-closing working capital adjustments that existed at the closing date. Thus, the Company's provisional measurement of goodwill is subject to change.

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 determined 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 March 31, 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 initially recorded indemnification assets of \$3.2 million and indemnification liabilities of \$9.9 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 measurement period adjusted balances

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are reflected on the accompanying consolidated balance sheet as of March 31, 2013. The Company expects the full amount of the liabilities related to these matters to be 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 March 31, 2013 as discussed above in Note 2. The Company will continue to evaluate these liabilities for remeasurement at the end of each reporting

**Table of Contents**

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.

Goodwill was calculated as the difference between the fair value of the consideration and the preliminary values assigned to the assets acquired and liabilities assumed. The goodwill allocation is expected to be finalized during 2013 as the Company finalizes any potential post-closing working capital adjustments that existed at the closing date. None of the goodwill will be deductible for tax purposes.

In connection with the acquisition, during the three months ended March 31, 2013 and 2012, the Company incurred \$124,000 and \$189,000, 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).

**NOTE 4: INVENTORY**

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

	March 31, 2013	December 31, 2012
Raw materials	\$ 4,400	\$ 3,561
Work in process	2,392	2,920
Finished goods:		
Pharmaceutical products - trade	6,134	6,991
Pharmaceutical products - samples	2	25
Total	12,928	13,497
Inventory allowances	(3,120)	(2,113)
Inventories, net	\$ 9,808	\$ 11,384

**NOTE 5: GOODWILL AND INTANGIBLE ASSETS****Goodwill**

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

**Table of Contents****Product Rights**

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

	March 31, 2013			Weighted-Average Amortization Period (yrs.)
	Gross Carrying Amount	Accumulated Amortization	Net Amount	
CUROSURF®	\$ 107,606	\$ 36,302	\$ 71,304	15.0
ZYFLO®	11,500	7,087	4,413	7.1
CARDENE I.V.	131,556	6,675	124,881	15.0
RETAVASE	26,858		26,858	n/a
Other	575	75	500	n/a
Total	\$ 278,095	\$ 50,139	\$ 227,956	14.6

	December 31, 2012			Weighted-Average Amortization Period (yrs.)
	Gross Carrying Amount	Accumulated Amortization	Net Amount	
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 seven to fifteen years. As of March 31, 2013, the Company had \$27.4 million of product rights related to RETAVASE and its Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product, both of which are expected to be launched in the future. The rights will be amortized over the product candidates' estimated useful lives.

**NOTE 6: ACCRUED EXPENSES**

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

	March 31, 2013	December 31, 2012
Accrued product returns	\$ 14,813	\$ 13,629
Accrued rebates	1,958	1,766
Accrued price adjustments and chargebacks	8,658	9,651
Accrued compensation and benefits	2,213	3,022
Accrued royalties	2,806	3,487
Accrued research and development	1,453	1,300
Accrued co-promotion	1,624	2,330
Accrued expenses, other	3,395	2,194



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Total accrued expenses	\$ 36,920	\$ 37,379
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**Table of Contents**

**NOTE 7: LONG TERM DEBT**

**Term Loans A and B**

On June 21, 2012, the Company entered into a credit agreement (the *Credit Agreement*) with Chiesi in connection with its acquisition of EKR. The *Credit Agreement* governs the senior secured term loan facility with Chiesi (the *Term Loan Facility*), which is comprised of a five-year Term Loan A of \$60.0 million and a five-year Term Loan B of \$30.0 million (the *Term Loans*). The *Term Loans* were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. The proceeds of the *Term Loan Facility* were used, together with the Company's cash on hand, to finance the acquisition of EKR and the related fees and expenses incurred by the Company in connection with the acquisition. All obligations under the *Term Loan Facility* 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. Under the *Credit Agreement*, Chiesi is the administrative agent and collateral agent in respect of the *Term Loan Facility*.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears on the last business day of each fiscal quarter beginning on September 28, 2012. Term Loan A requires quarterly principal payments of \$3.5 million commencing on the fiscal quarter ending December 31, 2014 with any remaining balance due at maturity. Term Loan B principal is payable at maturity. The *Term Loans* are due and payable on June 23, 2017, unless previously prepaid or, in the case of Term Loan B, converted into shares of common stock, prior to such date.

The Company may prepay the *Term Loans*, in whole or in part without any premium or penalty, provided any prepayments of principal amounts are \$5.0 million or whole multiples of \$1.0 million in excess thereof, plus any accrued and unpaid interest. The prepayments will be applied first, ratably to the remaining installments of principal of the *Term Loan A* (excluding the payment due at maturity), second, to any remaining amounts outstanding on *Term Loan A*, and third, to the outstanding principal on *Term Loan B*.

The Company is required to prepay all or a portion of the *Term Loan Facility* under the following conditions: (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*.

*Term Loan B* contains a conversion option for a two-year period, expiring on June 21, 2014, which provides Chiesi the option, exercisable in its sole discretion, to convert all or a portion of the *Term Loan B* into shares of common stock at a conversion price equal to \$7.098 per share, subject to adjustment under certain conditions. Conversions shall be no less than \$5.0 million unless the remaining principal amount of *Term Loan B* is less than \$5.0 million.

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 *Term Loan Facility* 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.

**Table of Contents**

The following table summarizes information on the Term Loans as of March 31, 2013 (in thousands):

	Maturity Date	March 31, 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		(286)
Net carrying amount		59,714
Term Loan B (6.5% interest payable quarterly and principal payable upon maturity, with conversion option through June 21, 2014)	June 2017	
Principal amount		30,000
Unamortized debt financing costs		(148)
Net carrying amount		29,852
Total debt, carrying amount		89,566
Less: current portion		
Total long-term debt, carrying amount		\$ 89,566

**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.

There were 0 and 69,478 stock options granted and exercised, respectively, during the three months ended March 31, 2013.

As of March 31, 2013, the aggregate intrinsic value of options outstanding and exercisable was \$4.6 million and \$3.6 million, respectively.

As of March 31, 2013, there was \$2.4 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.09 years.

**Restricted Stock**

During the three months ended March 31, 2013, 230,500 shares of restricted stock were issued and 10,080 shares vested. As of March 31, 2013, there were 361,830 restricted common shares outstanding and approximately \$2.1 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 2.98 years.

**Stock-Based Compensation Expense**

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately \$668,000 and \$675,000 for the three months ended March 31, 2013 and 2012, respectively.

**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 months ended March 31, 2013 and 2012 was 31.2% and (40.1)%, 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. The effective tax rate was also impacted by a change in the Company's treatment of its 2012 NOLs, which resulted in the Company recording a discrete item that reduced the effective tax rate for the first quarter of 2013 by 14.0 percentage points.

**Table of Contents**

As of March 31, 2013 and December 31, 2012 the Company had provided a valuation allowance related to federal NOL carryforwards 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 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 2009 through 2011 tax years of the Company are open to examination by federal and state tax authorities. Currently Cardiokine Inc. ( Cardiokine ) and EKR are under audit by the federal authorities. EKR is also currently under audit in the state of New Jersey. The Company is fully indemnified by the former shareholders and participating equityholders of EKR and Cardiokine, respectively, for any losses related to audits by federal and state tax authorities for pre-acquisition periods.

There were no changes in unrecognized tax positions for the three months ended March 31, 2013. As of March 31, 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):

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Numerator:</b>		
Net income (loss)	\$ 2,415	\$ (1,825)
Interest on convertible debt, net of tax effects	341	
Net income (loss) used to calculate diluted earnings per share	\$ 2,756	\$ (1,825)
<b>Denominator:</b>		
Weighted-average common shares, basic	26,364,035	25,817,185
Dilutive effect of stock options and restricted stock	382,008	
Dilutive effect of convertible debt	4,226,542	
<b>Weighted-average common shares, diluted</b>	<b>30,972,585</b>	<b>25,817,185</b>
Net income (loss) per share, basic	\$ 0.09	\$ (0.07)
Net income (loss) per share, diluted	\$ 0.09	\$ (0.07)
Anti-dilutive weighted-average shares	1,371,299	2,045,152

As of March 31, 2013 and 2012, there were 361,830 and 199,100 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 \$143,000 and \$234,000 for the three months ended March 31, 2013 and 2012,

respectively.

**Supply Agreements**

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately \$63.9 million as of March 31, 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

## **Table of Contents**

payments and the timing of those payments may differ from management's estimates. As of March 31, 2013, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately \$32.4 million.

### **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 March 31, 2013 and 2012, total royalty expenses were \$1.2 million and \$1.6 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 \$8.4 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 product candidates currently in its portfolio following their commercialization.

As of March 31, 2013, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately \$823,000.

### **Additional Consideration for the 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 NDA for its lixivaptan compound, LIXAR, 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. During 2012, the Company determined the fair value of the contingent liability was zero. During the three months ended March 31, 2012, 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 grants a third party the exclusive right to promote and sell ZYFLO CR and ZYFLO 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.

As of March 31, 2013, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately \$5.7 million.





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## **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 March 31, 2013, the Company had \$12,000 recorded as accrued severance related to the departure of one of its executive officers in 2012.

### **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 our business, consolidated financial condition, results of operations or cash flows.

### **NOTE 12: RELATED PARTY TRANSACTIONS**

Chiesi, the Company's majority stockholder, manufactures all of the Company's requirements for CUROSURF 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 \$6.5 million for the three months ended March 31, 2013. As of March 31, 2013, the Company had accounts payable of \$2.7 million due to Chiesi.

As discussed in Note 7, on June 21, 2012, the Company entered into the Term Loan Facility with Chiesi in connection with its acquisition of EKR. The Term Loan Facility, which is governed by 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 March 31, 2013, the net carrying value of the Term Loans was \$89.6 million, net of capitalized unamortized debt financing costs. During the three months ended March 31, 2013, the Company paid \$1.5 million of interest expense less withholding tax to Chiesi related to the Term Loans. There was no accrued interest payable due to Chiesi as of March 31, 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 product in the United States. BETHKIS is an FDA-approved inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. 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.

### **NOTE 13: SUBSEQUENT EVENTS**

On May 9, 2013, the Company and Digestive Care, Inc. (DCI), entered into a License and Distribution Agreement pursuant to which the Company 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 will make an initial payment of which a portion is earmarked to satisfy certain outstanding obligations of DCI. The Company will be required to make minimum investments in promotion during the first three years of the initial term and pay quarterly royalties based on a percentage of net sales in addition to 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 provide 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.

### **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.



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**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.

***First Quarter 2013 Highlights***

The following summarizes certain key financial measures for the three months ended March 31, 2013:

Net product sales were \$38.0 million for the first quarter of 2013 compared to \$22.2 million for the three months ended March 31, 2012, representing 71% year-over-year growth;

When calculated in accordance with accounting principles generally accepted in the United States, or GAAP, income from operations was \$4.6 million for the three months ended March 31, 2013 compared to a loss of \$3.0 million for the three months ended March 31, 2012 and net income was \$2.4 million for the three months ended March 31, 2013 compared to a loss of \$1.8 million for the three months ended March 31, 2012;

On a non-GAAP basis, income from operations increased \$10.4 million to \$12.6 million and net income increased \$5.8 million to \$7.1 million for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012;

and

Cash and cash equivalents were \$63.4 million at March 31, 2013.

***Opportunities and Trends***

We continue to promote CARDENE® I.V. and CUROSURF® with our hospital-based sales force and are managing the life cycle of ZYFLO CR®. We believe that the addition of RETAVASE®, if approved, to our product portfolio 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 addition, we continue to expand our product portfolio by acquiring or in-licensing products, including our recent license of PERTZYE®, a unique pancreatic enzyme replacement therapy drug product. PERTZYE is a U.S. Food and Drug Administration, or FDA, approved product indicated for the treatment of Exocrine Pancreatic Insufficiency due to cystic fibrosis. The addition of PERTZYE to our product portfolio complements our launch of BETHKIS® planned for later this year.

As we focus on the growth of our existing products and 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. In

**Table of Contents**

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:

acquiring products and companies in the hospital and adjacent specialty markets;

growing revenue from our existing product portfolio;

integrating PERTZYE into our product portfolio;

launching BETHKIS pursuant to our license agreement with Chiesi Farmaceutici S.p.A., or Chiesi;

launching our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product, which we expect to be distributed by Aristos; and

progressing toward validation of a new active pharmaceutical ingredient supplier and certain manufacturing process changes to allow for FDA approval and re-launch of RETAVASE.

***Going-Private Proposal***

On February 18, 2013, our Board of Directors received a proposal from Chiesi, the owner of approximately 60% of the outstanding shares of our common stock, 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. Our Board of Directors has formed a Special Committee comprised of five independent directors to coordinate our response to this proposal.

**Table of Contents****Results of Operations****Comparison of the Three Months Ended March 31, 2013 and 2012**

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

	<b>Three Months Ended March 31,</b>		<b>Change</b>	
	<b>2013</b>	<b>2012</b>	<b>\$</b>	<b>%</b>
<i>Net product sales</i>				
CARDENE I.V. product family	\$ 13,839	\$	\$ 13,839	100%
CUROSURF	9,520	7,613	1,907	25
ZYFLO® product family	14,624	12,448	2,176	17
Other products	(3)	2,096	(2,099)	(100)
Total net product sales	37,980	22,157	15,823	71
<i>License and royalty agreement revenues</i>		4	(4)	(100)
Net revenues	37,980	22,161	15,819	71
Cost of product sales (exclusive of amortization of product rights)	12,157	8,686	3,471	40
Selling, general and administrative	13,117	10,922	2,195	20
Research and development	827	1,045	(218)	(21)
Amortization of product rights	4,155	5,301	(1,146)	(22)
Change in acquisition-related contingent payments	2,398		2,398	100
Transaction-related expenses	683	742	(59)	(8)
Other operating expenses, net		(1,492)	1,492	100
Income (loss) from operations	4,643	(3,043)	7,686	NM
Total other expenses, net	(1,134)	(2)	(1,132)	NM
Income (loss) before income taxes	3,509	(3,045)	6,554	NM
(Provision for) benefit from income taxes	(1,094)	1,220	(2,314)	NM
Net income (loss)	\$ 2,415	\$ (1,825)	\$ 4,240	NM
Net income (loss) per share, diluted	\$ 0.09	\$ (0.07)	\$ 0.16	NM
Non-GAAP income from operations (1)	\$ 12,576	\$ 2,183	\$ 10,393	476
Non-GAAP net income (1)	\$ 7,105	\$ 1,307	\$ 5,798	444
Non-GAAP net income per share, diluted (1)	\$ 0.24	\$ 0.05	\$ 0.19	380

(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.*

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CARDENE I.V. net product sales were \$13.8 million during the three months ended March 31, 2013. We acquired the CARDENE I.V. product rights in our acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc. (collectively EKR ), on June 26, 2012.

CUROSURF net product sales increased \$1.9 million, or 25%, during the three months ended March 31, 2013 compared to the three months ended March 31, 2012, primarily due to increased unit volume, coupled with decreases in our estimated rates for chargebacks and price adjustments.

ZYFLO CR and ZYFLO net product sales increased \$2.2 million, or 17%, during the three months ended March 31, 2013 compared to the three months ended March 31, 2012, primarily driven by price increases, partially offset by a decline in unit volume and an increase in fees payable to distributor.

**Table of Contents**

Net product sales from other products decreased \$2.1 million during the three months ended March 31, 2013 compared to the three months ended March 31, 2012, primarily due to our divestiture of the product rights and certain related assets and liabilities in early March 2012.

***Costs and Expenses***

*Cost of Product Sales.* Cost of product sales (exclusive of amortization of product rights of \$4.2 million and \$5.3 million for the three months ended March 31, 2013 and 2012, respectively) increased \$3.5 million, or 40%, during the three months ended March 31, 2013 compared to the three months ended March 31, 2012 primarily due to the addition of CARDENE I.V. to our product portfolio, coupled with first quarter 2013 inventory obsolescence charges related to ZYFLO. 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 license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	<b>Three Months Ended</b>		<b>March 31,</b>		<b>Change</b>	
	<b>2013</b>	<b>2012</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Net product sales	\$ 37,980	\$ 22,157	\$		\$	