

BIOMARIN PHARMACEUTICAL INC

Form 10-Q

May 03, 2010

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, 2010

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes  No

**Applicable only to issuers involved in bankruptcy proceedings during the preceding 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: 101,626,704 shares of common stock, par value \$0.001, outstanding as of April 23, 2010.

**Table of Contents**

**BIOMARIN PHARMACEUTICAL INC.**

**TABLE OF CONTENTS**

	<b>Page</b>
PART I. <u>FINANCIAL INFORMATION</u>	3
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>	28
Item 3. <u>Quantitative and Qualitative Disclosure about Market Risk</u>	36
Item 4. <u>Controls and Procedures</u>	36
PART II. <u>OTHER INFORMATION</u>	37
Item 1. <u>Legal Proceedings</u>	37
Item 1A. <u>Risk Factors</u>	37
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
Item 3. <u>Defaults Upon Senior Securities</u>	37
Item 4. <u>(Removed and Reserved)</u>	37
Item 5. <u>Other Information</u>	37
Item 6. <u>Exhibits</u>	37
<u>SIGNATURE</u>	38

**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, 2009 (1)	March 31, 2010 (unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 167,171	\$ 108,963
Short-term investments	133,506	214,679
Accounts receivable, net	73,540	82,606
Inventory	78,662	79,761
Other current assets	14,848	14,422
Total current assets	467,727	500,431
Investment in BioMarin/Genzyme LLC	441	1,215
Long-term investments	169,849	128,722
Property, plant and equipment, net	199,141	203,949
Intangible assets, net	40,977	77,416
Goodwill	23,722	40,360
Other assets	15,306	14,112
Total assets	\$ 917,163	\$ 966,205
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable, accrued liabilities and other current liabilities	\$ 78,068	\$ 78,541
Deferred revenue	86	158
Total current liabilities	78,154	78,699
Convertible debt	497,083	497,083
Other long-term liabilities	19,741	45,183
Total liabilities	594,978	620,965
Stockholders equity:		
Common stock, \$0.001 par value: 250,000,000 shares authorized at December 31, 2009 and March 31, 2010; 100,961,922 and 101,551,221 shares issued and outstanding at December 31, 2009 and March 31, 2010, respectively	101	102
Additional paid-in capital	899,950	917,738
Company common stock held by Nonqualified Deferred Compensation Plan	(1,715)	(1,072)
Accumulated other comprehensive income	933	4,405
Accumulated deficit	(577,084)	(575,933)
Total stockholders equity	322,185	345,240

Total liabilities and stockholders' equity	\$ 917,163	\$ 966,205
--	------------	------------

- (1) December 31, 2009 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, 2009 and 2010****(In thousands, except for per share data, unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
<b>Revenues:</b>		
Net product revenues	\$ 71,914	\$ 84,073
Collaborative agreement revenues	509	201
Royalty and license revenues	1,557	679
<b>Total revenues</b>	<b>73,980</b>	<b>84,953</b>
<b>Operating expenses:</b>		
Cost of sales	14,362	17,412
Research and development	34,358	30,097
Selling, general and administrative	28,568	34,000
Intangible asset amortization and contingent consideration	1,093	654
<b>Total operating expenses</b>	<b>78,381</b>	<b>82,163</b>
Income (Loss) from operations	(4,401)	2,790
Equity in the loss of BioMarin/Genzyme LLC	(547)	(691)
Interest income	2,153	1,190
Interest expense	(4,087)	(2,429)
Impairment loss on equity investments	(5,853)	
Net gain from sale of investments		927
Income (loss) before income taxes	(12,735)	1,787
Provision for income taxes	417	636
<b>Net income (loss)</b>	<b>\$ (13,152)</b>	<b>\$ 1,151</b>
<b>Net income (loss) per share, basic and diluted</b>	<b>\$ (0.13)</b>	<b>\$ 0.01</b>
Weighted average common shares outstanding, basic	99,902	101,144
Weighted average common shares outstanding, diluted	99,933	103,720

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, 2009 and 2010****(In thousands, unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ (13,152)	\$ 1,151
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,103	5,410
Amortization of discount (premium) on investments	(643)	1,198
Imputed interest on acquisition obligation	1,077	
Equity in the loss of BioMarin/Genzyme LLC	547	691
Stock-based compensation	8,534	8,606
Impairment loss on equity investments	5,848	
Net gain from sale of investments		(927)
Unrealized foreign exchange (gain) loss on forward contracts	1,624	(60)
Changes in the fair value of contingent acquisition consideration payable		654
Excess tax benefit from stock option exercises	(4)	
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,057)	(9,066)
Inventory	(3,260)	(1,099)
Other current assets	25,719	2,925
Other assets	(221)	(871)
Accounts payable, accrued liabilities and other current liabilities	(4,046)	(6,483)
Other long-term liabilities	138	1,049
Deferred revenue	(187)	72
Net cash provided by operating activities	20,020	3,250
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(18,737)	(14,108)
Maturities and sales of investments	110,100	22,055
Purchase of investments	(112,801)	(62,956)
Business acquisitions, net of cash acquired		(14,124)
Investments in BioMarin/Genzyme LLC		(1,465)
Investment in La Jolla Pharmaceutical Company	(6,250)	
Net cash used in investing activities	(27,688)	(70,598)
<b>Cash flows from financing activities:</b>		
Proceeds from ESPP and exercise of stock options	891	9,183
Excess tax benefit from stock option exercises	4	
Repayment of acquisition obligation	(1,500)	
Repayment of capital lease obligations	(48)	(43)
Net cash provided by (used in) financing activities	(653)	9,140
Net decrease in cash and cash equivalents	(8,321)	(58,208)
Cash and cash equivalents:		

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Beginning of period	222,900	167,171
End of period	\$ 214,579	\$ 108,963
<b>Supplemental cash flow disclosures:</b>		
Cash paid for interest, net of interest capitalized into fixed assets	\$ 2,057	\$ 1,822
Cash paid for income taxes	407	254
Stock-based compensation capitalized into inventory	1,303	1,080
Depreciation capitalized into inventory	650	1,466
<b>Supplemental non-cash investing and financing activities disclosures:</b>		
Changes in accrued liabilities related to fixed assets	1,996	4,477
Changes in contingent acquisition consideration payable		21,110
See accompanying notes to unaudited consolidated financial statements.		



**Table of Contents**

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2010**

**(Unaudited)**

**(1) NATURE OF OPERATIONS AND BUSINESS RISKS**

BioMarin Pharmaceutical Inc. (the Company or BioMarin<sup>®</sup>) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin selects 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 or offer a significant benefit over existing products. The Company's product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme<sup>®</sup> (galsulfase), Kuvan<sup>®</sup> (sapropterin dihydrochloride), Aldurazyme<sup>®</sup> (laronidase) and Firdapse<sup>™</sup> (amifampridine phosphate).

Through March 31, 2010, the Company had accumulated losses of approximately \$575.9 million. Management believes that the Company's cash, cash equivalents and short-term and long-term investments at March 31, 2010 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. The Company expects to continue to finance net future cash needs that exceed its operating revenues primarily through its current cash, cash equivalents, short-term and long-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners.

The Company is subject to a number of risks, including the financial performance of Naglazyme, Kuvan, Aldurazyme and Firdapse; 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 new 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. (U.S. GAAP) 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 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. Management performed an evaluation of the Company's activities through the filing of this Quarterly Report on Form 10-Q, and has concluded that there are no subsequent events requiring disclosure through that date.

*(b) Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, 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*

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



## **Table of Contents**

### *(d) Investments*

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's securities are classified as either held-to-maturity or available-for-sale and reported in short-term investments or long-term investments. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investments are recorded at fair market value, with unrealized gains or losses included in accumulated other comprehensive income or loss, exclusive of other-than-temporary impairment losses, if any. Short-term and long-term investments are comprised of corporate securities, commercial paper, U.S. federal government agency securities, money market funds, equity securities and certificates of deposit. As of March 31, 2010, 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, or 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 recognized as cost of sales in the consolidated statements of operations.

Manufacturing costs for product candidates are 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 product candidates incurred prior to regulatory approval are not capitalized as inventory. When regulatory approval is obtained, the Company begins capitalizing inventory at the lower of cost or net realizable value.

Stock-based compensation capitalized into inventory for the three months ended March 31, 2009 and 2010, was \$1.3 million and \$1.1 million, respectively.

### *(f) Investment in BioMarin/Genzyme LLC and Equity in the Loss of BioMarin/Genzyme LLC*

Effective January 1, 2008, the Company restructured its relationship with Genzyme Corporation (Genzyme) (see Note 17 for further information). The Company accounts for its remaining investment in the joint venture between the Company and Genzyme (BioMarin/Genzyme LLC) using the equity method. Accordingly, the Company records an increase in its investment for contributions to 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 loss of BioMarin/Genzyme LLC includes the Company's 50% share of the joint venture's loss for the period. 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 10 for further information on property, plant and equipment balances as of December 31, 2009 and March 31, 2010.

Certain of the Company's operating lease agreements include scheduled rent escalations over the lease term, as well as tenant improvement allowances. 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 and free rent periods 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 Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopics ASC 605-15, *Revenue Recognition Products* and ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*. The Company's revenues consist of net product revenues from its commercial products, 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.

## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

*Net Product Revenues* The Company recognizes net product revenue 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 related to Naglazyme and Firdapse sales in foreign jurisdictions, are presented on a net basis in the Company's consolidated statements of operations, in that taxes billed to customers are not included as a component of net product revenues.

**Table of Contents**

The Company receives a 39.5% to 50% royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenues in the consolidated statements of operations. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme because all of the Company's performance obligations are fulfilled at that point and title to, and risk of loss for, the product has transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay the Company if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty rate 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 the terms of the related agreements with Genzyme and when the title and risk of loss for the product is transferred to Genzyme. As of December 31, 2009 and March 31, 2010, accounts receivable included \$20.3 million and \$18.3 million, respectively, of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme.

The Company sells Naglazyme worldwide, Kuvan in the U.S. and Canada and Firdapse in the EU. In the U.S., Naglazyme and Kuvan are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. The Company also sells Kuvan to Merck Serono at a price near its manufacturing cost, and Merck Serono resells the product to end users outside the U.S., Canada and Japan. The royalty earned from Kuvan product sold by Merck Serono in the EU is included as a component of net product revenues in the period earned and approximates 4%. Outside the U.S., Naglazyme and Firdapse are sold to the Company's authorized distributors or directly to government purchasers or hospitals, which act as the end-users. The Company records reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product revenues 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 quarter and records any necessary adjustments to its reserves. The Company records fees paid to distributors as a reduction of revenue.

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. Because of the pricing of Naglazyme, Kuvan and Firdapse, the limited number of patients and the customers' limited return rights, most Naglazyme and Kuvan customers and retailers carry a limited inventory. However, certain international customers, usually government entities, tend to purchase larger quantities of product less frequently. Although such buying patterns may result in revenue fluctuations from quarter to quarter, the Company has not experienced any increased product returns or risk of product returns. The Company relies on historical return rates to estimate returns for Aldurazyme, Naglazyme and Kuvan. Genzyme's return rights for Aldurazyme are limited to defective product. The Company's products are comparable in nature and sold to similar customers with limited return rights; therefore the Company relies on historical return rates for Aldurazyme, Naglazyme and Kuvan to estimate returns for Firdapse, which has a limited history of product returns. Based on these factors, management has concluded that product returns will be minimal, and the Company has not experienced significant product returns to date. 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, 2010, the Company has experienced no significant bad debts and the recorded allowance for doubtful accounts was insignificant.

*Collaborative Agreement Revenues* Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue under the Company's agreement with Merck Serono, which was executed in May 2005. 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's recognition of license revenue from Merck Serono was completed in 2008. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono's share of Kuvan development costs under the Merck Serono agreement, which are recorded as research and development expenses in the consolidated statements of operations. 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.

Collaborative agreement revenues totaled \$0.5 million and \$0.2 million during the three months ended March 31, 2009 and 2010, respectively. Collaborative agreement revenues in each of the first quarters of 2009 and 2010 were comprised of reimbursable development costs for Kuvan.

*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 at the time the royalty amount is fixed or determinable based on information received from the sublicensee and at the time collectibility is reasonably assured.



**Table of Contents**

Due to the significant role the Company plays in the operations of Aldurazyme and Kuvan, primarily the manufacturing and regulatory activities, as well as the rights and responsibilities to deliver the products to Genzyme and Merck Serono, respectively, the Company elected not to classify the Aldurazyme and Kuvan royalties earned as other royalty revenues and instead to include them as a component of net product revenues.

Royalty and license revenues for the three months ended March 31, 2010 include \$0.5 million of Orapred product royalties, a product the Company acquired in 2004 and sublicensed in 2006, and \$0.2 million of royalty revenues for 6R-BH4, the active ingredient in Kuvan, sold in Japan. Royalty and license revenues for the three months ended March 31, 2009 included \$1.4 million of Orapred product royalties and \$0.2 million of royalty revenue for 6R-BH4.

*(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 non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. 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.

The Company believes that regulatory approval of its product candidates is uncertain and does not assume that products manufactured prior to regulatory approval will be sold commercially. As a result, inventory costs for product candidates are expensed as research and development until regulatory approval is obtained in a major market, at which time inventory is capitalized at the lower of cost or net realizable value.

*(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 into 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 the Company's 2006 Employee Stock Purchase Plan (ESPP), restricted stock, contingent issuances of common stock related to convertible debt and through the first quarter of 2009, the portion of acquisition costs that was payable in shares of the Company's common stock at the Company's option.

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, 2009 and 2010 (in thousands, except per share data):

	Three Months Ended March 31, 2009		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
<b>Basic Net Loss Per Share:</b>			
Net Loss	\$ (13,152)	99,902	\$ (0.13)
<b>Effect of dilutive shares:</b>			
Common stock held in the Nonqualified Deferred			
Compensation Plan using the treasury method	(156)	31	
<b>Diluted Net Loss Per Share:</b>			
Net Loss	\$ (13,308)	99,933	\$ (0.13)





**Table of Contents**

	Three Months Ended March 31, 2010		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
<b>Basic Net Income Per Share:</b>			
Net Income	\$ 1,151	101,144	\$ 0.01
<b>Effect of dilutive shares:</b>			
Stock options using the treasury method		2,041	
Potentially issuable restricted common stock		131	
Potentially issuable common stock for ESPP purchases		404	
<b>Diluted Net Income Per Share:</b>			
Net Income	\$ 1,151	103,720	\$ 0.01

In addition to the equity instruments included in the table above, the following potential shares of common stock were excluded from the computation as they were anti-dilutive for the three months ended March 31, 2009 and 2010 using the treasury stock method. Excluded from the dilutive shares of common stock were (i) out-of-the-money options to purchase common stock, (ii) potentially issuable restricted stock, (iii) shares of common stock underlying the Company's convertible debt using the if-converted method whereby the related interest expense for the convertible debt is added to net income for the period and for the three months ended March 31, 2010 (iv) Company common stock issued to the Nonqualified Deferred Compensation Plan (in thousands):

	Three Months Ended March 31,	
	2009	2010
Options to purchase common stock	12,137	11,493
Common stock issuable under convertible debt	26,343	26,343
Portion of acquisition payable in common stock at the option of the Company	696	
Unvested restricted stock units	243	214
Common stock held in the Nonqualified Deferred Compensation Plan using the treasury method		60
Potentially issuable common stock for ESPP purchases	137	
<b>Total</b>	<b>39,556</b>	<b>38,110</b>

*(k) Stock-Based Compensation*

The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options and ESPP awards. The determination of the fair value of stock-based payment awards using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of complex and subjective variables. Stock-based compensation expense is recognized on a straight-line basis over the requisite service period for each award. Further, stock-based compensation expense recognized in the consolidated statements of operations is based on awards expected to vest and therefore the amount of expense has been reduced for estimated forfeitures, which are based on historical experience. If actual forfeitures differ from estimates at the time of grant they will be revised in subsequent periods.

If factors change and different assumptions are employed in determining the fair value of stock-based awards, the stock-based compensation expense recorded in future periods may differ significantly from what was recorded in the current period (see Note 3 for further information).

*(l) Nonqualified Deferred Compensation Plan*

The Company's Nonqualified Deferred Compensation Plan allows eligible employees, including management and certain highly-compensated employees as designated by the plan's administrative committee and members of the Company's Board of Directors (the Board), to make voluntary deferrals of compensation to specified dates, retirement or death. Participants are permitted to defer portions of their salary, annual cash bonus and restricted stock. The Company is not allowed to make additional direct contributions to the Nonqualified Deferred Compensation Plan on behalf of the participants without further action by the Board.

## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Other current assets and other non-current assets include \$1.8 million and \$2.3 million, of investments held in trust related to the Company's Nonqualified Deferred Compensation Plan for certain employees and directors as of December 31, 2009, and March 31, 2010, respectively. All of the investments held in the Nonqualified Deferred Compensation Plan are classified as trading securities and recorded at fair value with changes in the investments' fair values recognized in earnings in the period they occur. Restricted stock issued into the Nonqualified Deferred Compensation Plan is accounted for similarly to treasury stock in that the value of the employer

**Table of Contents**

stock is determined on the date the restricted stock vests and the shares are issued into the Nonqualified Deferred Compensation Plan. The restricted stock issued into the Nonqualified Deferred Compensation Plan is recorded in equity and changes in the fair value of the corresponding liability are recognized in earnings as incurred. The corresponding liability for the Nonqualified Deferred Compensation Plan is included in other current liabilities and other long-term liabilities.

*(m) 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 \$268.1 million at December 31, 2009. 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 net income/loss in the period such adjustment was made or additional paid-in-capital. For the three months ended March 31, 2009 and 2010, the Company recognized income tax expense of \$0.4 million and \$0.6 million, respectively. Income tax expense for the three months ended March 31, 2009 and 2010 was primarily related to income earned in certain of the Company's international subsidiaries, California state income tax and U.S. Federal Alternative Minimum Tax expense.

*(n) Foreign Currency and Other Hedging Instruments*

The Company has transactions denominated in foreign currencies and, as a result, is exposed to changes in foreign currency exchange rates. The Company manages some of these exposures on a consolidated basis, which results in the netting of certain exposures to take advantage of natural offsets and through the use of foreign currency forward contracts. Gains or losses on net foreign currency hedges are intended to offset gains or losses on the underlying net exposures in an effort to reduce the earnings and cash flow volatility resulting from fluctuating foreign currency exchange rates.

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value. Derivatives that are not defined as hedging instruments are adjusted to fair value through earnings. Gains and losses resulting from changes in fair value are accounted for depending on the use of the derivative and whether it is designated and qualifies for hedge accounting (see Note 14 for further information).

*(o) Fair Value of Financial Instruments*

The Company discloses the fair value of financial instruments for assets and liabilities for which the value is practicable to estimate. The carrying amounts of all cash equivalents, investments and forward exchange contracts approximate fair value based upon quoted market prices or discounted cash flows. The fair value of trade accounts receivables, accounts payable and other financial instruments approximates carrying value due to their short-term nature.

*(p) Contingent Acquisition Consideration Payable*

The Company determines the fair value of contingent acquisition consideration payable on the acquisition date using a probability-based income approach utilizing an appropriate discount rate. Contingent acquisition consideration payable is included in accrued expenses and other liabilities on the Company's consolidated balance sheet. Changes in the fair value of the contingent acquisition consideration payable are determined each period end and recorded in the Intangible asset amortization and contingent consideration expense line item on the consolidated statements of operations.

*(q) Comprehensive Income (Loss) and Accumulated Other Comprehensive Income (Loss)*

Comprehensive income (loss) includes net income/loss and certain changes in stockholders' equity that are excluded from net income/loss, such as changes in unrealized gains and losses on the Company's available-for-sale securities, unrealized gains/losses on foreign currency hedges and changes in the Company's cumulative foreign currency translation account. There were no tax effects allocated to any components of other comprehensive income (loss) during the three months ended March 31, 2009 and 2010 due to the Company's full valuation allowance against its net deferred tax assets

**Table of Contents**

Total comprehensive income was approximately \$4.6 million for the three months ended March 31, 2010, compared to comprehensive net loss of \$12.2 million for the three months ended March 31, 2009. The fluctuation in accumulated other comprehensive income (loss) is comprised of the following (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
Net unrealized gain (loss) on available-for-sale securities	\$ (632)	\$ 283
Net unrealized gain on foreign currency hedges	1,932	4,058
Net unrealized loss on equity investments	(337)	(866)
Net foreign currency translation loss		(3)
<b>Change in accumulated other comprehensive income (loss)</b>	<b>\$ 963</b>	<b>\$ 3,472</b>

*(r) Restricted Cash*

The Company's balance of restricted cash amounted to \$2.0 million and \$2.5 million at December 31, 2009, and March 31, 2010, respectively. Restricted cash is primarily comprised of investments held by the Company's Nonqualified Deferred Compensation Plan totaling \$1.8 million and \$2.3 million as of December 31, 2009 and March 31, 2010, respectively, which are included in other current assets and other non-current assets.

*(s) Recent Accounting Pronouncements*

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-17 (ASU 2010-17), *Revenue Recognition - Milestone Method (Topic 605)*, which provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. ASU 2010-17 is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010 with early adoption permitted. ASU 2010-17 is effective for the Company on January 1, 2011. The Company is currently evaluating the impact, if any, ASU 2010-17 will have on the Company's consolidated financial statements.

In January 2010, the FASB issued ASU 2010-6, *Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements* (ASU 2010-6), which expands fair value disclosure requirements. Transition will be in two phases with expanded disclosures regarding activity for Level 1 and 2 applicable to the Company on January 1, 2010 and expanded disclosures for Level 3 activity effective on January 1, 2011.

In September 2009, the FASB issued ASU 2009-13, *Multiple Deliverable Revenue Arrangements* (ASU 2009-13), which amended the accounting standards for multiple element arrangements to:

provide updated guidance on whether multiple deliverables exist, how the elements in an arrangement should be separated and how the consideration should be allocated;

require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of each element if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and

eliminate the use of the residual method and require a vendor to allocate revenue using the relative selling price method.

ASU 2009-13 is effective for fiscal years beginning after June 15, 2010, which for the Company will be January 1, 2011, with early application permitted. The Company is currently evaluating the impact, if any, ASU 2009-13 will have on the Company's consolidated financial statements.

*(t) Reclassifications and Adjustments*

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

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

**Table of Contents****(3) STOCK-BASED COMPENSATION**

The Company's stock-based compensation plans include the 2006 Share Incentive Plan and the ESPP. These plans are administered by the Compensation Committee of the Board, which selects persons to receive awards and determines the number of shares subject to each award and the terms, conditions, performance measures and other provision of the award. See Note 3 of the Company's consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 25, 2010, for additional information related to these stock-based compensation plans.

***Determining the Fair Value of Stock Options and Stock Purchase Rights***

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 tables 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, 2010. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of the Company's common stock and the implied volatility of traded options on the Company's common stock for fiscal periods in which there is sufficient trading volume in options on the Company's common 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 the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future. During the three months ended March 31, 2010, the Company granted 263,850 options with a weighted average option value of \$10.75 per option. The assumptions used to estimate the per share fair value of stock options granted and stock purchase rights granted under the Company's 2006 Share Incentive Plan and ESPP for the three months ended March 31, 2009 and 2010, respectively, are as follows:

<b>Stock Option Valuation Assumptions</b>	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
Weighted average fair value of common stock per share	\$ 12.49	\$ 20.43
Expected volatility	55%	52%
Dividend yield	0.0%	0.0%
Expected life	6.0 years	6.2 years
Risk-free interest rate	1.9%	2.7%

<b>Employee Stock Purchase Plan Valuation Assumptions</b>	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
Fair value of common stock on grant date	\$ 19.36	\$ 15.56
Expected volatility	51%	55%
Dividend yield	0.0%	0.0%
Expected life	6-24 months	6-24 months
Risk-free interest rate	1.1-1.5%	0.2 0.9%

***Restricted Stock Units***

Restricted stock units (RSUs) are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. During the three months ended March 31, 2010, the Company granted 20,000 RSUs with a weighted average fair market value of \$20.40 per share.

***Stock Option Grants to Non-Employees***

During the third quarter of 2009, the Company granted 54,000 stock options to non-employees. The non-employee grants vest over periods from nine months to two years depending on the grant. The unvested portion of the stock options will be re-measured at each reporting period. Total stock-based compensation expense for non-employee stock option grants for the first quarter of 2010 was approximately \$88,000.

**Table of Contents****Stock-based Compensation Expense**

The compensation expense that has been included in the Company's consolidated statements of operations for stock-based compensation arrangements for the three months ended March 31, 2009 and 2010, respectively, was as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
Cost of sales	\$ 564	\$ 1,028
Research and development expense	2,475	3,182
Selling, general and administrative expense	4,757	4,336
 Total stock-based compensation expense	 \$ 7,796	 \$ 8,546

There was no income tax benefit associated with stock-based compensation for the three months ended March 31, 2009 and 2010 because any deferred tax asset resulting from stock-based compensation was offset by additional valuation allowance.

Stock-based compensation of \$1.3 million and \$1.1 million was capitalized into inventory during the first quarters of 2009 and 2010, respectively. Capitalized stock-based compensation is recognized into cost of sales when the related product is sold.

**(4) GOODWILL**

The following table represents the changes in goodwill for the quarter ended March 31, 2010 (in thousands):

Balance at December 31, 2009	\$ 23,722
Goodwill related to the acquisition of LEAD Therapeutics, Inc. (LEAD) (See Note 6)	16,638
 Balance at March 31, 2010	 \$ 40,360

The \$16.6 million of LEAD goodwill represents \$14.0 million of goodwill recognized in connection with the deferred tax liability associated with the indefinite-lived intangible assets acquired and \$2.6 million of excess purchase price. See Note 6 for additional discussion.

**(5) ACQUISITION OF HUXLEY PHARMACEUTICALS, INC.**

On October 23, 2009, the Company acquired Huxley Pharmaceuticals, Inc. (Huxley), which had rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate, which the Company has branded Firdapse, for the rare autoimmune disease Lambert Eaton Myasthenic Syndrome (LEMS) for a total purchase price of \$37.2 million. As a result of the acquisition, the Company will be the first to market an approved treatment for LEMS in Europe.

In connection with its acquisition of Huxley, the Company paid \$15.0 million upfront for all of the outstanding common stock of Huxley. The Company has also agreed to pay Huxley stockholders additional consideration in future periods up to \$42.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and development milestones are met. The fair value of the contingent acquisition consideration payments was \$22.2 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as Level 3 inputs. Key assumptions include: (1) a discount rate of 6.3%; and (2) a probability adjusted contingency. As March 31, 2010, the range of outcomes and assumptions used to develop these estimates have not changed. In November 2009, the U.S. Food and Drug Administration (FDA) granted Firdapse U.S. orphan status, resulting in a payment of \$1.0 million to the former Huxley shareholders. In December 2009, the European Medicines Agency (EMA) granted marketing approval for Firdapse, which resulted in a payment of \$6.5 million in the second quarter of 2010 to the former Huxley shareholders.





**Table of Contents**

The following table presents the allocation of the purchase consideration, including the contingent acquisition consideration payable, based on fair value (in thousands):

Cash and cash equivalents	\$ 483
Intangible assets IPR&D	36,933
Other assets	179
 Total identifiable assets	 \$ 37,595
 Accounts payable and accrued expenses	 (387)
Deferred tax liability	(2,460)
 Total liabilities assumed	 (2,847)
 Net identified assets acquired	 \$ 34,748
Goodwill	2,460
 Net assets acquired	 \$ 37,208

Huxley's results of operations prior to and since the acquisition date were insignificant compared to the Company's consolidated financial statements.

The deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes. The \$2.5 million of goodwill represents the assets recognized in connection with the deferred tax liability and did not result from excess purchase price. In April 2010, the Company and the former Huxley stockholders executed an amendment to the acquisition agreements, which resulted in a \$1.0 million reduction to certain of the future milestone payments.

See Note 7 for further discussion of the acquired intangible assets.

**(6) ACQUISITION OF LEAD THERAPEUTICS, INC.**

On February 10, 2010, the Company acquired LEAD Therapeutics, Inc. (LEAD), a small private drug discovery and early stage development company with a key compound LT-673, now referred to as BMN-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with rare, genetically defined cancers for a total purchase price of \$39.1 million.

In connection with its acquisition of LEAD, the Company paid \$18.6 million in cash for all of the outstanding common stock of LEAD. The Company has also agreed to pay LEAD stockholders additional consideration in future periods up to \$68.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met. The fair value of the contingent acquisition consideration payments was \$20.5 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as Level 3 inputs. Key assumptions include: (1) a discount rate of 6.4%; and (2) a probability adjusted contingency.

The following table presents the allocation of the purchase consideration, including the contingent acquisition consideration payable, based on fair value (in thousands):

Cash and cash equivalents	\$ 1,187
Prepaid expenses	40
Property, plant and equipment	26
Acquired deferred tax assets	7,788
Intangible assets IPR&D	36,089

## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Total identifiable assets	\$ 45,130
Accounts payable and accrued expenses	(891)
Deferred tax liability	(13,981)
Valuation allowance for acquired deferred tax assets	(7,788)
 Total liabilities assumed	 \$ (22,660)
Net identifiable assets acquired	22,470
Goodwill	16,638
 Net Assets Acquired	 \$ 39,108

The deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes. The \$16.6 million of goodwill reflects the \$14.0 million deferred tax liability recognized in connection with the LEAD acquisition and \$2.6 million of goodwill attributable to the synergies expected from the acquisition and other benefits that do not qualify for separate recognition as acquired intangible assets.

**Table of Contents**

LEAD's results of operations prior to and since the acquisition date were insignificant compared to the Company's consolidated financial statements.

See Note 7 for further discussion of the acquired intangible assets.

**(7) INTANGIBLE ASSETS**

As of December 31, 2009 and March 31, 2010, intangible assets consisted of the following (in thousands):

	December 31, 2009	March 31, 2010
Intangible assets:		
Finite-lived intangible assets	\$ 35,239	\$ 35,740
Indefinite-lived intangible assets	6,710	42,799
Gross intangible assets:	41,949	78,539
Less: Accumulated amortization	(972)	(1,123)
Net carrying value	\$ 40,977	\$ 77,416

*Finite-Lived Intangible Assets*

The following table summarizes the annual amortization of the finite-lived intangible assets through 2018 (in thousands):

	Net Balance at March 31, 2010	Remaining Life	Annual Amortization
EU marketing rights for Firdapse	\$ 30,723	10 years	\$ 3,072
License payment for Kuvan FDA Approval	1,563	4.7 years	332
License payment for Kuvan EMEA Approval	2,331	8.7 years	269
Total	\$ 34,617		\$ 3,673

The Firdapse intangible assets consist of the Firdapse product technology purchased as part of the Huxley acquisition in the fourth quarter of 2009. As of December 31, 2009, the gross and net carrying value of the Firdapse product technology was comprised of \$30.2 million and \$6.7 million related to marketing rights in Europe and the U.S., respectively, which were both in-process research and development assets with indefinite lives as of the purchase date. Subsequently, in December 2009, the EMEA granted marketing approval for Firdapse in the EU. As a result the Company assigned a 10 year useful life to the European product technology, which corresponds to the period of market exclusivity conferred through the orphan drug protection. The EMEA did not enable the commercial launch of Firdapse until April 2010, at which time the Company began amortizing the European product technology at an annual rate of \$3.1 million. The increase in the Firdapse intangible assets relates to a \$0.5 million license payment made to a third party as a result of the EMEA approval of Firdapse.

Kuvan intangible assets relate to license payments made to third parties as a result of the FDA approval of Kuvan in December 2007 and the EMEA approval in December 2008, which resulted in a \$2.7 million addition to the Kuvan intangible assets. At December 31, 2009 and March 31, 2010, Kuvan intangible assets totaled a gross value of \$5.0 million. In each of the first quarters of 2009 and 2010, the Company recognized amortization expense related to the Kuvan intangible assets of \$0.2 million as a component of cost of sales in the consolidated statements of operations.

**Table of Contents***Indefinite-Lived Intangible Assets*

A substantial portion of the assets acquired in the Huxley and LEAD acquisitions consisted of in-process research and development (IPR&D) assets related to both early and late stage drug product candidates. The Company determined that the estimated acquisition-date fair values of the intangible assets related to rights to develop and commercialize the acquired assets as of December 31, 2009 and March 31, 2010, respectively were as follows (in thousands):

	December 31, 2009	March 31, 2010
In-Process Research and Development		
EU marketing rights for Firdapse	\$ 30,223	\$
U.S. marketing rights for Firdapse	6,710	6,710
BMN-673 compound acquired through LEAD		35,150
Other pre-clinical compounds acquired through LEAD		939
Net carrying value	\$ 36,933	\$ 42,799

Intangible assets related to IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development (R&D) efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D assets below their respective carrying amounts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. In estimating fair value of the IPR&D assets, the Company compensated for the differing phases of development of each asset by probability-adjusting its estimation of the expected future cash flows associated with each asset. The Company then determined the present value of the expected future cash flows. The projected cash flows from the IPR&D assets were based on key assumptions such as estimates of revenues and operating profits related to the feasibility and timing of achievement of development, regulatory and commercial milestones, expected costs to develop the IPR&D into commercially viable products and future expected cash flows from product sales. As discussed above, in December 2009, the EMEA granted approval for Firdapse at which time the asset became finite-lived.

**(8) SHORT-TERM AND LONG-TERM INVESTMENTS**

At December 31, 2009, the principal amounts of short-term and long-term investments by contractual maturity are summarized in the table below (in thousands):

	Contractual Maturity Date For the Years Ending December 31,			Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
	2010	2011	2012			
Certificates of deposit	\$ 30,924	\$ 18,833	\$	\$ 49,757	\$ (120)	\$ 49,637
Corporate securities	57,973	64,735	38,096	160,804	461	161,265
Commercial paper	7,981			7,981	12	7,993
Equity securities	701			701	1,052	1,753
U.S. Government agency securities	34,861	47,724		82,585	122	82,707
Total	\$ 132,440	\$ 131,292	\$ 38,096	\$ 301,828	\$ 1,527	\$ 303,355

**Table of Contents**

At March 31, 2010, the principal amounts of short-term and long-term investments by contractual maturity are summarized in the table below (in thousands):

	Contractual Maturity Date For the Years Ending December 31,			Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
	2010	2011	2012			
Certificates of deposit	\$ 26,812	\$ 23,525	\$ 983	\$ 51,320	\$ (95)	\$ 51,225
Corporate securities	88,696	77,389	44,634	210,719	800	211,519
Commercial paper	14,476			14,476	6	14,482
Equity securities	204			204	186	390
U.S. Government agency securities	10,055	45,650	10,020	65,725	60	65,785
Total	\$ 140,243	\$ 146,564	\$ 55,637	\$ 342,444	\$ 957	\$ 343,401

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of March 31, 2010. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized costs.

At December 31, 2009, the aggregate amounts of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands). All investments were classified as available-for-sale at December 31, 2009.

	Less Than 12 Months To Maturity		12 Months or More To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	\$ 23,744	\$ (55)	\$ 14,358	\$ (69)	\$ 38,102	\$ (124)
Corporate securities	12,265	(16)	45,488	(186)	57,753	(202)
U.S. Government agency securities	5,325	(1)	20,010	(93)	25,335	(94)
Total	\$ 41,334	\$ (72)	\$ 79,856	\$ (348)	\$ 121,190	\$ (420)

At March 31, 2010, the aggregate amounts of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands). All investments were classified as available-for-sale at March 31, 2010.

	Less Than 12 Months To Maturity		12 Months or More To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	\$ 26,182	\$ (54)	\$ 11,937	\$ (53)	\$ 38,119	\$ (107)
Corporate securities	38,151	(33)	11,880	(37)	50,031	(70)
U.S. Government agency securities			20,040	(48)	20,040	(48)
Total	\$ 64,333	\$ (87)	\$ 43,857	\$ (138)	\$ 108,190	\$ (225)

**(9) SUPPLEMENTAL BALANCE SHEET INFORMATION**

As of December 31, 2009 and March 31, 2010, inventory consisted of the following (in thousands):

	<b>December 31, 2009</b>	<b>March 31, 2010</b>
Raw materials	\$ 7,692	\$ 7,581
Work in process	40,416	41,774
Finished goods	30,554	30,406
Total inventory	\$ 78,662	\$ 79,761

**Table of Contents**

As of December 31, 2009 and March 31, 2010, other current assets consisted of the following (in thousands):

	<b>December 31, 2009</b>	<b>March 31, 2010</b>
Non-trade receivables	\$ 7,083	\$ 4,580
Prepaid expenses	5,202	5,291
Deferred cost of sales	2,232	1,311
Other	331	3,240
<b>Total other current assets</b>	<b>\$ 14,848</b>	<b>\$ 14,422</b>

As of December 31, 2009 and March 31, 2010, accounts payable, accrued liabilities and other current liabilities consisted of the following (in thousands):

	<b>December 31, 2009</b>	<b>March 31, 2010</b>
Accounts payable	\$ 7,567	\$ 3,276
Accrued accounts payable	28,353	23,692
Accrued vacation	4,652	5,362
Accrued compensation	14,544	8,964
Accrued interest and taxes	2,859	3,415
Accrued royalties	4,740	4,711
Other accrued expenses	1,525	3,346
Accrued rebates	4,786	5,423
Short-term portion of contingent acquisition consideration payable	8,124	18,136
Other	918	2,216
<b>Total accounts payable and accrued liabilities</b>	<b>\$ 78,068</b>	<b>\$ 78,541</b>

As of December 31, 2009 and March 31, 2010 other long-term liabilities consisted of the following (in thousands):

	<b>December 31, 2009</b>	<b>March 31, 2010</b>
Long-term portion of deferred rent	\$ 983	\$ 969
Long-term portion of capital lease liability	85	42
Long-term portion of contingent acquisition consideration payable	13,089	24,187
Long-term portion of deferred compensation liability	3,124	3,544
Deferred tax liabilities	2,460	16,441
<b>Total other long-term liabilities</b>	<b>\$ 19,741</b>	<b>\$ 45,183</b>

**Table of Contents****(10) PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment at December 31, 2009 and March 31, 2010 consisted of the following (in thousands):

Category	December 31, 2009	March 31, 2010	Estimated Useful Lives
Leasehold improvements	\$ 38,059	\$ 38,554	Shorter of life of asset or lease term
Building and improvements	69,564	73,382	20 years
Manufacturing and laboratory equipment	34,228	40,559	5 years
Computer hardware and software	28,695	29,883	3 to 5 years
Office furniture and equipment	5,529	5,088	5 years
Land	10,056	10,056	Not applicable
Construction-in-progress	74,914	73,181	Not applicable
Total property, plant and equipment, gross	\$ 261,045	\$ 270,703	
Less: Accumulated depreciation	(61,904)	(66,754)	
Total property, plant and equipment, net	\$ 199,141	\$ 203,949	

Depreciation for three months ended March 31, 2009 and 2010 was \$3.5 million and \$4.8 million, respectively. Depreciation capitalized into inventory for the three months ended March 31, 2009 and 2010 was \$0.7 million and \$1.5 million, respectively.

Capitalized interest related to the Company's property, plant and equipment purchases for the three months ended March 31, 2009 and 2010 was \$0.1 million and \$0.3 million, respectively.

**(11) INVESTMENT IN SUMMIT CORPORATION PLC**

In July 2008, the Company entered into an exclusive worldwide licensing agreement with Summit Corporation plc (Summit) related to Summit's preclinical drug candidate SMT C1100 and follow-on molecules (2008 Summit License), which are being developed for the treatment of Duchenne muscular dystrophy. The Company paid Summit \$7.1 million for an equity investment in Summit shares and licensing rights to SMT C1100. The initial equity investment represented the acquisition of approximately 5.1 million Summit shares with a fair value at the time of acquisition of \$5.7 million, based on public market quotes. The Company's investment in Summit represents less than 10% of Summit's outstanding shares.

In March 2009, the Company entered into an asset purchase agreement with Summit. Pursuant to the terms of the asset purchase agreement, the Company purchased certain of Summit's assets which included the rights, title to and interest in Summit's preclinical drug candidate SMT C1100, thus terminating the 2008 Summit License. These assets were acquired by issuing a secured promissory note and assuming \$56,000 in related liabilities. The promissory note is secured by all of the assets acquired from Summit. The value of the assumed liabilities was expensed in the first quarter of 2009, as the asset acquired does not have an alternative use. Under the secured promissory note, the Company is obligated to make up to \$50.0 million in future development and regulatory milestone payments contingent on achieving certain development and regulatory milestones, as well as tiered royalties based on future net sales.

The Company accounts for the Summit shares, which are traded on the London Stock Exchange, as an available-for-sale investment, with changes in the fair value reported as a component of accumulated other comprehensive income/loss, exclusive of other-than-temporary impairment losses, if any. Losses determined to be other-than-temporary are reported in earnings in the period in which the impairment occurs.

As of March 31, 2010, the Company has recognized cumulative impairment charges of \$5.5 million for the decline in the investment's value determined to be other-than-temporary. The impairment charges are comprised of \$4.1 million and \$1.4 million recognized in December 2008 and March 2009, respectively. The determination that the decline was other-than-temporary is, in part, subjective and influenced by several factors, including: the length of time and the extent to which the market value had been less than the value on the date of purchase, Summit's financial condition and near-term prospects, including any events that may influence its operations, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for the anticipated recovery in market value.





**Table of Contents**

**(12) INVESTMENT IN LA JOLLA PHARMACEUTICAL COMPANY**

On January 4, 2009, the Company entered into a co-exclusive worldwide (excluding Asia Pacific) licensing agreement with La Jolla Pharmaceutical Company (La Jolla) to develop and commercialize Riquent, La Jolla's investigational drug for lupus nephritis. The Company paid La Jolla \$7.5 million for the license rights and an additional \$7.5 million for 339,104 shares of La Jolla's Series B Preferred Stock. The initial equity investment represents the acquisition of the La Jolla Series B Preferred shares with a fair value of \$6.2 million. The \$1.3 million paid in excess of the fair value of the shares acquired was allocated to the license fee using the residual method and expensed in the first quarter of 2009, as the license acquired did not have an alternative future use. Research and development expense related to the Company's agreements with La Jolla in the first quarter of 2009 approximated \$8.8 million, and is comprised of the \$7.5 million up-front license fee and the \$1.3 million premium paid in excess of the preferred stock's fair value.

On February 12, 2009, the results of the first interim efficacy analysis for the Phase 3 study of Riquent were announced, and the Independent Data Monitoring Board determined that the continuation of the trial was futile. Based on the results of this interim efficacy analysis, the Company and La Jolla decided to stop the study.

On March 26, 2009, the Company terminated its licensing agreement with La Jolla, triggering the preferred stock's automatic conversion feature at a rate of one preferred share to thirty shares of common stock. Thus, as of the conversion date, the Company held approximately 10.2 million shares of common stock, or approximately 15.5% La Jolla's outstanding common stock. The Company accounted for the converted La Jolla shares, which were traded on the NASDAQ Stock Exchange, as an available-for-sale investment. The investment was classified as available-for-sale, with changes in the fair value reported as a component of accumulated other comprehensive income/loss, exclusive of other-than-temporary impairment losses, if any. Losses determined to be other-than-temporary were reported in earnings in the period in which the impairment occurs.

In March 2009, the Company recognized an impairment charge of \$4.5 million, for the decline in the La Jolla investment's value, which was determined to be other-than-temporary. The determination that the decline was other-than-temporary was, in part, subjective and influenced by several factors, including: the length of time and the extent to which the market value of La Jolla's common stock had been less than the value on the date of purchase, La Jolla's financial condition and near-term prospects, including any events which may influence its operations, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for the anticipated recovery in market value. Based on the then current market conditions, La Jolla's current financial condition and its business prospects, the Company determined that its investment in La Jolla was other-than-temporarily impaired and adjusted the recorded amount of the investment to the stock's market price on March 31, 2009. In June 2009, the Company sold its 10.2 million shares of La Jolla common stock through a series of open market trades, ranging in gross proceeds to the Company of \$0.17 to \$0.22 per share. In connection with the sale of the La Jolla common stock, the Company recognized a loss of \$66,000 on the sale of the equity investment during the second quarter of 2009.

**(13) CONVERTIBLE DEBT**

In April 2007, the Company sold approximately \$324.9 million of Senior Subordinated Convertible Notes due 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 not a 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. In each of the first quarters of 2009 and 2010, the Company recognized amortization of expense of \$0.2 million.

In March 2006, the Company sold \$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. 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 not a call provision included and the Company is unable to unilaterally redeem the debt prior to maturity on March 29, 2013. 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 March 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 amortization of expense of \$0.2 million in each of the first quarters of 2009 and 2010. Interest expense on the convertible debt for the three

months ended March 31, 2009 and 2010 was \$2.6 million in both periods.

**Table of Contents****(14) DERIVATIVE INSTRUMENTS AND HEDGING STRATEGIES**

The Company uses hedging contracts to manage the risk of its overall exposure to fluctuations in foreign currency exchange rates. All of the Company's designated hedging instruments are considered to be cash flow hedges.

**Foreign Currency Exposure**

The Company uses forward foreign exchange contracts to hedge certain operational exposures resulting from changes in foreign currency exchange rates. Such exposures result from portions of its forecasted revenues being denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound.

The Company designates certain of these foreign currency forward contract hedges as hedging instruments and enters into some foreign currency forward contracts that are considered to be economic hedges that are not designated as hedging instruments. Whether designated or undesignated, these forward contracts protect against the reduction in value of forecasted foreign currency cash flows resulting from Naglazyme and Aldurazyme revenues and net asset or liability positions designated in currencies other than the U.S. dollar. The fair values of foreign currency agreements are estimated as described in Note 15, taking into consideration current interest rates and the current creditworthiness of the counterparties or the Company, as applicable. Details of the specific instruments used by the Company to hedge its exposure to foreign currency fluctuations follow below.

At March 31, 2010, the Company had 53 foreign currency forward contracts outstanding to sell a total of 61.5 million Euros with expiration dates ranging from April 30, 2010 through December 31, 2011. These hedges were entered into to protect against the fluctuations in Euro denominated Naglazyme and Aldurazyme revenues. The Company has formally designated these contracts as cash flow hedges and expects them to be highly effective within the meaning of ASC Subtopic 815-30, *Derivatives and Hedging- Cash Flow Hedges*, in offsetting fluctuations in revenues denominated in Euros related to changes in the foreign currency exchange rates.

The Company also enters into forward foreign currency contracts that are not designated as hedges for accounting purposes. The changes in fair value of these foreign currency hedges are included as a part of selling, general and administrative expenses in the consolidated statements of operations. At March 31, 2010, the Company had one outstanding foreign currency contract to sell 16.0 million Euros that was not designated as a hedge for accounting purposes.

The maximum length of time over which the Company is hedging its exposure to the reduction in value of forecasted foreign currency cash flows through foreign currency forward contracts is through December 31, 2011. Over the next twelve months, the Company expects to reclassify \$3.1 million from accumulated other comprehensive income to earnings as related forecasted revenue transactions occur.

At December 31, 2009 and March 31, 2010, the fair value carrying amount of the Company's derivative instruments were recorded as follows (in thousands):

	Asset Derivatives December 31, 2009		Liability Derivatives December 31, 2009	
	Balance Sheet	Fair Value	Balance Sheet	Fair Value
	Location		Location	
<b>Derivatives designated as hedging instruments</b>				
Foreign currency forward contracts	Other current assets	\$ 77	Other current liabilities	\$ 768
Total		\$ 77		\$ 768
<b>Derivatives not designated as hedging instruments</b>				
Foreign currency forward contracts	Other current assets	\$ 6	Other current liabilities	\$ 27
Total		\$ 6		\$ 27
Total derivative contracts		\$ 83		\$ 795



**Table of Contents**

	Asset Derivatives March 31, 2010		Liability Derivatives March 31, 2010	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<b>Derivatives designated as hedging instruments</b>				
Foreign currency forward contracts	Other current assets	\$ 3,071	Other current liabilities	\$
Foreign currency forward contracts	Other assets	168	Other liabilities	
Total		\$ 3,239		\$
<b>Derivatives not designated as hedging instruments</b>				
Foreign currency forward contracts	Other current assets	\$	Other current liabilities	\$ 56
Total		\$		\$ 56
Total derivative contracts		\$ 3,239		\$ 56

The effect of derivative instruments on the consolidated statements of operations for the three months ended March 31, 2009 and 2010 was as follows (in thousands):

	Foreign Currency Forward Contracts Three Months Ended March 31,	
	2009	2010
<b>Derivatives Designated as Hedging Instruments</b>		
Net gain recognized in OCI (1)	\$ 1,740	\$ 4,058
Net gain (loss) reclassified from accumulated OCI into income (2)	1,184	274
Net gain (loss) recognized in income (3)	209	86
<b>Derivatives Not Designated as Hedging Instruments</b>		
Net gain (loss) recognized in income (4)	1,165	1,317

- (1) Net change in the fair value of the effective portion classified in other comprehensive income (OCI)
- (2) Effective portion classified as product revenue
- (3) Ineffective portion and amount excluded from effectiveness testing classified in selling, general and administrative expense
- (4) Classified in selling, general and administrative expense

At December 31, 2009 and March 31, 2010, accumulated other comprehensive income associated with foreign currency forward contracts qualifying for hedge accounting treatment was a loss of \$0.7 million and gain of \$3.4 million, respectively.

The Company is exposed to counterparty credit risk on all of its derivative financial instruments. The Company has established and maintained strict counterparty credit guidelines and enters into hedges only with financial institutions that are investment grade or better to minimize the Company's exposure to potential defaults. The Company does not require collateral to be pledged under these agreements.

**Table of Contents****(15) FAIR VALUE MEASUREMENTS**

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income, other equity securities and foreign currency derivatives. The tables below present the fair value of these financial assets and liabilities determined using the following inputs at December 31, 2009 and March 31, 2010 (in thousands).

	Fair Value Measurements at December 31, 2009			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash and cash equivalents				
Overnight deposits	\$ 18,761	\$ 18,761	\$	\$
Money market instruments	148,410		148,410	
<b>Total cash and cash equivalents</b>	<b>\$ 167,171</b>	<b>\$ 18,761</b>	<b>\$ 148,410</b>	<b>\$</b>
Available-for-sale securities				
Certificates of deposit (1)	\$ 49,637	\$	\$ 49,637	\$
Corporate securities (2)	161,265		161,265	
Government agency securities (2)	82,707		82,707	
Commercial paper (2)	7,993		7,993	
Equity securities (3)	1,753	1,361	392	
<b>Total available-for-sale securities</b>	<b>\$ 303,355</b>	<b>\$ 1,361</b>	<b>\$ 301,994</b>	<b>\$</b>
Deferred compensation asset (4)	\$ 1,791	\$	\$ 1,791	\$
Foreign currency derivatives (5)	83		83	
<b>Total</b>	<b>\$ 472,400</b>	<b>\$ 20,122</b>	<b>\$ 452,278</b>	<b>\$</b>
<b>Liabilities:</b>				
Deferred compensation liability (6)	\$ 3,505	\$ 1,714	\$ 1,791	\$
Foreign currency derivatives (7)	795		795	
Contingent acquisition consideration payable (8)	21,213			21,213
<b>Total</b>	<b>\$ 25,513</b>	<b>\$ 1,714</b>	<b>\$ 2,586</b>	<b>\$ 21,213</b>

**Table of Contents**

	Fair Value Measurements at March 31, 2010			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash and cash equivalents				
Overnight deposits	\$ 18,524	\$ 18,524	\$	\$
Money market instruments	90,439		90,439	
<b>Total cash and cash equivalents</b>	<b>\$ 108,963</b>	<b>\$ 18,524</b>	<b>\$ 90,439</b>	<b>\$</b>
Available-for-sale securities				
Certificates of deposit (1)	\$ 51,225	\$	\$ 51,225	\$
Corporate securities (2)	211,519		211,519	
Commercial paper (2)	14,482		14,482	
Government agency securities (2)	65,785		65,785	
Equity securities (3)	390		390	
<b>Total available-for-sale securities</b>	<b>\$ 343,401</b>	<b>\$</b>	<b>\$ 343,401</b>	<b>\$</b>
Deferred compensation asset (4)	\$ 2,287	\$	\$ 2,287	\$
Foreign currency derivatives (5)	3,239		3,239	
<b>Total</b>	<b>\$ 457,890</b>	<b>\$ 18,524</b>	<b>\$ 439,366</b>	<b>\$</b>
<b>Liabilities:</b>				
Deferred compensation liability (6)	\$ 3,693	\$ 1,406	\$ 2,287	\$
Foreign currency derivatives (7)	56		56	
Contingent acquisition consideration payable (8)	42,323			42,323
<b>Total</b>	<b>\$ 46,072</b>	<b>\$ 1,406</b>	<b>\$ 2,343</b>	<b>\$ 42,323</b>

(1) At December 31, 2009 and March 31, 2010, 62% and 67% are included in short-term investments in the Company's consolidated balance sheets, respectively. The remaining balances are included in long-term investments.

(2) These amounts are included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2009, 64% of corporate securities and 58% of government agencies were included in long-term investments and the remaining balances were included in short-term investments. At March 31, 2010, 36% of corporate securities and 53% of government agencies were included in long-term investments and the remaining balances were included in short-term investments.

(3) These amounts are included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2009 and March 31, 2010, 22% and 100%, respectively, are included in long-term investments and the remaining balances are included in short-term investments.

(4) At December 31, 2009 and March 31, 2010, 95% and 100%, respectively of this balance is included in other assets and the remainder of the balance is included in other current assets on the Company's consolidated balance sheet.

(5) These amounts are included in other current assets on the Company's consolidated balance sheet. Foreign currency derivatives at December 31, 2009 and March 31, 2010 include forward foreign exchange contracts for the Euro.

(6) At December 31, 2009 and March 31, 2010, 89% and 96%, respectively, was included in other long-term liabilities and the remainder is included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.

(7) These amounts are included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.

(8) At December 31, 2009 and March 31, 2010, 62% and 57% of these amounts are included in other long-term liabilities, respectively, and 38% and 43% are included in accrued expenses, respectively. See Notes 6 and 7 for additional discussion.

The Company's level 2 securities are valued using third-party pricing sources, which generally use interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing. See Note 8 for further information regarding the fair value of the Company's financial instruments.



## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The Company's level 3 liabilities are estimated using a probability-based income approach utilizing an appropriate discount rate. Subsequent changes in the fair value of the contingent acquisition consideration payable will be recorded in the Intangible asset and contingent consideration expense line item in the consolidated statements of operations under operating expenses. During the first quarter of 2010, the fair value of the contingent acquisition consideration payable increased by \$0.6 million. The following table represents the changes in the Company's level 3 liabilities for the quarter ended March 31, 2010 (in thousands):

	<b>Contingent Acquisition Payable</b>
Fair value at December 31, 2009	\$ 21,213
Contingent acquisition consideration payable resulting from the LEAD acquisition	20,456
Change in valuation of contingent consideration payable to former Huxley shareholders	654
Fair value at March 31, 2010	\$ 42,323

**Table of Contents**

As discussed in Notes 6 and 7, the Company acquired intangible assets as a result of Huxley and LEAD acquisitions. The estimated fair value of these long-lived assets was measured using level 3 inputs.

**(16) REVENUE AND CREDIT CONCENTRATIONS**

The Company considers there to be revenue concentration risks for regions where net product revenue exceeds 10% of consolidated net product revenue. The concentration of the Company's revenue within the regions below may expose the Company to a material adverse effect if sales in the respective regions were to experience difficulties. The table below summarizes product revenue concentrations based on patient location for Naglazyme, Kuvan and Firdapse and Genzyme's location for Aldurazyme for the three months ended March 31, 2009 and 2010.

Region:	Three Months Ended	
	March 31,	
	2009	2010
United States	52%	51%
Europe	24%	22%
Latin America	11%	13%
Rest of World	13%	14%
Total Net Product Revenue	100%	100%

The accounts receivable balances at December 31, 2009 and March 31, 2010 are comprised of amounts due from customers for net product sales of Naglazyme and Kuvan and Aldurazyme product transfer and royalty revenues. On a consolidated basis, the three largest customers accounted for 46% of the Company's net product revenues during the first quarter of 2010, compared to the first quarter of 2009 during which the three largest customers accounted for 51% of the Company's net product revenues. On a consolidated basis, the three largest customers accounted for 41%, 16% and 11% of the March 31, 2010 accounts receivable balance, compared to December 31, 2009 when the two largest customers accounted for 49% and 18% of the accounts receivable balance. 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.

**(17) JOINT VENTURE**

Effective January 2008, the Company and Genzyme restructured BioMarin/Genzyme LLC. Under the revised structure, the operational responsibilities for the Company and Genzyme did not significantly change, as Genzyme continues to globally market and sell Aldurazyme and the Company continues to manufacture Aldurazyme. The restructuring had two significant business purposes. First, since each party now has full control over its own operational responsibilities, without the need to obtain the approval of the other party, and the parties do not need to review and oversee the activities of the other, it reduces management's time and effort and therefore improves overall efficiencies. Second, since each party will realize 100% of the benefit of their own increased operational efficiencies, it increases the incentives to identify and implement cost saving measures. Under the previous 50/50 structure, each company shared 50% of the expense associated with the other's inefficiencies and only received 50% of the benefit of its own efficiencies. Specifically, the Company will be able to realize the full benefit of any manufacturing cost reductions and Genzyme will be able to realize the full benefit of any sales and marketing efficiencies.

Genzyme records sales of Aldurazyme to third party customers and pays the Company a tiered payment ranging from approximately 39.5% to 50% of worldwide net product sales depending on sales volume, which is recorded by the Company as product revenue. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme because all of the Company's performance obligations are fulfilled at this point and title to, and risk of loss for, the product has transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay the Company if the product is unsold by Genzyme. The amount of product transfer revenue is deducted from the calculated royalty rate when the product is sold by Genzyme. Genzyme's return rights for Aldurazyme are limited to defective product. Certain research and development activities and intellectual property related to Aldurazyme continue to be managed in the joint venture with the costs shared equally by the Company and Genzyme.

**Table of Contents**

The Company presents 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 includes the Company's 50% share of the net income/loss of BioMarin/Genzyme LLC related to intellectual property management and ongoing research and development activities.

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

This Quarterly Report on 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, and similar expressions. These forward-looking statements may be found in *Overview*, of this Item 2 and other sections of this Quarterly Report on 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 Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the Securities and Exchange Commission (SEC) on February 25, 2010 as well as those discussed elsewhere in this Quarterly Report on 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 Quarterly Report on Form 10-Q to reflect later events or circumstances or the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q.

**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 or offer a significant benefit over existing products. Our product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme, Kuvan and Firdapse.

Naglazyme received marketing approval in the U.S. in May 2005, in the EU in January 2006 and subsequently in other countries. Naglazyme net product revenues for the three months ended March 31, 2009 and 2010 totaled \$39.4 million and \$48.6 million, respectively.

Aldurazyme, which was developed in collaboration with Genzyme Corporation (Genzyme), has been approved for marketing in the U.S., EU and other countries. Pursuant to our arrangement with Genzyme, Genzyme sells Aldurazyme to third parties and we recognize royalty revenue on net sales by Genzyme. We recognize a portion of the royalty as product transfer revenue when product is released to Genzyme because all obligations related to the transfer have been fulfilled at that point and title to, and risk of loss for, the product has been transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalties earned when the product is sold by Genzyme. Aldurazyme net product revenues for the three months ended March 31, 2009 and 2010 were \$17.0 million and \$14.2 million, respectively.

Kuvan was granted marketing approval in the U.S. and EU in December 2007 and December 2008, respectively. Kuvan net product revenues for the three months ended March 31, 2009 and 2010 totaled \$15.5 million and \$21.2 million, respectively.

In December 2009, the EMEA granted marketing approval for Firdapse. We launched this product on a country by country basis starting in March 2010. Firdapse net product revenues for the three months ended March 31, 2010 totaled \$0.1 million and were comprised solely of named patient sales. Firdapse was launched commercially in Europe in April 2010. We also continue to develop Firdapse for the possible treatment of LEMS in the U.S.

We are conducting clinical trials on several investigational product candidates for the treatment of genetic diseases, including: GALNS, an enzyme replacement therapy for the treatment of Mucopolysaccharidosis Type IV or Morquio Syndrome Type A, (MPS IV A), PEG-PAL, an enzyme substitution therapy for the treatment of phenylketonurics (PKU) for patients who do not respond well to Kuvan and a small molecule for the treatment of Duchenne muscular dystrophy. In September 2009, we initiated a Phase 2 clinical trial to evaluate PEG-PAL in PKU patients. Results from this clinical trial are expected in the third quarter of 2010. In the first half of 2009, we initiated a Phase 1/2 clinical trial of GALNS. We have completed enrollment in this clinical trial and reported results in April 2010. In January 2010, we initiated a Phase 1 clinical trial of our small molecule for the treatment of Duchenne muscular dystrophy. Initial top-line results from this trial are expected in the second quarter of 2010.



**Table of Contents**

Key components of our results of operations for the three months ended March 31, 2009 and 2010 include the following (in millions):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2010</b>
Total net product revenues	\$ 71.9	\$ 84.1
Cost of sales	14.4	17.4
Research and development expense	34.4	30.1
Selling, general and administrative expense	28.6	34.0
Net income (loss)	(13.2)	1.2
Stock-based compensation expense	7.8	8.5

See *Results of Operations* below for a discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, short-term investments and long-term investments totaled \$452.4 million as of March 31, 2010, compared to \$470.5 million as of December 31, 2009. See *Liquidity and Capital Resources* below for a further discussion of our liquidity and capital resources.

**Critical Accounting Policies and Estimates**

In preparing our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. and pursuant to the rules and regulations promulgated by the SEC, we make assumptions, judgments and estimates that can have a significant impact on our net income/loss and affect the reported amounts of certain assets, liabilities, revenue and expenses, and related disclosures. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates. We also discuss our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

We believe that the assumptions, judgments and estimates involved in the accounting for the valuation and impairment reviews of long-lived assets, revenue recognition and related reserves, income taxes, inventory, research and development expenses, stock-based compensation and business combinations have the greatest impact on our consolidated financial statements, so we consider these to be our critical accounting policies. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results.

Except for our critical accounting policy for the valuation of our contingent acquisition consideration payable noted below, there have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2010, as compared to the critical accounting policies and estimates disclosed in *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 25, 2010.

**Valuation of Contingent Acquisition Consideration Payable**

Each period we revalue the contingent acquisition consideration payable associated with certain acquisitions to their then fair value and record increases in the fair value as contingent consideration expense and record decreases in the fair value as a reduction of contingent consideration expense. Increases or decreases in the fair value of the contingent acquisition consideration payable can result from changes in assumed discount periods and rates, changes in the assumed timing of when milestones will be achieved and amount of revenue and expense estimates and changes in assumed probability adjustments with respect to regulatory approval. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, future business and economic conditions, as well as changes in any of the assumptions described above, can materially impact the amount of contingent consideration expense that we record in any given period.

**Recent Accounting Pronouncements**

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



**Table of Contents****Results of Operations****Net Income (Loss)**

Our net income for the three months ended March 31, 2010 was \$1.2 million compared to net loss of \$13.2 million for the three months ended March 31, 2009, representing a change of \$14.4 million. The change of \$14.4 million was primarily a result of the following (in millions):

Net loss for the year period ended March 31, 2009	\$ (13.2)
Increased Naglazyme gross profit	8.0
Increased Kuvan gross profit	4.6
Increased selling, general and administrative expense	(5.4)
Decreased Aldurazyme gross profit	(3.6)
Decreased impairment loss on equity investments	5.9
Decreased research and development expense	4.3
Decreased interest expense	1.7
Decreased interest income	(1.0)
Decreased Orapred royalty revenue	(0.9)
Gain on the sale of equity investments	0.9
Other individually insignificant fluctuations	(0.1)
<b>Net income for the period ended March 31, 2010</b>	<b>\$ 1.2</b>

The increase in selling, general and administrative expense in the first quarter of 2010 is primarily due to increased facility and employee related costs and the continued international expansion of Naglazyme and commercialization of Firdapse in Europe. The decrease in research and development expense is primarily attributed to the absence of the \$8.8 million of up-front costs associated with a product licensed from La Jolla in 2009, offset by increased development expenses for our PEG-PAL and Duchenne muscular dystrophy programs. The increase in Naglazyme gross profit in the first quarter of 2010 as compared is the same period in 2009 primarily a result of additional patients initiating therapy outside the U.S. The increase in Kuvan gross profit in the first quarter of 2010 as compared to the same period in 2009 is primarily a result of additional patients initiating therapy in the U.S. The decrease in Aldurazyme gross profit in the first quarter of 2010, as compared to the same period in 2009 is primarily attributed to less shipments of Aldurazyme to Genzyme than Genzyme's shipments to third parties resulting in lower royalties payable to us and the write-off of approximately \$2.1 million of Aldurazyme product for an outdated registration lot as a result of delays in the qualification of a new fill finish vendor during the first quarter of 2010. See below for additional information related to the primary net income/loss fluctuations presented above, including details of our operating expense fluctuations.

**Net Product Revenues, Cost of Sales and Gross Profit**

The following table shows a comparison of net product revenues for the three months ended March 31, 2009 and 2010 (in millions):

	<b>Three Months Ended March 31,</b>		
	<b>2009</b>	<b>2010</b>	<b>Change</b>
Naglazyme	\$ 39.4	\$ 48.6	\$ 9.2
Kuvan	15.5	21.2	5.7
Aldurazyme	17.0	14.2	(2.8)
Firdapse		0.1	0.1
<b>Total Net Product Revenues</b>	<b>\$ 71.9</b>	<b>\$ 84.1</b>	<b>\$ 12.2</b>

Net product revenues for Naglazyme in the first quarter of 2010 totaled \$48.6 million, of which \$41.2 million was earned from customers based outside the U.S. The impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar was insignificant in the first quarter of 2010. Gross profit from Naglazyme sales in the first quarter of 2010 was approximately \$39.3 million, representing gross margins of 81%, compared to gross profits of \$31.3 million in the first quarter of 2009, representing gross margins of approximately 80%. The slight increase in gross margins during the first quarter of 2010 as compared to the first quarter of 2009 is primarily due



to the impact of improved manufacturing yields.

**Table of Contents**

Net product revenue for Kuvan during the first quarter of 2010 was \$21.2 million, compared to \$15.5 million during the same period in 2009. With the commercial launch of Kuvan in the EU during the first half of 2009, we began receiving a royalty of approximately 4% on net sales of Kuvan from Merck Serono. During the first quarter of 2010, we earned \$0.2 million in royalties from Merck Serono on net sales of \$4.8 million. Royalties earned from Merck Serono during the first quarter of 2009 were insignificant. Gross profit from Kuvan in the first quarter of 2010 was approximately \$17.7 million, representing gross margins of approximately 84%, compared to the first quarter of 2009 when gross profit totaled \$13.1 million, representing gross margins of approximately 84%. Both periods reflect royalties paid to third parties 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. We expect U.S. gross margins for Kuvan for the foreseeable future to be in the lower 80% range as the pre-approval inventory has been mostly depleted.

Pursuant to our relationship with Genzyme, we record a 39.5% to 50% royalty on worldwide net product sales of Aldurazyme. We also recognize product transfer revenue when product is released to Genzyme and all of our obligations have been fulfilled. Genzyme's return rights for Aldurazyme are limited to defective product. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty rate when the product is sold by Genzyme.

	<b>Three Months Ended March 31,</b>		
	<b>2009</b>	<b>2010</b>	<b>Change</b>
Aldurazyme revenue reported by Genzyme	\$ 36.8	\$ 39.9	\$ 3.1
Royalties due from Genzyme	14.5	15.9	1.4
Incremental (previously recognized) Aldurazyme product transfer revenue	2.5	(1.7)	(4.2)
Total Aldurazyme net product revenues	\$ 17.0	\$ 14.2	\$ (2.8)
Gross profit	\$ 13.2	\$ 9.6	\$ (3.6)

In the first quarter of 2010, Aldurazyme gross margins were 67%, compared to 77% in the first quarter of 2009. Aldurazyme gross margins reflect the profit earned on royalty revenue and net incremental product transfer revenue. The change in gross margins is attributed to a shift in revenue mix between royalty revenue and net product transfer revenues as well as a \$2.1 million write-off of an outdated registration lot of Aldurazyme as a result of delays in the qualification of a new fill finish vendor during the first quarter of 2010. In the first quarter of 2010 Aldurazyme net product revenues were solely comprised of royalty revenues, compared to the same period in 2009, when the revenue mix was 85% royalty revenues and 15% net product transfer revenues. In the future, to the extent that Genzyme's 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 margins are expected to 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.

Total cost of sales in the first quarter of 2010 was \$17.4 million, compared to \$14.4 million in the first quarter of 2009. The increase in cost of sales in the first quarter of 2010 compared the same period in 2009 is attributed to the increase in Naglazyme and Kuvan product sales and the Aldurazyme inventory write-off discussed above.

**Collaborative Agreement Revenues**

Collaborative agreement revenues for the first quarters of 2009 and 2010 are comprised of contract research revenue under our agreement with Merck Serono, which was executed in May 2005. Contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. Our performance obligations related to the initial \$25.0 million up-front license payment were completed in December 2008; as such, periods subsequent to December 31, 2008 no longer include amortization of the \$25.0 million up-front license payment received from Merck Serono. As shared development spending increases or decreases, contract research revenues will also change proportionately. Reimbursable revenues are expected to increase if PEG-PAL successfully completes Phase 2 clinical trials and Merck Serono exercises its right to co-develop it. The related costs are included in research and development expenses.

Collaborative agreement revenue in the first quarters of 2009 and 2010 were \$0.5 million and \$0.2 million, respectively. In both periods collaborative agreement revenue was comprised solely of reimbursable Kuvan development costs.



**Table of Contents****Royalty and License Revenues**

The following table details the components of royalty and license revenues for the three months ended March 31, 2009 and 2010 (in millions):

	<b>Three Months Ended March 31,</b>		
	<b>2009</b>	<b>2010</b>	<b>Change</b>
Orapred product royalties	\$ 1.4	\$ 0.5	\$ (0.9)
6R-BH4 royalty revenues	0.2	0.2	
<b>Total</b>	<b>1.6</b>	<b>0.7</b>	<b>(0.9)</b>

Royalty and license revenues include Orapred product royalties, a product we acquired in 2004 and sublicensed in 2006, and 6R-BH4 royalty revenues for product sold in Japan. 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.

**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 expense decreased by \$4.3 million to \$30.1 million for the three months ended March 31, 2010, from \$34.4 million for the three months ended March 31, 2009. The change in research and development expense for the three months ended March 31, 2010 was primarily a result of the following (in millions):

Research and development expense for period ended March 31, 2009	\$ 34.4
Absence of license payment related to collaboration with La Jolla Pharmaceutical Company	(8.8)
Decreased 6R-BH4 development expenses for indications other than PKU	(2.0)
Increased PEG-PAL development expenses	2.1
Increased Duchenne muscular dystrophy program development expense	1.4
Decreased Prodrug development expenses	(0.9)
Decreased GALNS for Morquio Syndrome Type A development expense	(0.2)
Increased stock-based compensation expense	0.7
Increased development expenses related to commercial products	0.7
Increased research and development expenses on early development stage programs	1.6
Increase in non-allocated research and development expenses and other net changes	1.1
 Research and development expense for the period ended March 31, 2010	 \$ 30.1

During the first quarter of 2009, we paid La Jolla an up-front license fee for the rights to develop and commercialize La Jolla's investigational drug, Riquent. We terminated the license agreement with La Jolla in 2009 and there will not be any additional development expense for Riquent. The increase in PEG-PAL development expense is attributed to increased clinical trial activities related to the product candidate. The increase in Duchenne muscular dystrophy program development expense is primarily attributed to increased pre-clinical activities and Phase I clinical trial related to the product candidate. The decrease in 6R-BH4 development expense expenses for indications other than PKU is primarily due to a decline in clinical studies in the first quarter of 2010 compared to the same period in 2009. The increase in stock-based compensation expense is a result of an increased number of options outstanding due to an increased number of employees. The increase in research and development expenses related to commercial products is attributed to long-term Kuvan clinical activities related to post-approval regulatory commitments. The increase in non-allocated research and development expense primarily includes increases in general research costs and research and development personnel costs that are not allocated to specific programs. We expect to continue incurring significant research and development expense for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments related to our products and spending on our GALNS, PEG-PAL, Duchenne muscular dystrophy and Firdapse programs and our other product candidates.

*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; human resources; finance; legal and support personnel expenses and other external corporate costs such as insurance, audit and legal fees.

**Table of Contents**

Selling, general and administrative expenses increased by \$5.4 million to \$34.0 million for the three months ended March 31, 2010, from \$28.6 million for the three months ended March 31, 2009. The components of the change for the three months ended March 31, 2010 was primarily include the following (in millions):

Selling, general and administrative expense for the period ended March 31, 2009	\$ 28.6
Increased Naglazyme sales and marketing expenses	1.0
Increased Firdapse commercial preparation expenses	1.2
Decreased Kuvan commercialization expenses	(1.0)
Decreased stock-based compensation expense	(0.4)
Increased depreciation expense	0.4
Increased foreign exchange losses on un-hedged transactions	0.3
Net increase in corporate overhead and other administrative expenses	3.9
Selling, general and administrative expense for the period ended March 31, 2010	\$ 34.0

The increase in Naglazyme sales and marketing expenses in the first quarter of 2010 is attributed to continued expansion of our international activities. We incurred spending related to the commercialization of Firdapse for the product's European launch in April 2010. The decrease in Kuvan commercialization expense is attributed to a decline in publication and media development expense for Kuvan during the first quarter of 2010 compared to the same period in 2009. The increase in corporate overhead and other administrative costs during the first quarter of 2010 is primarily comprised of increased employee related costs. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme, the European launch of Firdapse and the U.S. commercialization activities for Kuvan.

***Intangible Asset Amortization and Contingent Consideration Expense***

Intangible asset amortization and contingent consideration expense for the first quarter of 2010 was \$0.7 million, compared to \$1.1 million in the first quarter of 2009. Intangible asset amortization and contingent consideration expense during the first quarter of 2010 was comprised of the change in fair value of the contingent consideration payable to the former shareholders of Huxley Pharmaceuticals, Inc. (See Note 15 of the accompanying unaudited consolidated financial statements for additional discussion). Amortization of intangible assets for the first quarter of 2009 included three months of amortization expense related to the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology. In June 2009, we completed the purchase of all of the outstanding shares of capital stock of BioMarin Pediatrics II (formerly known as Ascent Pediatrics, Inc. and Medicis Pediatrics, Inc.), a wholly-owned subsidiary of Medicis Pharmaceutical Corporation (Medicis) as required by the original transaction agreement of 2004 for \$70.6 million. Medicis' sole substantive asset was the intellectual property related to the Orapred franchise. Subsequently, we transferred the exclusive intellectual property rights to our sublicense in July 2009.

***Equity in the Loss of BioMarin/Genzyme LLC***

Equity in the loss of BioMarin/Genzyme LLC includes our 50% share of the joint venture's loss for the period. BioMarin/Genzyme LLC's operations consist primarily of certain research and development activities and the intellectual property which are managed by the joint venture with costs shared equally by BioMarin and Genzyme.

Equity in the loss of the joint venture totaled \$0.7 million for the three months ended March 31, 2010, compared to \$0.5 million for the three months ended March 31, 2009.

***Interest Income***

We invest our cash, short-term and long-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income totaled \$2.2 million and \$1.2 million in the three months ended March 31, 2009 and 2010, respectively. The reduced interest yield during the first quarter of 2010 was due to lower market interest rates and decreased levels of cash and investments. We expect that interest income will decline during the remainder of 2010 as compared to 2009 due to reduced interest yields and lower cash and investment balances.

***Interest Expense***

## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

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 during the first quarter of 2010 was \$2.4 million, compared to the same period of 2009 when interest expense amounted to \$4.1 million. Interest expense in the first quarter of 2009 included imputed interest of \$1.1 million. Imputed interest will not be incurred in periods subsequent to June 2009 as the Medicis obligation was paid in full in June 2009.

**Table of Contents****Changes in Financial Position****March 31, 2010 Compared to December 31, 2009**

From December 31, 2009 to March 31, 2010, our cash, cash equivalents, and short-term and long-term investments decreased by \$18.1 million, primarily as a result the acquisition of LEAD Therapeutics, Inc. and capital expenditures, offset by cash flows from operating activities and proceeds from ESPP contributions and stock option exercises. Our accounts receivable increased by \$9.1 million due to increased sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. Our net property, plant and equipment increased by approximately \$4.8 million from December 31, 2009 to March 31, 2010, primarily as a result of continued expansion and improvements to our facilities during the period. Intangible assets, goodwill and other long-term liabilities increased by approximately \$36.4 million, \$16.7 million and \$25.5 million primarily as a result of the LEAD acquisition. Due to several ongoing facility improvement projects substantially completed in 2009, we expect depreciation expense to increase as the assets are placed into service.

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

As of March 31, 2010, our combined cash, cash equivalents, short-term and long-term investments totaled \$452.4 million, a decrease of \$18.1 million from \$470.5 million at December 31, 2009.

The decrease in our combined cash, cash equivalents, short-term investments and long-term investments during the first quarter of 2010 was \$18.1 million, which was \$12.6 million more than the net decrease in the first quarter of 2009 of \$5.5 million. The primary items contributing to the decrease in net cash outflow in the first quarter of 2010 were as follows (in millions):

Absence of milestone payment received for Kuvan EMEA approval	\$ (30.0)
Acquisition of LEAD Therapeutics, Inc.	14.1
Increased proceeds from ESPP and stock option exercises	8.3
Absence of investment in La Jolla Pharmaceuticals, Inc.	6.3
Decreased capital asset purchases	4.6
Decreased Orapred acquisition payments	1.5
Increased investments in BioMarin/Genzyme LLC	(1.5)
Net increase in cash provided by operating activities, including net payments for working capital, and other	12.3
<b>Total increase in net cash outflow</b>	<b>\$ (12.6)</b>

The net decrease in operating spend includes increases in cash receipts from net revenues, partially offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, as discussed in *Results of Operations* above. Decreased capital purchases reflect the substantial completion of our manufacturing facilities at our Novato, California campus in the second half of 2009. Net payments for working capital in the first quarter of 2010, primarily includes decreased inventory build of \$2.2 million, increased accounts receivable build of \$2.0 million and decreased reduction of other current assets of \$22.8 million. The decrease in other current assets reduction is primarily attributed to the receipt of the Merck Serono \$30.0 million milestone payment earned in December 2008 related to the EMEA approval of Kuvan in January 2009.

On October 23, 2009, we acquired Huxley, which has rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate for the treatment of the rare autoimmune disease LEMS for a total purchase price of \$37.2 million, of which \$15.0 million was paid in cash and \$22.2 million is contingent acquisition consideration payable, of which \$1.0 million was paid in the fourth quarter of 2009 and \$6.5 million was paid in April 2010. In connection with the acquisition, we agreed to pay Huxley stockholders additional consideration in future periods of up to \$41.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and U.S. development milestones are met.

On February 10, 2010, we acquired LEAD, which has the key compound, LT-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with rare, genetically defined cancers for a total purchase price of \$39.1 million, of which \$18.6 million was paid in cash and \$20.5 million is contingent acquisition consideration payable. We paid \$3.0 million of the \$18.6 million in cash during December 2009. In connection with the acquisition, we agreed to pay LEAD stockholders additional consideration in future periods of up to



## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

\$68.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met.

We expect that our net cash outflow in 2010 related to capital asset purchases will decrease significantly compared to 2009. The expected decrease in capital asset purchases primarily reflects the substantial completion of our manufacturing facility and the related spending on manufacturing and laboratory equipment.

**Table of Contents**

We have historically financed our operations primarily by the issuance of common stock and convertible debt and by relying on equipment and other commercial financing. During 2010, and for the foreseeable future, we will be highly dependent on our net product revenue to supplement our current liquidity and fund our operations. We may in the future elect to supplement this with further debt or equity offerings or commercial borrowing. Further, depending on market conditions, our financial position and performance and other factors, in the future we may choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities.

**Funding Commitments**

We expect to fund our operations with our net product revenues from our commercial products; cash; cash equivalents; short-term and long-term investments supplemented by proceeds from equity or debt financings; and loans or collaborative agreements with corporate partners, each to the extent necessary. We expect our current cash, cash equivalents, and short-term and long-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 and continued development of our existing commercial products has a major impact on our operating performance. Our research and development expenses for the three months ended March 31, 2009 and 2010 and for the period since inception (March 1997 for the portion not allocated to any major program) represent the following (in millions):

	Three Months Ended March 31,		Since Program Inception
	2009	2010	
Naglazyme	\$ 2.3	\$ 2.2	\$ 134.6
Kuvan	2.6	3.0	104.3
GALNS for Morquio Syndrome Type A	4.1	3.9	38.0
6R-BH4 for indications other than PKU	3.1	0.2	46.7
PEG-PAL	2.3	4.4	46.8
Not allocated to specific major current projects	12.1	16.4	257.9
	\$ 26.5	\$ 30.1	\$ 628.3

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, 2009, which was filed with the SEC on February 25, 2010, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in such Annual Report on Form 10-K: *If we fail to maintain regulatory approval to commercially market and 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 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 timeframes 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, Kuvan and Firdapse; preclinical studies and clinical trials for our other product candidates; potential licenses and other acquisitions of complementary technologies, products and companies; general corporate purposes; 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, Kuvan and Firdapse;

Genzyme's ability to continue to successfully market and commercialize Aldurazyme;

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

**Table of Contents**

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 our 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 \$497.1 million of convertible debt will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

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, 2010 is presented in the table below (in thousands).

	Payments Due by Period					Total
	2010	2011	2012 -2013	2014-2015	2016 and Thereafter	
Convertible debt and related interest	\$ 8,246	\$ 10,401	\$ 190,853	\$ 12,183	\$ 334,012	\$ 555,695
Operating leases	3,247	4,037	6,495	2,238	2,378	18,395
Research and development and purchase commitments	24,977	8,853	5,806	3,446	4,049	47,131
Total	\$ 36,470	\$ 23,291	\$ 203,154	\$ 17,867	\$ 340,439	\$ 621,221

We are also subject to contingent payments related to various development activities totaling approximately \$268.7 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 Disclosures About Market Risk**

Our market risks at March 31, 2010 have not materially changed from those in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 25, 2010.

**Item 4. Controls and Procedures**

**(a) 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, regarding 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 (the Exchange Act)) as of the end of the period covered by this report.

## **Table of Contents**

Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in the reports that we filed or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

### **(b) Change in Internal Controls over Financial Reporting**

There were no changes in our internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act, during our most recently completed quarter that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

None.

### **Item 1A. Risk Factors**

In the three months ended March 31, 2010, there have not been any material changes from the risk factors previously disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, which was filed with the SEC on February 25, 2010.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

### **Item 3. Defaults upon Senior Securities.**

None.

### **Item 4. (Removed and Reserved).**

### **Item 5. Other Information.**

None.

### **Item 6. Exhibits.**

- 10.1# Stock Purchase Agreement by and among BioMarin Pharmaceutical Inc., and LEAD Therapeutics Inc. and the stockholders of LEAD Therapeutics, Inc. dated February 4, 2010. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 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.

## Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

- 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.

# Confidential treatment registered for a portion of this document. Omitted parts have been filed separately with the SEC.

**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, 2010

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**

- 10.1# Stock Purchase Agreement by and among BioMarin Pharmaceutical Inc., and LEAD Therapeutics Inc. and the stockholders of LEAD Therapeutics, Inc. dated February 4, 2010. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 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.

# Confidential treatment registered for a portion of this document. Omitted parts have been filed separately with the SEC.