

BIOMARIN PHARMACEUTICAL INC

Form 10-Q

May 01, 2008

[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2008

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: 000-26727

BioMarin Pharmaceutical Inc.

(Exact name of registrant issuer as specified in its charter)

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Delaware (State of other jurisdiction of Incorporation or organization)	68-0397820 (I.R.S. Employer Identification No.)
105 Digital Drive, Novato, California (Address of principal executive offices)	94949 (Zip Code)
Registrant's telephone number: (415) 506-6700	
(Former name, former address and former fiscal year, if changed since last report)	

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

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

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

Applicable only to issuers involved in bankruptcy proceedings during the proceeding five years:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 98,550,824 shares common stock, par value \$0.001, outstanding as of April 24, 2008.

Table of Contents

BIOMARIN PHARMACEUTICAL INC.

TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. <u>Consolidated Financial Statements (Unaudited)</u>	3
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
Item 3. <u>Quantitative and Qualitative Disclosure about Market Risk</u>	26
Item 4. <u>Controls and Procedures</u>	27
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	27
Item 1A. <u>Risk Factors</u>	27
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
Item 3. <u>Defaults Upon Senior Securities</u>	28
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	28
Item 5. <u>Other Information</u>	28
Item 6. <u>Exhibits</u>	28
<u>SIGNATURE</u>	29

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Consolidated Financial Statements
BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(In thousands, except for share and per share data)**

	December 31, 2007 (1)	March 31, 2008 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 228,343	\$ 319,990
Short-term investments	357,251	254,772
Accounts receivable, net	16,976	47,253
Advances to BioMarin/Genzyme LLC	2,087	323
Inventory	32,445	54,736
Other current assets	7,195	6,654
Total current assets	644,297	683,728
Investment in BioMarin/Genzyme LLC	44,881	905
Property, plant and equipment, net	76,818	95,732
Intangible assets, net	9,596	8,420
Goodwill	21,262	21,262
Restricted cash	2,889	4,547
Other assets	15,536	13,108
Total assets	\$ 815,279	\$ 827,702
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 49,907	\$ 42,367
Current portion of acquisition obligation, net of discount	6,309	6,065
Deferred revenue	5,327	4,879
Total current liabilities	61,543	53,311
Convertible debt	497,375	497,300
Long-term portion of acquisition obligation, net of discount	66,553	66,156
Other long-term liabilities	2,082	1,769
Total liabilities	627,553	618,536
Stockholders' equity:		
Common stock, \$0.001 par value: 250,000,000 shares authorized at December 31, 2007 and March 31, 2008; 97,114,159 and 98,450,912 shares issued and outstanding at December 31, 2007 and March 31, 2008, respectively	97	98
Additional paid-in capital	794,917	814,458
Accumulated other comprehensive income	139	351
Accumulated deficit	(607,427)	(605,741)

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Total stockholders' equity	187,726	209,166
Total liabilities and stockholders' equity	\$ 815,279	\$ 827,702

- (1) December 31, 2007 balances were derived from the audited consolidated financial statements.
See accompanying notes to unaudited consolidated financial statements.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****For the Three Months Ended March 31, 2007 and 2008****(In thousands, except for per share data, unaudited)**

	Three Months Ended March 31,	
	2007	2008
Revenues:		
Net product revenues	\$ 18,334	\$ 57,625
Collaborative agreement revenues	4,147	2,465
Royalty and license revenues	357	306
Total revenues	22,838	60,396
Operating expenses:		
Cost of sales	4,117	17,188
Research and development	18,159	17,628
Selling, general and administrative	16,258	23,669
Amortization of acquired intangible assets	1,093	1,093
Total operating expenses	39,627	59,578
Income (Loss) from operations	(16,789)	818
Equity in the income (loss) of BioMarin/Genzyme LLC	6,163	(533)
Interest income	3,694	5,649
Interest expense	(2,335)	(4,110)
Income (loss) before income taxes	(9,267)	1,824
Provision for income taxes	26	138
Net income (loss)	\$ (9,293)	\$ 1,686
Net income (loss) per share, basic	\$ (0.10)	\$ 0.02
Net income (loss) per share, diluted	\$ (0.10)	\$ 0.02
Weighted average common shares outstanding, basic	94,557	97,647
Weighted average common shares outstanding, diluted	94,557	103,869

See accompanying notes to unaudited consolidated financial statements.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****For the Three Months Ended March 31, 2007 and 2008****(In thousands, unaudited)**

	Three Months Ended March 31,	
	2007	2008
Cash flows from operating activities		
Net income (loss)	\$ (9,293)	\$ 1,686
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,036	3,870
Amortization of discount on short-term investments	(2,193)	(2,839)
Imputed interest on acquisition obligation	1,146	1,108
Equity in the (income) loss of BioMarin/Genzyme LLC	(6,163)	533
Stock-based compensation	3,815	5,210
Loss on disposals and impairments of property and equipment	9	
Unrealized foreign exchange gain on forward contracts	(21)	(161)
Changes in operating assets and liabilities:		
Accounts receivable	145	(30,277)
Advances to BioMarin/Genzyme LLC	782	1,764
Inventory	(2,363)	4,474
Other current assets	(443)	541
Other assets	(524)	(143)
Accounts payable and accrued liabilities	(6,817)	(7,681)
Other liabilities	401	143
Deferred revenue	(1,664)	(448)
Net cash used in operating activities	(20,147)	(22,220)
Cash flows from investing activities		
Purchase of property, plant and equipment	(3,235)	(19,889)
Maturities and sales of short-term investments	130,250	254,556
Purchase of short-term investments	(103,358)	(149,025)
Distributions from BioMarin/Genzyme LLC	6,000	16,679
Settlement of forward contracts	(32)	(959)
Net cash provided by investing activities	29,625	101,362
Cash flows from financing activities		
Proceeds from ESPP and exercise of stock options	1,440	14,255
Repayment of acquisition obligation	(1,750)	(1,750)
Net cash provided by (used in) financing activities	(310)	12,505
Effect of foreign currency translation on cash	1	
Net increase in cash and cash equivalents	9,169	91,647
Cash and cash equivalents:		

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Beginning of period	89,162	228,343
End of period	\$ 98,331	\$ 319,990

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2008

(Unaudited)

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin[®]) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin received marketing approval for Naglazyme[®] (galsulfase) in the U.S. in May 2005, and in the E.U. in January 2006. Aldurazyme[®] (laronidase) has been approved in the U.S and E.U. and is marketed by Genzyme Corporation (Genzyme). Effective January 2008, the Company restructured its relationship with Genzyme as discussed in Note 4. In December 2007, Kuvan[®] (sapropterin dihydrochloride) received marketing approval in the U.S. The Company is incorporated in the state of Delaware.

Through March 31, 2008, the Company had accumulated losses of approximately \$605.7 million. Management believes that the Company's cash, cash equivalents and short-term investments at March 31, 2008 will be sufficient to meet the Company's obligations for the foreseeable future based on management's current long-term business plans and assuming that the Company achieves its long-term goals. If the Company elects to increase its spending on development programs significantly above current long-term plans or enter into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance net future cash needs primarily through its current cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners. In April 2007, the Company raised approximately \$316.4 million in net proceeds from a public offering of senior subordinated convertible debt due in 2017. The proceeds are intended to fund future business development transactions and for general corporate purposes.

The Company is subject to a number of risks, including the financial performance of Naglazyme, Kuvan, and Aldurazyme; the potential need for additional financings; its ability to successfully commercialize its product candidates, if approved; the uncertainty of the Company's research and development efforts resulting in successful commercial products; obtaining regulatory approval for such products; significant competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; dependence on corporate partners and collaborators; and possible restrictions on reimbursement, as well as other changes in the health care industry.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

These unaudited consolidated financial statements include the accounts of BioMarin and its wholly owned subsidiaries. All significant intercompany transactions have been eliminated. These unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and the Securities and Exchange Commission (SEC) requirements for interim reporting. However, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. (U.S. GAAP) for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included.

Operating results for the three months ended March 31, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. These consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2007, included in the Company's Annual Report on Form 10-K.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(c) Cash and Cash Equivalents

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The Company treats liquid investments with original maturities of less than three months when purchased as cash and cash equivalents.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2008

(Unaudited)

(d) Short-Term Investments

The Company records its investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investments are recorded at fair market value, with unrealized gains or losses being included in accumulated other comprehensive income (loss). Short-term investments are comprised mainly of corporate securities, commercial paper, repurchase agreements, federal agency investments and money market funds. As of March 31, 2008, the Company had no held-to-maturity investments.

(e) Inventory

The Company values inventories at the lower of cost or net realizable value. The Company determines the cost of inventory using the average cost method. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales.

United States regulatory approval for Kuvan was received in December 2007, and manufacturing costs for this product prior to this date were expensed as research and development expenses. The Company considers regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for Kuvan prior to regulatory approval were not capitalized as inventory. When regulatory approval was obtained, the Company began capitalizing inventory at the lower of cost or net realizable value.

In the first quarter of 2008, the Company received \$26.8 million of inventory distributed by the Company's joint venture with Genzyme pursuant to the terms of the joint venture restructuring (See Note 4 for further information). The inventory distribution was recorded at the historical production cost, which represented the lower of cost or market value.

Stock-based compensation of \$0.4 was capitalized into inventory in the three months ended March 31, 2007 and \$0.9 million was capitalized into inventory in the three months ended March 31, 2008. See Note 5 for further information on inventory balances as of December 31, 2007 and March 31, 2008.

(f) Investment in and Advances to BioMarin/Genzyme LLC and Equity in the Income (Loss) of BioMarin/Genzyme LLC

Effective January 1, 2008, the Company restructured its relationship with Genzyme (See Note 4 for further information). The Company accounts for its remaining investment in the joint venture using the equity method. Accordingly, the Company records an increase in its investment for contributions to the joint venture and for its 50% share of the income of the joint venture, and a reduction in its investment for its 50% share of any losses of the joint venture or disbursements of profits from the joint venture. Equity in the Income (Loss) of BioMarin/Genzyme LLC includes the Company's 50% share of the joint venture's loss/income for the period. Advances to BioMarin/Genzyme LLC include the current receivable from the joint venture for the reimbursement related to services provided to the joint venture by the Company during the most recent month, and the investment in BioMarin/Genzyme LLC includes the Company's share of the net equity of the joint venture.

(g) Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the related estimated useful lives, except for leasehold improvements, which are depreciated over the shorter of the useful life of the asset or the lease term. Significant additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Property and equipment purchased for specific research and development projects with no alternative uses are expensed as incurred. See Note 6 for further information on property, plant and equipment balances as of March 31, 2007 and 2008.

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Certain of the Company's operating lease agreements include scheduled rent escalations over the lease term, as well as tenant improvement allowances. The Company accounts for these operating leases in accordance with SFAS No. 13, *Accounting for Leases*, and FASB Technical Bulletin No. 85-3, *Accounting for Operating Leases with Scheduled Rent Increases*. Accordingly, the scheduled increases in rent expense are recognized on a straight-line basis over the lease term. The difference between rent expense and rent paid is recorded as deferred rent and included in other liabilities in the accompanying consolidated balance sheets. The tenant improvement allowances are recognized as a credit to rent expense over the lease term on a straight-line basis.

(h) Revenue Recognition

The Company recognizes revenue in accordance with the provisions of SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104), and Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. The Company's revenues consist of net product revenues from Naglazyme and Kuvan and, starting January 1, 2008, Aldurazyme, revenues from its collaborative agreement with Merck Serono and other license and royalty revenues. Milestone payments are recognized in full when the related milestone performance goal is achieved and the Company has no future performance obligations related to that payment.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2008

(Unaudited)

Net Product Revenue The Company recognizes net product revenue from Aldurazyme, Naglazyme and Kuvan when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Product sales transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) related to Naglazyme sales in foreign jurisdictions, are presented on a net basis in the Company's statements of operations, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*.

The Company began recognizing revenue related to Aldurazyme in the first quarter of 2008 effective with the restructuring of the Company's Aldurazyme joint venture with Genzyme (See Note 4 for further information). According to the terms of the joint venture restructuring, BioMarin receives a 39.5 to 50 percent royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenue in the consolidated statements of operations. In addition, the Company recognizes product transfer revenue when product is shipped to Genzyme. The amount of product transfer revenue will eventually be deducted from royalties earned when the product is sold by Genzyme. The Company records the Aldurazyme royalty revenue based on net sales information provided by Genzyme and records product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with SAB 104 and the terms of the related agreements with Genzyme. As of March 31, 2008, accounts receivable included \$9.5 million of unbilled accounts receivable related to Aldurazyme product transfers to Genzyme.

The Company sells Naglazyme worldwide and sells Kuvan in the U.S. In the U.S., Naglazyme and Kuvan are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. In the E.U., Naglazyme is sold to the Company's authorized European distributors or directly to hospitals, which act as the end users. Additionally, the Company receives revenue from named patient sales of Naglazyme in other countries, which are generally made to local distributors. Because of the pricing of Naglazyme and Kuvan, the limited number of patients and the customers' limited return rights, Naglazyme and Kuvan customers and retailers generally carry a very limited inventory. Accordingly, the Company expects that sales related to Naglazyme and Kuvan will be closely tied to end-user demand.

The Company records reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product sales are recorded. The Company's reserve calculations require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions each period, and records any necessary adjustments to its reserves. The Company records fees paid to distributors as a reduction of revenue, in accordance with EITF Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor's Products)*.

The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including market exclusivity of the products based on their orphan drug status, the patient population, the customers' limited return rights and the Company's experience with returns. Genzyme's return rights for Aldurazyme are generally limited to product defects. Based on these factors, management has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required. The Company maintains a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of March 31, 2008, the Company has experienced no bad debts and had no allowance for doubtful accounts.

Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue. Nonrefundable up-front license fees where the Company has continuing involvement through research and development collaboration are initially deferred and recognized as collaborative agreement license revenue over the estimated period for which the Company continues to have a performance obligation. The Company estimates that its performance obligation related to the \$25.0 million upfront payment from Merck Serono will end in the fourth quarter of 2008. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono's share of Kuvan development costs under the agreement, which are recorded as research and development expenses. Allowable costs during the development period must have been included in the pre-approved annual budget in order to be subject to reimbursement, or must be separately approved by both parties.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)**

Collaborative agreement revenues during the first quarter of 2007 and 2008 include \$1.8 million and \$1.5 million, respectively, of the up-front license fee received from Merck Serono recognized as revenue and \$2.3 million and \$1.0 million of reimbursable Kuvan development costs incurred during the first quarter of 2007 and 2008, respectively.

Royalty and license revenues Royalty revenue includes royalties on net sales of products with which the Company has no direct involvement and is recognized based on data reported by licensees or sublicensees. Royalties are recognized as earned in accordance with the contract terms, when the royalty amount is fixed or determinable based on information received from the sublicensee and when collectibility is reasonably assured.

Royalty and license revenues include royalty revenues from Orapred product sold by the sublicensee of \$0.3 in each of the first quarters of 2007 and 2008. There is no cost of sales associated with the royalty and license revenues recorded during the periods and no related costs are expected in future periods.

(i) Research and Development

Research and development expenses include expenses associated with contract research and development provided by third parties, product manufacturing prior to regulatory approval, clinical and regulatory costs, and internal research and development costs. In instances where the Company enters into agreements with third parties for research and development activities, costs are expensed upon the earlier of when goods are received or as services are performed. The accounting for amounts due under arrangements that include upfront payments and payments upon the completion of milestones are evaluated based on the nature of the underlying service and whether there is an alternative future use in other research and development projects. When non-refundable amounts are paid in advance of future services, the cost is capitalized and expensed as the services are performed. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the activities.

(j) Net Income (Loss) Per Share

Basic net income/loss per share is calculated by dividing net income/loss by the weighted average shares of common stock outstanding during the period. Diluted net income/loss per share reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted in to common stock; however, potential common equivalent shares are excluded if their effect is anti-dilutive. Potential shares of common stock include shares issuable upon the exercise of outstanding employee stock option awards, common stock issuable under our Employee Stock Purchase Plan and contingent issuances of common stock related to convertible debt and acquisition obligation payable. For the three months ended March 31, 2007, such potential shares of common stock were excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Potentially dilutive securities for the three months ended March 31, 2007 include (in thousands):

	March 31, 2007
Options to purchase common stock	10,280
Common stock issuable under convertible debt	10,404
Portion of acquisition payable in common stock at the option of the Company	498
Potentially issuable common stock for ESPP purchases	146
Total	21,328

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The following represents a reconciliation from basic weighted shares outstanding to diluted weighted shares outstanding and the earnings per share for the three months ended March 31, 2008 (in thousands, except per share data):

	For the Three Months Ended March 31, 2008		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per-Share Amount
Basic Earnings Per Share:			
Net Income	\$ 1,686	97,647	\$ 0.02
Effect of Dilutive Shares:			
Stock options using the treasury method		5,637	
Portion of acquisition payable in common stock at the option of the Company		243	
Potentially issuable restricted stock		85	
Potentially issuable common stock for ESPP purchases		257	
Diluted Earnings Per Share:			
Net Income	\$ 1,686	103,869	\$ 0.02

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2008

(Unaudited)

Options to purchase approximately 0.3 million shares of common stock were outstanding during the first quarter of 2008 but were not included in the computation of diluted earnings per share because they were anti-dilutive during the period using the treasury stock method. Additionally, approximately 26.4 million of the underlying shares of the Company's convertible debt were not included in the diluted average common shares outstanding because they were antidilutive during the period using the if-converted method whereby the related interest expense on the convertible debt is added to net income for the period.

(k) Stock-Based Compensation

Stock-based compensation is accounted for in accordance with SFAS No. 123R, *Share-Based Payment* and related interpretations. Under the fair value recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating future stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and results of operations could be materially impacted.

Expected volatility is based upon proportionate weightings of the historical volatility of the Company's stock and the implied volatility of traded options on the Company's stock. The expected life of options is based on observed historical exercise patterns, which can vary over time.

As stock-based compensation expense recognized in the consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience.

If factors change and different assumptions are employed in the application of SFAS No. 123R, the compensation expense recorded in future periods may differ significantly from what was recorded in the current period. See Note 3 for further discussion of the Company's accounting for stock-based compensation.

(l) Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred taxes are determined based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded to reduce deferred tax assets to the amount that is more likely than not to be realized. There was a full valuation allowance against net deferred tax assets of \$294.4 million at December 31, 2007, which remained at March 31, 2008. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease income in the period such adjustment was made. For the three months ended March 31, 2007 and 2008 the Company recognized \$26,000 and \$0.1 million of income tax expense related to income earned in certain of the Company's international subsidiaries, respectively. Despite the Company's earning net income during the first quarter of 2008, the Company's analysis under FASB Interpretation No. 18, *Accounting for Income Taxes In Interim Periods (An Interpretation of APB Opinion No. 28)*, resulted in a projected ordinary loss for 2008 due to the exclusion of uncertain development milestone revenue and other permanent differences between book and tax income. Therefore the Company has not recorded current U.S. Federal or state income tax expense and has not adjusted the valuation allowance against net deferred tax assets.

(m) Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board released Statement of Financial Accounting Standards (SFAS) No. 141(R), *Business Combinations*. This Statement applies prospectively to business combinations for which the acquisition date is on or after the

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

beginning of the first annual reporting period beginning on or after December 15, 2008, which would impact business combinations in the year ending December 31, 2009 for the Company. The objective of this Statement is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. The effect of this statement on the Company's consolidated financial position, results of operations or cash flows will depend on the potential future business combinations entered into by the Company that will be subject to the statement.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)**

In December 2007, the Financial Accounting Standards Board released SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51*. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, which for the Company is the year ending December 31, 2009, and the interim periods within that fiscal year. Management does not expect the adoption of SFAS 160 to have a material effect on the Company's consolidated financial position, results of operations or cash flows.

(n) Accumulated Other Comprehensive Income

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss, such as changes in unrealized gains and losses on the Company's available-for-sale securities and changes in the Company's cumulative foreign currency translation account. Comprehensive loss for the three months ended March 31, 2007 and 2008 is included in the Company's consolidated statements of stockholders' equity. There were no tax effects allocated to any components of other comprehensive income during the first quarter of 2007 or 2008.

Comprehensive income was approximately \$1.9 million for the three months ended March 31, 2008 and comprehensive loss was approximately \$9.3 million for the three months ended March 31, 2007, and included the following changes in accumulated other comprehensive income (in thousands):

	Three Months Ended March 31,	
	2007	2008
Net unrealized gain on available-for-sale securities	\$ 20	\$ 213
Net foreign currency translation loss		(1)
Other comprehensive income	\$ 20	\$ 212

(o) Reclassifications

Certain items in the prior years' consolidated financial statements have been reclassified to conform to the current presentation.

(3) STOCK-BASED COMPENSATION

BioMarin records compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123R, *Share Based Payment*, as interpreted by SAB No. 107. Effective January 1, 2006, BioMarin adopted the modified prospective transition method provided for under SFAS No. 123R, and consequently has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (1) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123; and (2) amortization related to all restricted stock and stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. In addition, the Company records expense related to shares issued under its employee stock purchase plan over the offering period.

The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the requisite service period of the options using the straight-line method. Benefits of tax deductions in excess of recognized compensation costs are recorded as a financing cash inflow rather than as a reduction of taxes paid. For the three months ended March 31, 2008, net excess tax benefits recognized

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

from option exercises were insignificant due to the Company's valuation allowance. The Company evaluated the need to record a cumulative effect adjustment for estimated forfeitures upon the adoption of SFAS No. 123R and determined the amount to be insignificant. Pursuant to the income tax provisions included in SFAS 123R, the Company has elected the long method of computing its hypothetical additional paid-in capital pool.

Stock-based compensation expense for the three months ended March 31, 2008 totaled \$4.5 million, of which \$2.7 million was included in selling, general and administrative expense, \$1.6 million was included in research and development expense and \$0.2 million was included in cost of sales. Stock-based compensation expense for the three months ended March 31, 2007 totaled \$3.6 million, of which \$2.1 million was included in selling, general and administrative expense, \$1.3 million was included in research and development expense and \$0.2 million was included in cost of sales. Stock-based compensation of \$0.4 million and \$0.9 million was capitalized into inventory for the three months ended March 31, 2007 and 2008, respectively, and will be recognized as cost of sales when the related product is sold.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)****Share Incentive Plan**

BioMarin's 2006 Share Incentive Plan, which was approved in June 2006 and replaces the Company's previous stock option plans for new grants, provides for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date, as well as other forms of equity compensation, such as restricted stock units. As of March 31, 2008, awards issued under the 2006 Share Incentive Plan include both stock options and restricted stock units. Stock option awards generally vest over a four-year period on a cliff basis six months after the grant date and then monthly thereafter. The term of the outstanding options is generally ten years. Options assumed under past business acquisitions generally vest over periods ranging from immediately upon grant to five years from the original grant date and have terms ranging from two to ten years. Restricted stock units granted to employees generally vest in four equal annual tranches on each anniversary of the grant date. Restricted stock units granted to directors generally vest in full one year after the grant date.

The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the table below. The expected life of options is based on observed historical exercise patterns. Groups of employees that have similar historical exercise patterns were considered separately for valuation purposes, but none were identified that had distinctly different exercise patterns as of March 31, 2008. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of BioMarin stock and the implied volatility of traded options on the Company's stock for fiscal periods in which there is sufficient trading volume in options on the Company's stock. The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that BioMarin has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

Stock Option Valuation Assumptions	Three Months Ended March 31,	
	2007	2008
Expected volatility	48.28%	44.68%
Dividend yield	0.0%	0.0%
Expected life	5.2 years	5.2 years
Risk-free interest rate	4.68%	2.76%

The Company recorded \$3.6 million and \$4.5 million of compensation expense related to current period vesting of stock options for the three months ended March 31, 2007 and 2008, respectively, recognized in accordance with SFAS No. 123R. As of March 31, 2008, there was \$44.6 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 2.8 years.

A summary of stock option activity under all plans, including plans that were suspended upon adoption of the 2006 Share Incentive Plan, for the three months ended March 31, 2008 is presented as follows:

Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Options Granted	Weighted	Aggregate Intrinsic Value (in thousands)
			Remaining Contractual Term (Years)	

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Balance as of December 31, 2007	11,413,452	\$	13.65		
Granted	262,637	\$	36.78	\$	15.98
Exercised	(1,330,275)	\$	10.69		\$ 35,418
Expired and Forfeited	(98,656)	\$	16.88		
Balance as of March 31, 2008	10,247,158	\$	14.59	7.5	\$ 213,448
Options expected to vest at March 31, 2008	4,519,041	\$	16.81	9.1	\$ 84,289
Exercisable as of March 31, 2008	4,659,569	\$	11.93	6.4	\$ 109,233

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock as of the end of the period. There were 10.0 million options that were in-the-money at March 31, 2008. The aggregate intrinsic value of options exercised was determined as of the date of option exercise.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)**

An initial option is granted to each new outside member of BioMarin's Board of Directors to purchase 30,000 shares of common stock at the fair value on the date of the grant. On the date of each annual meeting of stockholders, other than newly elected directors, each outside director is granted options for the purchase of 15,000 shares of common stock and 2,500 restricted stock units. The options vest over one year and have a term of ten years. The restricted stock units vest on the anniversary of the date of grant.

A summary of non-vested restricted stock unit activity under the plan for the three months ended March 31, 2008 is presented as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested units as of December 31, 2007	116,625	\$ 17.39
Granted	8,500	36.07
Vested		
Forfeited		
Non-vested units as of March 31, 2008	125,125	\$ 18.66

The Company recorded \$0.1 million of compensation expense related to restricted stock units for the three months ended March 31, 2008, recognized in accordance with SFAS No. 123R. There were no restricted stock unit grants prior to the second quarter of 2007 and therefore no compensation expense was recognized related to restricted stock units in previous periods. As of March 31, 2008, there was \$1.7 million of total unrecognized compensation cost related to unvested restricted stock units. These costs are expected to be recognized over a weighted average period of 3.1 years.

At March 31, 2008, an aggregate of approximately 11.3 million unissued shares were authorized for future issuance under the Company's stock plans, which include shares issuable under the Company's 2006 Share Incentive Plan and the Company's Employee Stock Purchase Plan. Awards under the 2006 Share Incentive Plan that expire or are cancelled without delivery of shares generally become available for issuance under the plan. Awards that expire or are cancelled under the Company's suspended 1997 Stock Plan or 1998 Director Option Plan may not be reissued.

Employee Stock Purchase Plan

Under BioMarin's Employee Stock Purchase Plan, which was approved in June 2006 and replaces the Company's previous plan, U.S. employees meeting specific employment qualifications are eligible to participate and can purchase shares on established dates semi-annually through payroll deductions at the lower of 85% of the fair market value of the stock at the commencement or each purchase date of the offering period. Each offering period will span up to two years. The Employee Stock Purchase Plan permits eligible employees to purchase common stock through payroll deductions for up to 10% of qualified compensation, up to an annual limit of \$25,000. The Employee Stock Purchase Plan has been treated as a compensatory plan. The Company recorded compensation expense of \$0.1 million and \$0.3 million related to the Employee Stock Purchase Plan in the three months ended March 31, 2007 and 2008, respectively.

The fair value of each award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the table below. The expected volatility of Employee Stock Purchase Plan shares is based on the implied volatility of traded options on the Company's stock for periods in which there is sufficient trading volume in those options. Otherwise, historical volatility is utilized. The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

yield reflects that BioMarin has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

Employee Stock Purchase Plan	Three Months Ended March 31,	
	2007	2008
Expected volatility	44 to 54%	44 to 54%
Dividend yield	0.0%	0.0%
Expected life	6-24 months	6-24 months
Risk-free interest rate	3.9 to 5.2%	3.8 to 5.2%

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)****(4) JOINT VENTURE**

Effective January 2008, the Company and Genzyme restructured BioMarin/Genzyme LLC. Under the revised structure, the operational responsibilities for BioMarin and Genzyme did not significantly change, as Genzyme will continue to globally market and sell Aldurazyme and BioMarin will continue to manufacture Aldurazyme. As of January 1, 2008, instead of sharing all costs and profits equally through the 50/50 joint venture, Genzyme will record sales of Aldurazyme to third party customers and will pay BioMarin a tiered payment ranging from approximately 39.5 to 50 percent of worldwide net product sales depending on sales volume, which will be recorded by BioMarin as product revenue. In addition, the Company recognizes product transfer revenue when product is shipped to Genzyme. The amount of product transfer revenue will eventually be deducted from royalties earned when the product is sold by Genzyme. Certain research and development activities related to Aldurazyme and intellectual property will continue to be managed in the joint venture with the costs shared equally by BioMarin and Genzyme. Pursuant to the terms of the joint venture restructuring, the Company received distributions of \$16.7 million of cash and \$26.8 million of inventory from the joint venture in the first quarter of 2008.

The Company will also present the related cost of sales and its Aldurazyme-related operating expenses as operating expenses in the consolidated statements of operations. Equity in the loss of BioMarin/Genzyme LLC subsequent to the restructuring will include BioMarin's 50% share of the net loss of BioMarin/Genzyme LLC related to intellectual property management and ongoing research and development activities. The results of the joint venture's operations for the three months ended March 31, 2007 and 2008, are presented in the table below (in thousands).

	Three Months Ended	
	March 31,	
	2007	2008
Net Product Sales	\$ 26,822	\$
Cost of goods sold	6,302	
Gross profit	20,520	
Operating expenses	8,366	1,122
Income (loss) from operations	12,154	(1,122)
Other income	171	57
Net income (loss)	\$ 12,325	\$ (1,065)
Equity in the income (loss) of BioMarin/Genzyme LLC	\$ 6,163	\$ (533)

At March 31, 2008, the summarized assets and liabilities of the joint venture and the components of the Company's investment in the joint venture are as follows (in thousands):

	December 31,	March 31,
	2007	2008
Assets	\$ 98,340	\$ 2,871
Liabilities	(8,577)	(1,061)

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Net equity	\$ 89,763	\$ 1,810
Investment in BioMarin/Genzyme LLC (50% share of net equity)	\$ 44,881	\$ 905

The critical accounting policies of BioMarin/Genzyme LLC relevant to its operations prior to the restructuring are discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)****(5) SUPPLEMENTAL BALANCE SHEET INFORMATION**

As of December 31, 2007 and March 31, 2008, accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31, 2007	March 31, 2008
Accounts payable	\$ 1,169	\$ 2,326
Accrued accounts payable	27,377	21,232
Accrued vacation	2,820	3,427
Accrued compensation	9,931	5,835
Accrued interest and taxes	2,533	2,885
Accrued royalties	1,329	2,024
Other accrued expenses	1,154	1,688
Accrued rebates	1,816	2,109
Acquired rebates and returns reserve	743	697
Returns reserve	61	20
Short-term portion of deferred compensation liability	859	
Current portion of deferred rent	115	124
	\$ 49,907	\$ 42,367

As of December 31, 2007 and March 31, 2008, other long-term liabilities consisted of the following (in thousands):

	December 31, 2007	March 31, 2008
Long-term portion of deferred rent	\$ 1,635	\$ 1,165
Long-term portion of deferred compensation liability	447	604
Total other long-term liabilities	\$ 2,082	\$ 1,769

As of December 31, 2007 and March 31, 2008, inventory consisted of the following (in thousands):

	December 31, 2007	March 31, 2008
Raw materials	\$ 5,716	\$ 8,401
Work in process	14,413	9,585
Finished goods	12,316	36,750
Total inventory	\$ 32,445	\$ 54,736

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

As of December 31, 2007 and March 31, 2008, short-term investments consisted of the following (in thousands):

	December 31, 2007	March 31, 2008
Corporate securities	\$ 88,225	\$ 51,053
Commercial paper	259,222	190,979
U.S. Government agency securities	9,804	12,740
 Total short-term investments	 \$ 357,251	 \$ 254,772

(6) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2007 and March 31, 2008, consisted of (in thousands):

Category	December 31, 2007	March 31, 2008	Estimated Useful Lives
Leasehold improvements	\$ 33,583	\$ 27,076	Shorter of life of asset or lease term
Building and improvements	26,784	47,073	20 years
Manufacturing and laboratory equipment	19,403	21,148	5 years
Computer hardware and software	9,657	10,562	3 years
Office furniture and equipment	3,991	3,994	5 years
Land	4,259	10,056	Not applicable
Construction-in-progress	13,952	12,915	Not applicable
	\$ 111,629	\$ 132,824	
Less: Accumulated depreciation	(34,811)	(37,092)	
 Total property, plant and equipment, net	 \$ 76,818	 \$ 95,732	

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2008

(Unaudited)

Depreciation for the three months ended March 31, 2007 and 2008 was, \$1.7 million and \$2.4 million, respectively, of which \$0.4 and \$0.6 million was capitalized into inventory, respectively.

Capitalized interest related to the Company's fixed asset purchases during the three months ended March 31, 2007 and 2008 was insignificant.

In January 2008, the Company purchased its previously leased office building located at 300 Bel Marin Keys Drive and retained ownership of all leasehold improvements made to the property. The purchase price of the facility was approximately \$12.0 million, of which \$11.5 million was paid in cash in January 2008 and a \$0.5 million deposit was paid in 2007. As a result of the purchase, the Company capitalized certain pre-existing deferred rent liabilities of approximately \$0.5 million as a reduction to the acquisition cost of the building.

(7) CONVERTIBLE DEBT

In April 2007, the Company sold approximately \$324.9 million of senior subordinated convertible notes due on April 23, 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of Company common stock at a conversion price of approximately \$20.36 per share, subject to adjustment in certain circumstances. There is no call provision included and the Company is unable to unilaterally redeem the debt prior to maturity on April 23, 2017. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the April 2007 debt, the Company paid approximately \$8.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt, and the Company recognized \$0.2 million of amortization expense during the three months ended March 31, 2008.

In March 2006, the Company sold \$172.5 million of senior subordinated convertible debt due on March 29, 2013. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of Company common stock at a conversion price of approximately \$16.58 per share, subject to adjustment in certain circumstances. There is no call provision included and the Company is unable to unilaterally redeem the debt prior to maturity in 2013. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock. During the first quarter of 2008, certain note holders voluntarily exchanged \$0.1 million of convertible notes for shares of the Company's common stock.

In connection with the placement of the 2006 debt, the Company paid approximately \$5.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt, and the Company recognized \$0.2 million of amortization expense during each of the three months ended March 31, 2007 and 2008.

Interest expense for the three months ended March 31, 2007 and 2008 was, \$2.3 million and \$4.1 million, respectively, and each period included \$1.1 million in imputed interest expense related to the Company's acquisition obligation.

(8) DERIVATIVE FINANCIAL INSTRUMENTS

The Company periodically enters into foreign currency forward contracts, which have a maturity of less than one year. At March 31, 2008, the Company had net outstanding foreign exchange forward contracts to sell \$16.2 million, comprised of sell contracts of \$17.0 million of equivalent Euros and \$5.0 million of equivalent British Pounds and buy contracts of \$5.8 million of equivalent Euros, all of which have a term of less than 3 months. The notional settlement value of all foreign currency forward contracts outstanding as of December 31, 2007 was \$12.9 million.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)**

None of the Company's forward exchange contracts are designated as hedges under SFAS No. 133. As a result, the fair value changes of all contracts are reported in earnings as foreign exchange gain or loss. For the three months ended March 31, 2008, approximately \$1.1 million of net loss has been included in the Company's consolidated statement of operations with respect to these forward exchange contracts, as compared to \$48,000 for the three months ended March 31, 2007.

(9) SUPPLEMENTAL CASH FLOW INFORMATION

The following significant non-cash transactions took place in the periods presented (in thousands):

	Three Months Ended March 31,	
	2007	2008
Conversion of 3.5% convertible notes due 2008	\$ 51,440	\$
Distribution of inventory resulting from the joint venture restructure		26,780
Deferred offering costs reclassified to additional paid in capital as a result of the conversion of a portion of notes due in 2008	512	
Change in accrued payables related to fixed asset additions	(460)	1,261
Stock-based compensation capitalized into inventory	416	944

Cash paid for interest for each of the three months ended March 31, 2007 and 2008 was \$2.2 million.

Cash paid for income taxes for the three months ended March 31, 2007 and 2008 was \$0 and \$0.1 million, respectively.

(10) FINANCIAL INSTRUMENTS CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. All cash, cash equivalents, and short-term investments are placed in financial institutions with strong credit ratings, which minimizes the risk of loss due to nonpayment. Accounts receivable as of March 31, 2008 related to net product sales of Naglazyme and Kuvan and Aldurazyme product transfer and royalty revenues. A significant portion of net product sales are made to a limited number of financially viable specialty pharmacies and distributors. The Company's two largest customers accounted for 49% and 13% of Naglazyme net product sales, respectively. The Company's three largest customers accounted for 32%, 20% and 19% of Kuvan net product sales. Genzyme accounted for all of the Aldurazyme net product revenues. For the first quarter of 2008, net product sales of Naglazyme were \$5.1 million from customers based in the U.S. and \$22.6 million from customers based outside of the U.S., as compared to \$4.2 million and \$14.2 million for the first quarter of 2007, respectively. All net product sales of Kuvan were from customers based in the U.S. during the first quarter of 2008. Significant specific concentrations of the Company's total net product sales include net product sales of Naglazyme related to sales in Germany and France totaling \$5.3 million and \$3.3 million, respectively, for the three months ended March 31, 2008, and \$5.0 million and \$2.0 million, respectively, for the year ended March 31, 2007.

The Company does not require collateral from its customers, but performs periodic credit evaluations of its customers' financial condition and requires immediate payment in certain circumstances. The Company has not experienced any significant losses related to its financial instruments and management does not believe a significant credit risk existed at March 31, 2008.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2008****(Unaudited)**

In the first quarter of 2008, the Company adopted SFAS No. 157, Fair Value Measurements for financial assets and liabilities. SFAS No. 157 utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. Level 1 involves observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 involves inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly, which include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active. Level 3 involves unobservable inputs that reflect the reporting entity's own assumptions. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income and equity securities, other equity securities and foreign currency derivatives. The table below presents the fair value of these certain financial assets and liabilities determined using the inputs defined at March 31, 2008, by SFAS No. 157. In February 2008, the FASB issued FASB FSP 157-2 which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The partial adoption of SFAS No. 157 for financial assets and liabilities did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

	Fair Value Measurements (in thousands) at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Fixed income available-for-sale ⁽¹⁾	\$ 554,962	\$	\$ 554,962	\$
Foreign currency derivatives ⁽²⁾	65		65	
Total	\$ 555,027	\$	\$ 555,027	\$
Liabilities:				
Foreign currency derivatives ⁽³⁾	83		83	
Total	\$ 83	\$	\$ 83	\$

⁽¹⁾ Included in short-term investments on the Company's consolidated balance sheet.

⁽²⁾ Included in other assets on the Company's consolidated balance sheet.

⁽³⁾ Included in accrued expenses on the Company's consolidated balance sheet.

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Fixed income available-for-sale securities primarily include money market funds (48% of total), commercial paper (34% of total) and corporate bonds (9 % of total). Included in fixed income available-for-sale securities is approximately \$300.1 million of cash equivalents. Cash equivalents consist of \$32.6 million in instruments with original maturities of three months or less at the date of purchase. The remaining balance of cash equivalents consists primarily of money market funds, for which the carrying amount is a reasonable estimate of fair value.

Foreign currency derivatives include forward foreign exchange contracts for the Euro and the British Pound.

Table of Contents**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
Forward-Looking Statements**

This Form 10-Q contains forward-looking statements as defined under securities laws. Many of these statements can be identified by the use of terminology such as believes, expects, anticipates, plans, may, will, projects, continues, estimates, potential, opportunity and risk. These forward-looking statements may be found in Overview, and other sections of this Form 10-Q. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in Risk Factors, in our Form 10-K for the year ended December 31, 2007 as well as those discussed elsewhere in this Form 10-Q. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these statements, which speak only as of the date that they were made. These cautionary statements should be considered in connection with any written or oral forward-looking statements that we may issue in the future. We do not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Form 10-Q to reflect later events or circumstances, or to reflect the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the notes thereto appearing elsewhere in this quarterly report.

Overview

We develop and commercialize innovative biopharmaceuticals for serious diseases and medical conditions. We select product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market. Our product portfolio is comprised of three approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme, and Kuvan. Additionally, we have rights to receive royalties related to Orapred® and Orapred ODT®.

Naglazyme received marketing approval in the U.S. in May 2005 and in the E.U. in January 2006. Naglazyme net product sales for the first quarter of 2007 totaled \$18.4 million and increased to \$27.7 million for the first quarter of 2008.

Aldurazyme has been approved for marketing in the U.S., E.U., Japan and in other countries. Prior to 2008, we developed and commercialized Aldurazyme through a joint venture with Genzyme. Effective January 2008, we restructured our relationship with Genzyme whereby Genzyme sells Aldurazyme to third parties and we recognize royalty revenue on net sales by Genzyme. In addition, we recognize product transfer revenue when product is shipped to Genzyme. The amount of product transfer revenue will eventually be deducted from royalties earned when the product is sold by Genzyme. Our Aldurazyme net product revenue for the first quarter of 2008 totaled \$24.1 million.

Kuvan was granted marketing approval in the U.S. in December 2007. Kuvan net product sales for the first quarter of 2008 were \$5.8 million.

We are developing several product candidates for the treatment of genetic diseases including: PEG-PAL, a preclinical enzyme substitution therapy for the treatment of PKU for patients that are not responsive to Kuvan. We are also developing 6R-BH4, the active ingredient in Kuvan, for the treatment of certain cardiovascular indications including peripheral arterial disease and sickle cell disease, as well as other indications.

Key components of our results of operations for the three months ended March 31, 2007 and 2008, include the following (in thousands):

	Three Months Ended March 31,	
	2007	2008
Total net product revenues	\$ 18,334	\$ 57,625
Collaborative agreement revenue	4,147	2,465
Research and development expense	18,159	17,628
Selling, general and administrative expense	16,258	23,669
Net income (loss)	(9,293)	1,686
Orapred acquisition-related expenses	2,239	2,201
Stock-based compensation expense	3,564	4,464

See *Results of Operations* for discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, and short-term investments totaled \$574.8 million as of March 31, 2008 compared to \$585.6 million as of December 31, 2007.

Table of Contents

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates" in our 2007 Form 10-K. Additional information regarding updates to our policies for Aldurazyme Revenue Recognition are included below. There have been no significant changes to our other critical accounting policies or estimates since December 31, 2007.

Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104: *Revenue Recognition*, and Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Our revenues consist of Naglazyme and Kuvan product sales during 2007 and 2008, Aldurazyme product transfer and royalty revenues starting with the first quarter of 2008, revenues from our collaborative agreement with Merck Serono and revenues from our Orapred sublicense agreement.

We began recognizing revenue related to Aldurazyme in the first quarter of 2008 effective with the restructuring of our joint venture with Genzyme (See Note 4 to the Consolidated Financial Statements for further information). According to the terms of the joint venture restructuring, we receive a 39.5 to 50 percent royalty on worldwide net Aldurazyme sales by Genzyme, which is included in net product revenue in the consolidated statements of operations. In addition, we recognize product transfer revenue when product is shipped to Genzyme. The amount of product transfer revenue will eventually be deducted from royalties earned when the product is sold by Genzyme. In periods where BioMarin shipments of Aldurazyme to Genzyme exceed quantities sold to third parties by Genzyme, we will report incremental product transfer revenue. In periods where Genzyme sales to third parties exceed quantities shipped by BioMarin to Genzyme, we will report net product revenue representing the royalty from Genzyme related to current period sales by Genzyme less the previously recognized product transfer revenue related to the net decrease in Aldurazyme quantities at Genzyme. We record the Aldurazyme royalty revenue based on net sales information provided by Genzyme and recognize product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with SAB 104 and the terms of the related agreements with Genzyme.

We rely on Genzyme's revenue recognition policies and procedures with respect to net sales reporting and our recording of Aldurazyme royalty revenue. Our experience with the commercial aspects of Aldurazyme through BioMarin/Genzyme LLC and our relationship with Genzyme provide a reasonable basis to place such reliance on Genzyme and to make our own internal judgments and estimates regarding Aldurazyme revenue recognition. Genzyme's historical judgments and estimates have been accurate and have not changed significantly over time.

We understand that Genzyme recognizes revenue from Aldurazyme product sales when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. The timing of product shipment and receipts can have a significant impact on the amount of Aldurazyme royalty revenue that we recognize in a particular period. Also, Aldurazyme is sold in part through distributors. Inventory in the distribution channel consists of inventory held by distributors, and inventory held by retailers, such as pharmacies and hospitals. Aldurazyme royalty revenue in a particular period can be impacted by increases or decreases in distributor inventories. If distributor inventories increased to excessive levels, we could experience reduced royalty revenue in subsequent periods. To determine the amount of Aldurazyme inventory in the U.S. distribution channel, we understand that Genzyme receives data on sales and inventory levels directly from its primary distributors for the product.

Recent Accounting Pronouncements

See Note 2(m) of our accompanying consolidated financial statements for a full description of recent accounting pronouncements and our expectation of their impact on our results of operations and financial condition.

Results of Operations

Net Loss

Our net income for the first quarter of 2008 increased by \$11.0 million, to \$1.7 million, from a loss of \$9.3 million for the first quarter of 2007. Net income for the first quarter of 2008 increased primarily as a result of the following (in millions):

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Net loss for the first quarter of 2007	\$ (9.3)
Increased Naglazyme gross profit	7.9
Increased Kuvan gross profit	5.1
Increased Aldurazyme gross profit	13.2
Decreased collaborative agreement revenues	(1.7)
Decreased research and development expense	0.5
Increased selling, general and administrative expense	(7.4)
Increased losses from BioMarin/Genzyme LLC	(6.7)
Increased interest income	2.0
Increased interest expense	(1.8)
Increase in corporate overhead and other	(0.1)
Net income for the first quarter of 2008	\$ 1.7

Table of Contents

The increase in Naglazyme gross profit during the first quarter of 2008 as compared to the first quarter of 2007 is primarily the result of additional patients initiating Naglazyme therapy in the U.S., E.U. and other countries. The increase in Kuvan gross profit during the first quarter of 2008 as compared to the first quarter of 2007 is due to the December 2007 approval to sell Kuvan in the U.S. The increase in Aldurazyme gross profit during the first quarter of 2008 as compared to the first quarter of 2007 is the result of restructuring the joint venture with Genzyme and is partially offset by increased losses from BioMarin/Genzyme LLC also due to the restructuring. The decrease in collaborative agreement revenues primarily relates to lower reimbursable Kuvan development expenses. The increase in selling, general and administrative expense was primarily due to the continued international expansion of Naglazyme and commercialization of Kuvan in the United States. See below for additional information related to the primary net loss fluctuations presented above, including details of our operating expense fluctuations.

Net Product Revenue and Gross Profit

Net product revenue increased \$39.3 million to \$57.6 million in the first quarter of 2008 from \$18.3 million in the first quarter of 2007 driven by increased Naglazyme, Aldurazyme and Kuvan sales. Net product revenue in the first quarter of 2008 included \$27.7 million of net product sales of Naglazyme, \$24.1 million of net product revenue of Aldurazyme and \$5.8 million of net product sales of Kuvan. Net product sales in the first quarter of 2007 of \$18.3 million included \$18.4 million of net product sales of Naglazyme which was partially offset by \$0.1 million of Orapred net product returns. We expect net product revenues to increase in future periods, primarily due to additional patients initiating therapy.

Net product sales for Naglazyme in the first quarter of 2008 were \$27.7 million, of which \$22.6 million was from customers based outside of the U.S. The impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. was approximately \$1.7 million in the first quarter of 2008. Gross profit from Naglazyme in the first quarter of 2008 was approximately \$22.2 million, representing gross margins of approximately 80% as compared to \$14.2 million in the first quarter of 2007, representing gross margins of approximately 78%. The increase in gross margin is attributable to both improved manufacturing yields and the foreign exchange benefits discussed above.

Prior to the restructuring of BioMarin/Genzyme LLC effective January 2008, we did not record Aldurazyme revenue and instead recorded our share of the net profits from the joint venture. As a result of the restructuring of the joint venture, we record a 39.5 to 50 percent royalty on worldwide net product sales of Aldurazyme. In addition, we recognize product transfer revenue when product is shipped to Genzyme. The amount of product transfer revenue will eventually be deducted from royalties earned when the product is sold by Genzyme. Aldurazyme net revenues of \$24.1 million for the first quarter of 2008 represent \$14.6 million of royalty revenue on net Aldurazyme sales by Genzyme and \$9.5 million of incremental net product transfer revenue. Royalty revenue from Genzyme is based on 39.5 percent of net Aldurazyme sales by Genzyme, which totaled \$36.8 million for the first quarter of 2008. Incremental Aldurazyme net product transfer revenue of \$9.5 million for the first quarter of 2008 reflects incremental shipments of Aldurazyme to Genzyme to meet future product demand. As the first quarter of 2008 was the initial period after the restructuring of BioMarin/Genzyme LLC, the incremental net product transfer revenue was significant due to the transfer of existing finished goods quantities on hand. In the future, to the extent that Genzyme Aldurazyme inventory quantities on hand remain flat, we expect that our total Aldurazyme revenues will approximate the 39.5% to 50% royalties on net product sales by Genzyme. Aldurazyme gross profit was \$13.2 million representing a gross margin of 55%, which primarily reflects the profit earned on royalty revenue and net product transfer revenue. Our Aldurazyme gross margins may fluctuate depending on the mix of royalty revenue, from which we earn higher gross profit, and product transfer revenue, from which we earn a lower gross profit.

We received marketing approval for Kuvan in the U.S. in December 2007 and began shipping product that same month. Net product sales for Kuvan in the first quarter of 2008 were \$5.8 million, all of which were from customers based in the U.S. Gross profit from Kuvan in the first quarter of 2008 was approximately \$5.1 million, representing gross margins of approximately 88% which includes a royalty payment of 11%. In accordance with our inventory accounting policy, we began capitalizing Kuvan inventory production costs after U.S. regulatory approval was obtained in December 2007. As a result, all of the product sold in the first quarter of 2008 had an insignificant cost basis. We expect that the majority of Kuvan sales into 2009 will be previously expensed product and will have a minimal cost basis. The cost of goods for Kuvan in the quarter ended March 31, 2008 is principally royalties paid to third parties based on Kuvan net sales.

Table of Contents**Collaborative Agreement Revenues**

Collaborative agreement revenues include both license revenue and contract research revenue under our agreement with Merck Serono, executed in May 2005. License revenues are related to amortization of the \$25.0 million up-front license payment received from Merck Serono and contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. As development spending on Kuvan and 6R-BH4 for other indications increases or decreases, contract research revenues may also change proportionately following the completion of Phase 2 clinical trials for each indication. The related costs are included in research and development expenses.

Collaborative agreement revenues in the first quarter of 2007 and 2008 were \$4.1 million and \$2.5 million, respectively, and includes the amortization of \$1.8 million and \$1.5 million, respectively, of the up-front license fee received from Merck Serono and recognized as revenue during the period, and \$2.3 million and \$1.0 million, respectively, of reimbursable Kuvan development costs incurred during the period. Reimbursable Kuvan development costs decreased during the first quarter of 2008 compared to the same period in 2007 due primarily to reductions in Kuvan clinical trial activities due to FDA approval received in December 2007.

Royalty and License Revenues

Royalty and license revenues for each of the first quarters of 2007 and 2008 include royalty revenues from Orapred product sold by the sublicensee of \$0.3 million.

Research and Development Expense

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates and products. These research and development costs primarily include preclinical and clinical studies, manufacturing of our product candidates prior to regulatory approval, quality control and assurance and other product development expenses, such as regulatory costs.

Research and development expenses decreased by \$0.6 million to \$17.6 million for the three months ended March 31, 2008, from \$18.2 million for the three months ended March 31, 2007. Research and development expenses changed for the first quarter of 2008 primarily as a result of the following (in millions):

Research and development expenses for the first quarter of 2007	\$ 18.2
Decreased Naglazyme development expenses	(0.2)
Decreased Kuvan clinical trial and manufacturing costs	(3.4)
Decreased 6R-BH4 development costs for endothelial dysfunction	(0.8)
Decreased PEG-PAL development costs	(0.5)
Increased stock-based compensation expense	0.2
Increased Aldurazyme development expenses	0.4
Increase in research and development expense on early stage programs	2.3
Non-allocated research and development expense and other changes	1.4
Research and development expenses for the first quarter of 2008	\$ 17.6

The decrease in 6R-BH4 development costs is related to decreases in the ongoing pre-clinical studies of 6R-BH4 in other indications including endothelial dysfunction and costs related to planning and conducting Phase 2 clinical trials in peripheral arterial disease and sickle cell disease. The decrease in PEG-PAL development costs is related to decreases for pre-clinical studies and manufacturing costs. The decrease in Kuvan clinical trial and manufacturing costs is primarily due to decreased clinical trial and manufacturing expenses now that Kuvan is approved. However, we expect to continue incurring significant Kuvan research and development costs for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments. The increase in research and development on other programs primarily includes increases in facilities costs, general research costs and research and development personnel. We expect research and development expense to increase in future periods, primarily as a result of spending on our 6R-BH4 program for other indications and on our PEG-PAL program.

Table of Contents***Selling, General and Administrative Expense***

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support our commercialized products and product development programs. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations in support of Naglazyme, Kuvan and our product candidates; human resources; finance, legal and support personnel expenses; and other corporate costs such as insurance, audit and legal expenses.

Selling, general and administrative expenses increased by \$7.4 million, to \$23.7 million for the three months ended March 31, 2008, from \$16.3 million for the three months ended March 31, 2007. The components of the increase for the first quarter of 2008 primarily include the following (in millions):

Selling, general and administrative expenses for the first quarter of 2007	\$ 16.3
Increased Naglazyme sales and marketing expenses	1.2
Increased stock-based compensation expense	0.6
Increased Kuvan commercialization costs	2.7
Net increase in corporate overhead and other administrative costs	2.9
 Selling, general and administrative expenses for the first quarter of 2008	 \$ 23.7

We initiated commercial operations in the E.U. during 2006 and in Latin America and other parts of the world during 2007. As such, commercialization costs of Naglazyme continued to grow during the first quarter of 2008. We also incurred increased spending related to the Kuvan commercial efforts following the launch in December 2007. The increase in stock-based compensation expense is the result of an increased number of options outstanding due to increased headcount and a higher average stock price on the related grant date. The increase in corporate overhead and other administrative costs is primarily related to increases in salaries and benefits due to a significant growth in headcount. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme and the United States commercialization activities for Kuvan.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets includes the current amortization expense of the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology. The acquired intangible assets are being amortized over approximately 3.5 years and the amortization expense for each of the first quarters of 2007 and 2008 was \$1.1 million. Following our expected purchase of the common stock of Ascent Pediatrics from Medicis in August 2009, the underlying intellectual property will be transferred to Sciele. We expect that the annual amortization expense associated with the intangible assets will be approximately \$4.4 million in 2008 and \$2.9 million through the end of the expected useful life in August 2009.

Equity in the Income (Loss) of BioMarin/Genzyme LLC

Equity in the Income (Loss) of BioMarin/Genzyme LLC includes our 50% share of the joint venture's income or loss for the period. Effective January 2008, we and Genzyme restructured BioMarin/Genzyme LLC regarding the manufacturing, marketing and sale of Aldurazyme. Under the revised structure, the operational responsibilities for us and Genzyme did not significantly change, as Genzyme will continue to globally market and sell Aldurazyme and we will continue to manufacture Aldurazyme. As of January 1, 2008, instead of sharing all costs and profits equally through the 50/50 joint venture, BioMarin/Genzyme LLC's operations will consist primarily of certain research and development activities and intellectual property will continue to be managed in the joint venture with the costs shared equally by BioMarin and Genzyme.

Equity in the loss of BioMarin/Genzyme LLC was \$0.5 million for the first quarter of 2008, compared to equity in the income of BioMarin/Genzyme LLC of \$6.2 million for the first quarter of 2007. The decrease in profit from BioMarin/Genzyme LLC in the first quarter of 2008 was due the restructuring of the joint venture, whereby the joint venture no longer records the sales and related commercial operations of Aldurazyme and instead is primarily responsible for certain ongoing Aldurazyme research and development activities, including \$1.1 million of primarily clinical trial costs during the first quarter of 2008.

Equity in the income of the joint venture in 2007 of \$6.2 million was primarily attributable to \$26.8 million of net product sales. Gross profit was \$20.5 million and gross margins were approximately 77% for the first quarter of 2007. During the first quarter of 2007, operating costs included the costs associated with the development and commercial support of Aldurazyme and totaled \$8.4 million. Operating expenses in the

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

first quarter of 2007 included \$5.8 million of selling, general and administrative expenses associated with the commercial efforts of Aldurazyme, and \$2.6 million of research and development expenses, primarily clinical trial costs.

Table of Contents**Interest Income**

We invest our cash and short-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income increased to \$5.6 million for the first quarter of 2008, from \$3.7 million for the first quarter of 2007, primarily due to increased levels of cash and investments during the first quarter of 2008, partially offset by reduced interest yields. We expect that interest income will decline in future quarters in 2008 as compared to 2007 due to reduced interest yields.

Interest Expense

We incur interest expense on our convertible debt. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction. Interest expense was \$4.1 million for the first quarter of 2008, as compared to \$2.3 million for the first quarter of 2007, representing an increase of \$1.8 million. The increase in the first quarter of 2008 is primarily due to the April 2007 convertible debt issuance of approximately \$324.9 million of 1.875% Senior Subordinated Convertible Notes due in 2017.

Imputed interest expense totaled \$1.1 million for each of the first quarters of 2007 and 2008.

Changes in Financial Position**March 31, 2008 Compared to December 31, 2007**

From December 31, 2007 to March 31, 2008 our inventory increased by approximately \$22.3 million. The increase in inventory was primarily attributable to the distribution of Aldurazyme inventory from the joint venture and the capitalization of Kuvan inventory costs as a result of the FDA approval in December 2007. Our accounts receivable increased by \$30.3 million due to increased Kuvan sales and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. During the first quarter of 2008 we received distributions of \$16.7 million of cash and \$26.8 million of inventory from BioMarin/Genzyme LLC as a result of the restructuring of the joint venture. Our other assets decreased by approximately \$2.4 million during that period, primarily as a result of the amortization of offering costs related to our convertible notes. Our net property, plant and equipment increased by approximately \$18.9 million from December 31, 2007 to March 31, 2008, primarily as a result of the purchase of our facility at 300 Bel Marin Keys, capital equipment and improvements to our other facilities, partially offset by depreciation expense during the period. We expect net property, plant and equipment to continue to increase in future periods, due to several ongoing facility improvement projects. Our total current liabilities decreased by approximately \$8.2 million in the first quarter of 2008 primarily due to net payments of accounts payable and accrued liabilities.

Liquidity and Capital Resources**Cash and Cash Flow**

As of March 31, 2008, our combined cash, cash equivalents and short-term investments totaled \$574.8 million, a decrease of \$10.8 million from \$585.6 million at December 31, 2007. During the first quarter of 2008 and all of 2007, we financed our operations primarily through available cash, cash equivalents and short-term investments, the related interest income earned thereon and net product sales.

The decrease in cash, cash equivalents, and short-term investments during the first quarter of 2008 was \$10.8 million, which was \$4.7 million less than the net decrease in cash, cash equivalents, and short-term investments during the first quarter of 2007 of \$15.5 million. The primary items contributing to the decrease in net cash outflow in the first quarter of 2008 were as follows (in millions):

Net cash outflow for the first quarter of 2007	\$ (15.5)
Increased capital asset purchases	(16.7)
Increased cash flows from BioMarin/Genzyme LLC	11.7
Increased proceeds from stock option exercises and the ESPP	12.9
Net increased operating spend, including net payments for working capital, and other	(3.2)
Net cash outflow for the first quarter of 2008	\$ (10.8)

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The net increased operating spend includes increases in cash receipts from net revenues offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, as discussed in the Results of Operations section above. Increased capital asset purchases include the purchase of our facility at 300 Bel Marin Keys Drive. Increased cash flows from BioMarin/Genzyme LLC include the cash distribution resulting from the restructure of the joint venture of \$16.7 million. Increases in net payments for working capital in the first quarter of 2008 primarily include decreased inventory build of \$6.9 million, increased accounts receivable build of \$30.4 million and decreased accounts payable and accrued liabilities build of \$0.9 million.

Table of Contents

Pursuant to our settlement of a dispute with Medicis in January 2005, Medicis made available to us a convertible note of up to \$25.0 million beginning July 1, 2005 based on certain terms and conditions and provided that we do not experience a change of control. Money advanced under the convertible note is convertible into our common stock, at Medicis' option, according to the terms of the convertible note. As of March 31, 2008, we have not made any draws on the note. We do not anticipate that we will draw funds from this note.

Funding Commitments

We expect to fund our operations with our net product revenues from Naglazyme, Aldurazyme and Kuvan, cash, cash equivalents and short-term investments supplemented by proceeds from equity or debt financings, loans or collaborative agreements with corporate partners, to the extent necessary. We expect our current cash, cash equivalents and short-term investments will meet our operating and capital requirements for the foreseeable future based on our current long-term business plans and assuming that we are able to achieve our long-term goals. This expectation could also change depending on how much we elect to spend on our development programs and for potential licenses and acquisitions of complementary technologies, products and companies.

Our investment in our product development programs has a major impact on our operating performance. Our research and development expenses for the three months ended March 31, 2007 and 2008 and for the period since inception (March 1997) represent the following (in millions):

	Three Months Ended March 31,		Since Program Inception
	2007	2008	
Naglazyme	\$ 2.4	\$ 2.2	\$ 115.2
Kuvan	5.4	2.0	81.0
6R-BH4 for other indications, including endothelial dysfunction	3.4	3.5	30.9
PEG-PAL	2.8	2.3	22.5
Not allocated to specific major current projects	4.2	7.6	164.2
	\$ 18.2	\$ 17.6	\$ 413.8

We cannot estimate the cost to complete any of our product development programs. Additionally, except as disclosed under Overview above, we cannot estimate the time to complete any of our product development programs or when we expect to receive net cash inflows from any of our product development programs. Please see Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2007, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in our Form 10-K

If we fail to maintain regulatory approval to commercially market or sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased; To obtain regulatory approval to market our products, preclinical studies and costly and lengthy preclinical and clinical trials are required and the results of the studies and trials are highly uncertain; If we are unable to successfully develop manufacturing processes for our drug products to produce sufficient quantities and at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program; If we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be adversely affected; and If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.

We may elect to increase our spending above our current long-term plans and may be unable to achieve our long-term goals. This could increase our capital requirements, including: costs associated with the commercialization of our products; additional clinical trials and the manufacturing of Naglazyme, Aldurazyme and Kuvan; preclinical studies and clinical trials for our other product candidates; potential licenses and other acquisitions of complementary technologies, products and companies; general corporate purposes; payment of the amounts due with respect to the Ascent Pediatrics transaction; and working capital.

Our future capital requirements will depend on many factors, including, but not limited to:

our ability to successfully market and sell Naglazyme and Kuvan;

Genzyme's ability to successfully market and sell Aldurazyme;

Table of Contents

the progress, timing, scope and results of our preclinical studies and clinical trials;

the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;

the time and cost necessary to develop commercial manufacturing processes, including quality systems and to build or acquire manufacturing capabilities;

the time and cost necessary to respond to technological and market developments;

any changes made to or new developments in our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and

whether our convertible debt is converted to common stock in the future.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our financial position or results of operations.

Borrowings and Contractual Obligations

In April 2007, we sold approximately \$324.9 million of senior subordinated convertible debt due April 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately \$20.36 per share, subject to adjustment in certain circumstances. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2017. We also must repay the debt if there is a qualifying change in control or termination of trading of its common stock. In March 2006, we sold approximately \$172.5 million of senior subordinated convertible notes due 2013. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2013. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately \$16.58 per share, subject to adjustment in certain circumstances. However, we must repay the debt prior to maturity if there is a qualifying change in control or termination of trading of our common stock. Our \$497.3 million of convertible debt will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

As a result of the Ascent Pediatrics transaction, we expect to pay Medicis \$78.4 million through 2009, of which \$4.8 million is payable during the remainder of 2008. At our option, we may elect to pay Medicis \$8.6 million of the amounts due in 2009 through the issuance of our common stock.

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of March 31, 2008 is presented below (in thousands).

	Payments Due by Period					Total
	Remainder of 2008	2009	2010-2011	2012-2013	2014 and Thereafter	
Medicis obligations	\$ 4,750	\$ 73,600	\$	\$	\$	\$ 78,350
Convertible debt and related interest	8,248	10,404	20,808	191,077	346,195	576,732
Operating leases	2,187	2,936	5,820	4,783	40	15,766
Research and development and purchase commitments	17,218	1,940	592	483	1,185	21,418

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Total	\$ 32,403	\$ 88,880	\$ 27,220	\$ 196,343	\$ 347,420	\$ 692,266
-------	-----------	-----------	-----------	------------	------------	------------

We are also subject to contingent payments related to various development activities totaling approximately \$62.8 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our market risks at March 31, 2008 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007, on file with the Securities and Exchange Commission (SEC).

Table of Contents

Item 4. Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report.

Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls are sufficiently effective to ensure that the information required to be disclosed by us in this Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and instructions for Form 10-Q. There was no change in our internal control over financial reporting that occurred during the period covered by this Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

In April 2008, the U.S. Environmental Protection Agency (EPA) notified us that it intends to file an administrative complaint against us for certain violations of the Clean Water Act. Specifically, over the last several years, on numerous instances, the pH level of the waste water discharged into the City of Novato sanitary sewer was outside of the levels specified in our waste water discharge permit. These excursions were all very short in duration and small in quantity. On January 31, 2008, we completed construction of a PH neutralization system to avoid future excursions. We are actively negotiating a settlement with the EPA related to this issue and expect to resolve the matter in the near future.

Item 1A. Risk Factors

The risk factors previously disclosed in Part 1, Item 1A of our Form 10-K for fiscal year ended December 31, 2007 have remained substantially unchanged, except as noted below.

The U.S. Patent and Trademark Office (USPTO) has issued three patents to a third-party that relate to alpha-L-iduronidase and a related patent has issued in Canada. If we are not able to successfully challenge these patents or a related patent in Japan, if it issues, we may be prevented from producing Aldurazyme in countries with issued patents unless and until we obtain a license.

The USPTO has issued three patents to a third-party that cover composition-of-matter, isolated genomic nucleotide sequences, vectors including the sequences, host cells containing the vectors, and method of use claims for human, recombinant alpha-L-iduronidase. Aldurazyme is based on human, recombinant alpha-L-iduronidase. A corresponding patent application was filed by a third party in the European Patent Office claiming composition-of-matter for human, recombinant alpha-L-iduronidase, and it was rejected over prior art and withdrawn and cannot be re-filed. However, a corresponding application is still pending in Japan, and this application is being prosecuted by the applicants. We do not know whether the Japanese application will issue or the scope of the claims that would issue. A corresponding Canadian patent recently issued and covers enzyme, pharmaceutical composition, nucleic acid encoding the enzyme, host and cell vector. We believe that the U.S. and Canadian patents, and the Japanese patent application, if issued, are invalid or not infringed on a number of grounds. In addition, under U.S. law, issued patents are entitled to a presumption of validity, and a challenge to the U.S. patents may be unsuccessful. Even if we are successful, challenging the patents may be expensive, require our management to devote significant time to this effort and may adversely impact commercialization of Aldurazyme in the U.S. and Canada (or in Japan, should a patent issue in that country.)

The holder of the patents, an affiliate of Women's and Children's Hospital, Adelaide, Australia, recently terminated an exclusive license for products relating to these patents to one of our competitors, Transkaryotic Therapies Inc. (TKT), which was acquired by Shire PLC in 2005. If we are sued by the patent holder and are unable to successfully challenge the patents, we may be forced to pay damages to the patent holder and we may be unable to produce Aldurazyme in the U.S. and Canada (or in Japan, should patents issue in that country) unless we can reach an accommodation with the patent holder. The patent holder is not required to grant us a license or other accommodation and even if a license or other accommodation is available, we may have to pay substantial license fees, which could adversely affect our business and operating results.

Table of Contents

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3. Defaults upon Senior Securities.
None.

Item 4. Submission of Matters to a Vote of Security Holders.
None.

Item 5. Other Information.
None.

Item 6. Exhibits.

31.1* Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.

31.2* Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.

32.1* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of The Securities Exchange Act of 1934, as amended.

* Filed herewith

Table of Contents

SIGNATURE

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.

BIOMARIN PHARMACEUTICAL INC.

Dated: April 30, 2008

By /s/ JEFFREY H. COOPER
Jeffrey H. Cooper, Senior Vice President, Chief Financial
Officer

(On behalf of the registrant and as principal financial officer)

Table of Contents

Exhibit Index

- 31.1* Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2* Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of The Securities Exchange Act of 1934, as amended.

* Filed herewith