BIOMARIN PHARMACEUTICAL INC
Form 10-Q
July 31, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2009

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)

Delaware	**68-0397820**
(State of other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
105 Digital Drive, Novato, California	**94949**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number: (415) 506-6700

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of the 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 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 ¨

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	x	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 x

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

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

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 100,284,116 shares common stock, par value $0.001, outstanding as of July 24, 2009.

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BIOMARIN PHARMACEUTICAL INC.

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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, 2008 (1)	June 30, 2009 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 222,900	$ 200,050
Short-term investments	336,892	146,341
Accounts receivable, net	54,298	72,576
Inventory	73,162	72,836
Other current assets	50,444	15,178
Total current assets	737,696	506,981
Investment in BioMarin/Genzyme LLC	915	462
Long-term investments	1,633	138,863
Property, plant and equipment, net	124,979	159,789
Intangible assets, net	7,626	4,391
Goodwill	21,262	21,262
Other assets	12,584	12,689
Total assets	$ 906,695	$ 844,437
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 59,033	$ 59,104
Acquisition obligation, net of discount	70,741	
Deferred revenue	307	929
Total current liabilities	130,081	60,033
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	3,887
Total liabilities	630,020	561,003
Stockholders equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and June 30, 2009; 99,868,145 and 100,235,218 shares issued and outstanding at December 31, 2008 and June 30, 2009, respectively	100	100
Additional paid-in capital	852,947	873,378
Company common stock held by deferred compensation plan	(882)	(1,709)
Accumulated other comprehensive income	1,106	101
Accumulated deficit	(576,596)	(588,436)

Total stockholders equity	276,675	283,434
Total liabilities and stockholders equity	$ 906,695	$ 844,437

(1) December 31, 2008 balances were derived from the audited consolidated financial statements.

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

For the Three and Six Months Ended June 30, 2008 and 2009

(In thousands, except for per share data, unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Revenues:				
Net product revenues	$ 60,458	$ 81,472	$ 118,083	$ 153,386
Collaborative agreement revenues	2,509	868	4,975	1,377
Royalty and license revenues	1,207	447	1,513	2,004
Total revenues	64,174	82,787	124,571	156,767
Operating expenses:				
Cost of sales	9,593	19,848	26,781	34, 210
Research and development	23,755	26,324	41,383	60,682
Selling, general and administrative	25,203	30,527	48,872	59,095
Amortization of acquired intangible assets	1,093	1,775	2,185	2,868
Total operating expenses	59,644	78,474	119,221	156,855
Income (loss) from operations	4,530	4,313	5,350	(88)
Equity in the loss of BioMarin/Genzyme LLC	(587)	(546)	(1,120)	(1,093)
Interest income	4,101	886	9,750	3,039
Interest expense	(4,081)	(4,404)	(8,193)	(8,496)
Impairment loss on equity investments				(5,848)
Net gain from sale of investments		1,585		1,585
Income (loss) before income taxes	3,963	1,834	5,787	(10,901)
Provision for income taxes	153	522	291	939
Net income (loss)	$ 3,810	$ 1, 312	$ 5,496	$ (11,840)
Net income (loss) per share, basic	$ 0.04	$ 0.01	$ 0.06	$ (0.12)
Net income (loss) per share, diluted	$ 0.04	$ 0.01	$ 0.05	$ (0.12)
Weighted average common shares outstanding, basic	98,923	100,065	98,285	99,984
Weighted average common shares outstanding, diluted	104,120	101,217	103,948	100,075

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Six Months Ended June 30, 2008 and 2009

(In thousands, unaudited)

	Six Months Ended June 30,	
	2008	2009
Cash flows from operating activities:		
Net income (loss)	$ 5,496	$ (11,840)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	8,320	11,273
Amortization of discount on investments	(4,282)	(341)
Imputed interest on acquisition obligation	2,206	2,859
Equity in the loss of BioMarin/Genzyme LLC	1,120	453
Stock-based compensation	11,865	17,494
Impairment loss on investments		5,848
Gain on sale of investments		(1,585)
Unrealized foreign exchange gain (loss) on forward contracts	(100)	3,323
Excess tax benefit from stock option exercises		(131)
Changes in operating assets and liabilities:		
Accounts receivable, net	(35,180)	(18,278)
Advances to BioMarin/Genzyme LLC	1,839	110
Inventory	(2,576)	326
Other current assets	(5,971)	31,793
Other assets	(1,621)	(1,674)
Accounts payable and accrued liabilities	4,442	(2,183)
Other liabilities	291	1,122
Deferred revenue	(2,091)	622
Net cash provided by (used in) operating activities	(16,242)	39,191
Cash flows from investing activities:		
Purchase of property and equipment	(32,332)	(40,621)
Maturities and sales of investments	444,406	326,703
Purchase of investments	(406,668)	(271,119)
Distributions from BioMarin/Genzyme LLC	16,679	
Investment in La Jolla Pharmaceutical Company		(6,250)
Net cash provided by investing activities	22,085	8,713
Cash flows from financing activities:		
Proceeds from ESPP and exercise of stock options	21,523	2,805
Excess tax benefit from stock option exercises		131
Repayment of acquisition obligation	(3,500)	(73,600)
Repayment of capital lease obligations		(91)
Net cash provided by (used in) financing activities	18,023	(70,755)
Net increase (decrease) in cash and cash equivalents	23,866	(22,850)

Cash and cash equivalents:		
Beginning of period	228,343	222,900
End of period	$ 252,209	$ 200,050
Supplemental cash flow disclosures:		
Cash paid for interest	$ 5,210	$ 5,198
Cash paid for income taxes	103	813
Stock-based compensation capitalized into inventory	2,043	2,672
Depreciation capitalized into inventory	1,327	1,339
Supplemental non-cash investing and financing activities disclosures:		
Conversion of convertible notes	$ 129	$
Distribution of inventory resulting from the joint venture restructure	26,780	
Changes in accrued liabilities related to fixed assets	854	1,480
Equipment acquired through capital lease	313	

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2009

(Unaudited)

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin®) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin 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 three approved products and multiple investigational product candidates. Approved products include Naglazyme ® (galsulfase), Kuvan ® (sapropterin dihydrochloride), and Aldurazyme ® (laronidase).

Through June 30, 2009, the Company had accumulated losses of approximately $588.4 million. Management believes that the Company s cash, cash equivalents, and short-term and long-term investments at June 30, 2009 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, and Aldurazyme; the potential need for additional financings; its ability to successfully commercialize its product candidates, if approved; the uncertainty of the Company s research and development efforts resulting in successful commercial products; obtaining regulatory approval for such products; significant competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; dependence on corporate partners and collaborators; and possible restrictions on reimbursement, as well as other changes in the health care industry.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

These unaudited consolidated financial statements include the accounts of BioMarin and its wholly owned subsidiaries. All significant intercompany transactions have been eliminated. These unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (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 Form 10-Q, and has concluded that there are no significant subsequent events requiring disclosure through that date.

Operating results for the three and six months ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008, which was filed with the SEC on February 27, 2009.

(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.

(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 cash equivalents, 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 being included in accumulated other comprehensive income/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, U.S. treasury bills, money market funds and certificates of deposit. As of June 30, 2009, the Company had no held-to-maturity investments.

As of June 30, 2009, long-term investments included an equity investment denominated in British Pounds. The Company classified the investment as available-for-sale and accordingly the investment is recorded at fair market value. Changes in the fair market value are reported as a component of accumulated other comprehensive income, exclusive of other-than-temporary impairment losses, if any. Translation gains/losses on the equity investment, a non-monetary asset, resulting from fluctuations in foreign exchange rates are included in accumulated other comprehensive income. Losses related to changes in market value and exchange rates determined to be other-than-temporary are reported in earnings in the period in which the impairment occurs.

(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 written off to cost of sales.

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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.

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

Stock-based compensation of $2.0 million and $2.7 million was capitalized into inventory for the six months ended June 30, 2008 and 2009, 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 (see Note 4 for further information). The Company accounts for its remaining investment in the joint venture using the equity method. Accordingly, the Company records an increase in its investment for contributions to the joint venture and for its 50% share of the loss of the joint venture, and a reduction in its investment for its 50% share of any losses of the joint venture or disbursements of profits from the joint venture. Equity in the 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 7 for further information on property, plant and equipment balances as of December 31, 2008 and June 30, 2009.

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

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 sales in foreign jurisdictions, are presented on a net basis in the Company s statements of operations, in accordance with EITF No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement,* in that taxes billed to customers are not included as a component of net product revenues.

BioMarin 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 as 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 SAB 104 and the terms of the related agreements with Genzyme. As of June 30, 2009, accounts receivable included $20.3 million of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme.

The Company sells Naglazyme worldwide and sells Kuvan in the U.S. In the U.S., Naglazyme and Kuvan are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. The Company also sells Kuvan to Merck Serono at near 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 E.U. is included as a component of net product revenues in the period earned. Outside the U.S. Naglazyme is 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 period, and records any necessary adjustments to its reserves. The Company records fees paid to distributors as a reduction of revenue, in accordance with EITF Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor s Products).*

The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including market exclusivity of the products based on their orphan drug status, the patient population, the customers limited return rights and the Company s experience with returns. Because of the pricing of Naglazyme and Kuvan, the limited number of patients and the customers limited return rights, most Naglazyme and Kuvan customers and retailers carry a limited inventory. 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 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 and Naglazyme to estimate returns for

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Kuvan, which has a limited history. Genzyme s return rights for Aldurazyme are limited to defective product. 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 June 30, 2009, 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 our 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 performance obligation related to the $25.0 million upfront payment from Merck Serono ended in the fourth quarter of 2008. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related 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. 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 during the three and six months ended June 30, 2009 included $0.9 million and $1.4 million of reimbursable development costs for Kuvan, respectively, compared to the three and six months ended June 30, 2008 which totaled $2.5 million and $5.0 million, respectively, and included the recognition of $1.5 million and $3.0 million, respectively, of the $25.0 million up-front license fee received from Merck Serono and $1.0 million and $2.0 million, respectively, 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 when the royalty amount is fixed or determinable based on information received from the sublicensee and when collectibility is reasonably assured.

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 during the three and six months ended June 30, 2009 include $0.2 million and $1.6 million, respectively, of Orapred product royalties, a product the Company acquired in 2004 and sublicensed in 2006, and $0.3 million and $0.4 million, respectively, of 6R-BH4 royalty revenues for product sold in Japan compared to royalty and license revenues for the three and six months ended June 30, 2008, which included $1.2 million and $1.5 million, respectively, of Orapred product royalties. There is no cost of sales associated with the royalty and license revenues recorded during the periods and no related costs are expected in future periods.

(i) Research and Development

Research and development expenses include expenses associated with contract research and development provided by third parties, product manufacturing prior to regulatory approval, clinical and regulatory costs, and internal research and development costs. In instances where the Company enters into agreements with third parties for research and development activities, costs are expensed upon the earlier of when 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 our 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.

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The following represents a reconciliation from basic weighted shares outstanding to diluted weighted shares outstanding and the earnings per share for the three and six months ended June 30, 2008 (in thousands, except per share data):

	For the Three Months Ended June 30, 2008			For the Six Months Ended June 30, 2008		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Earnings Per Share:						
Net Income	$ 3,810	98,923	$ 0.04	$ 5,496	98,285	$ 0.06
Effect of dilutive shares:						
Stock options using the treasury method		4,702			5,163	
Portion of acquisition obligation payable in common stock at the option of the Company		297			297	
Potentially issuable restricted common stock		80			83	
Potentially issuable common stock for ESPP purchases		118			120	
Diluted Earnings Per Share:						
Net Income	$ 3,810	104,120	$ 0.04	$ 5,496	103,948	$ 0.05

In addition to the stock options included in the above table, options to purchase approximately 1.5 million and 0.9 million shares of common stock were outstanding during the three and six months ended June 30, 2008, but were not included in the computation of diluted earnings per share because they were anti-dilutive during the period using the treasury stock method. These options were anti-dilutive because the fair value of the Company s stock exceeded the assumed proceeds from the exercise of the stock options. Additionally, approximately 26.4 million underlying shares of the Company s convertible debt were not included in the diluted average common shares outstanding because they were antidilutive during the three and six months ended June 30, 2008 using the if-converted method whereby the related interest expense on the convertible debt is added to net income for the period.

The following represents a reconciliation from basic weighted shares outstanding to diluted weighted shares outstanding and the earnings per share for the three ended June 30, 2009 (in thousands, except per share data):

	For the Three Months Ended June 30, 2009			For the Six Months Ended June 30, 2009		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount	Net Loss (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Earnings Per Share:						
Net Income (Loss)	$ 1,312	100,065	$ 0.01	$ (11,840)	99,984	$ (0.12)
Effect of dilutive shares:						
Stock options using the treasury method		839				
Potentially issuable common stock for ESPP purchases		222				
Nonqualified Deferred Compensation Plan obligation using the treasury method	(116)	91		(111)	91	
Diluted Earnings Per Share:						

Net Income	$ 1,196	101,217	$ 0.01	$ (11,951)	100,075	$ (0.12)

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 during the three and six month periods ended June 30, 2009 using the treasury stock method (in thousands):

	Three Months Ended June 30, 2009	Six Months Ended June 30, 2009
Options to purchase common stock	11,593	14,668
Common stock issuable under convertible debt	26,343	26,343
Potentially issuable common stock for ESPP purchases		242
Potentially issuable restricted common stock	400	400
Total	38,336	41,653

(k) Stock-Based Compensation

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

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

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

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If factors change and different assumptions are employed in the application of SFAS No. 123R, the compensation expense recorded in future periods may differ significantly from what was recorded in the current period (see Note 3 for further information).

(l) Nonqualified Deferred Compensation Plan

Other non-current assets include $0.9 million and $1.5 million, respectively, of investments held in trust related to the Company s Nonqualified Deferred Compensation Plan for certain employees and directors as of December 31, 2008 and June 30, 2009, 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 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 its fair value are recognized in earnings as incurred. Additionally, the Company has recorded a corresponding liability for the Nonqualified Deferred Compensation Plan in other liabilities.

The 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 Board of Directors 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 of Directors.

(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 $294.7 million at December 31, 2008. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease net income/loss in the period such adjustment was made. During the three and six months ended June 30, 2009, the Company recognized income tax expense of $0.5 million and $0.9 million, respectively, compared to the three and six months ended June 30, 2008 when the Company recognized income tax expense of $0.2 million and $0.3 million respectively. Income tax expense in the three and six months ended June 30, 2008 and 2009 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 forward contracts. Gains or losses on net foreign currency hedges are intended to offset losses or gains 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 hedges in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, 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 11 for further information).

(o) Fair Value of Financial Instruments

SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, requires the Company to disclose the fair value of financial instruments for assets and liabilities for which it is practicable to estimate that value.

The carrying amounts of all cash equivalents 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) 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 exchange 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 and six months ended June 30, 2008 and 2009.

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During the three and six months ended June 30, 2009, comprehensive loss was approximately $0.7 million and $12.8 million, respectively, compared to comprehensive net income of $2.9 million and $4.8 million for the three and six months ended June 30, 2008, respectively. The fluctuation in accumulated other comprehensive income (loss) is comprised of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Net unrealized loss on available-for-sale securities	$ (534)	$ (205)	$ (321)	$ (838)
Net unrealized loss on foreign currency hedges	(391)	(2,877)	(391)	(945)
Net unrealized gain on equity investments		1,112		774
Net foreign currency translation gain (loss)	(1)	2	(2)	4
Change in accumulated other comprehensive income	$ (926)	$ (1,968)	$ (714)	$ (1,005)

(q) Restricted Cash

The Company s balance of restricted cash amounted to $7.3 million and $1.7 million at December 31, 2008 and June 30, 2009, respectively. The December 31, 2008 balance included $6.2 million related to cash received for royalties earned pursuant to the Orapred sublicense agreement, which was restricted from use until June 2009 when the Company paid the remaining acquisition obligation resulting from the Ascent Pediatrics transaction to Medicis (see Note 14). The $6.2 million was included in other current assets on the December 31, 2008 consolidated balance sheet. Restricted cash also includes investments of $0.9 million and $1.4 million held by the Company s Nonqualified Deferred Compensation Plan as of December 31, 2008 and June 30, 2009, respectively, which is included in other assets.

(r) Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No.167, *Amendments to FASB Interpretation No. 46(R)* (SFAS No. 167). SFAS No.167 eliminates FASB Interpretation No. 46(R) s exceptions to consolidating qualifying special-purpose entities, contains new criteria for determining the primary beneficiary, and increases the frequency of required reassessments to determine whether a company is the primary beneficiary of a variable interest entity. SFAS No.167 also contains a new requirement that any term, transaction, or arrangement that does not have a substantive effect on an entity s status as a variable interest entity, a company s power over a variable interest entity, or a company s obligation to absorb losses or its right to receive benefits of an entity must be disregarded in applying FASB Interpretation No. 46(R) s provisions. The elimination of the qualifying special-purpose entity concept and its consolidation exceptions means more entities will be subject to consolidation assessments and reassessments. SFAS No. 167 is effective for fiscal years beginning after November 15, 2009, which for the Company is January 1, 2010, with earlier adoption prohibited. The Company is currently assessing the potential impacts, if any, that SFAS No. 167 will have on its consolidated financial statements.

In June 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Assets an amendment of FASB Statement No. 140* (SFAS No. 166). SFAS No. 166 eliminates the concept of a qualifying special-purpose entity, creates more stringent conditions for reporting a transfer of a portion of a financial asset as a sale, clarifies other sale-accounting criteria, and changes the initial measurement of a transferor s interest in transferred financial assets. SFAS No. 166 will be effective for transfers of financial assets in fiscal years beginning after November 15, 2009, which for the Company is January 1, 2010, and in interim periods within those fiscal years, with earlier adoption prohibited. The Company is currently assessing the potential impacts, if any, that SFAS No. 166 will have on its consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position (FSP) FAS 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed,* (FSP FAS 157-4). FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS No. 157. FSP FAS 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (*i.e.*, financial and nonfinancial) and will require enhanced disclosures. This standard is effective for periods ending after June 15, 2009, which for the Company was the second quarter of fiscal 2009. The adoption of this standard did not have a material impact on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP FAS 115-2, FAS 124-2, and EITF 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, (FSP FAS 115-2, FAS 124-2, and EITF 99-20-2, respectively). FSP FAS 115-2, FAS 124-2, and EITF 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities and was effective for

periods ending after June 15, 2009, with early adoption permitted. The adoption of this standard did not have a material impact on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and Accounting Practice Bulletin (APB) 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, (FSP FAS 107-1 and APB 28-1, respectively). FSP FAS 107-1 and APB 28-1 amended FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends Accounting Principles Board Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. This FSP is effective for periods ending after June 15, 2009, which for the Company was the second quarter of fiscal 2009. The adoption of this standard did not have a material impact on the Company s consolidated financial statements.

(s) Reclassifications and Adjustments

Certain items in the prior year s consolidated financial statements have been reclassified to conform to the current presentation. During the second quarter of 2009, the Company recorded a $0.6 million liability for government rebates related to prior periods back to the first quarter of 2008, mostly related to a recent Federal mandate to pay rebates for certain product sales through government-related channels. The Company determined that the amounts that related to prior periods were immaterial to all prior periods and therefore recognized the reduction to net product revenues during the second quarter of 2009.

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(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 of Directors, which selects persons to receive awards and determines the number of shares subject to each award and the terms, conditions, performance measures and other provisions of the award. See Note 3 of the Company s consolidated financial statements in the Annual Report on Form 10-K for the fiscal year ended December 31, 2008, which was filed with the SEC on February 27, 2009, 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 June 30, 2009. 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 six months ended June 30, 2009, the Company granted approximately 3.0 million stock options under the 2006 Share Incentive Plan, with a weighted average fair value of $7.49 per share. The Company also granted approximately 370,400 stock purchase rights under the ESPP with a weighted average fair value of $5.11 per share during the six months ended June 30, 2009. 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 and six months ended June 30, 2008 and 2009 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Stock options:				
Weighted average fair value of per share common stock	$ 38.44	$ 14.34	$ 38.32	$ 14.20
Expected life	5.4 years	6.1 years	5.2 - 5.4 years	6.0 - 6.1 years
Volatility	47%	54%	45 - 47%	54%
Risk-free interest rate	3.2%	2.0%	2.8 - 3.2%	1.9 - 2.0%
Dividend yield	0%	0%	0%	0%

	Three and Six Months Ended June 30,	
	2008	2009
ESPP:		
Per share fair market value of common stock	$ 37.61	$ 13.69
Expected life	6 - 24 months	6 - 24 months
Volatility	47%	55%
Risk-free interest rate	1.7 - 5.2%	0.3 - 0.9%
Dividend yield	0%	0%

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 RSU at the date of grant, ratably over the period during which the vesting restrictions lapse. During the six months ended June 30, 2009, the Company granted 197,295 RSUs with a weighted average fair market value of $14.04 per share.

Stock-based Compensation Expense

The compensation expense that has been included in the Company s consolidated statement of operations for stock-based compensation arrangements were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Cost of sales	$ 392	$ 1,423	$ 589	$ 1,987
Research and development expense	2,059	2,605	3,617	5,080
Selling, general and administrative expense	3,497	4,986	6,206	9,743
Total stock-based compensation expense	$ 5,948	$ 9,014	$ 10,412	$ 16,810

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There was no income tax benefit associated with stock-based compensation in the first quarters of 2008 and 2009 because the deferred tax asset resulting from stock-based compensation was offset by an additional valuation allowance for deferred tax assets.

Stock-based compensation of $2.0 million and $2.7 million was capitalized into inventory for the six months ended June 30, 2008 and 2009, respectively. Capitalized stock-based compensation is recognized into cost of sales when the related product is sold.

(4) JOINT VENTURE

Effective January 2008, the Company and Genzyme restructured BioMarin/Genzyme LLC. Under the revised structure, the operational responsibilities for BioMarin and Genzyme did not significantly change, as Genzyme continues to globally market and sell Aldurazyme and BioMarin 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.

On January 1, 2008, Genzyme began to record sales of Aldurazyme to third party customers and pay BioMarin a tiered payment ranging from approximately 39.5% to 50% of worldwide net product sales depending on sales volume, which is recorded by BioMarin as product revenue. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme as 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 continues to be managed in the joint venture with the costs shared equally by BioMarin and Genzyme. Pursuant to the terms of the joint venture restructuring, the Company received distributions of $16.7 million of cash and $26.8 million of inventory from the joint venture in the first quarter of 2008.

As a result of restructuring the joint venture, the Company made an initial transfer of inventory on-hand to Genzyme, resulting in the recognition of product transfer revenue of $14.0 million during the first quarter of 2008. A portion of that initial inventory transfer representing $4.5 million of the related product transfer revenue was also sold by Genzyme during the first quarter of 2008, which resulted in a royalty due to the Company totaling $14.6 million.

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

(5) SHORT-TERM AND LONG-TERM INVESTMENTS

At December 31, 2008, 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 Year Ending December 31, 2009		December 31, 2008
	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Corporate securities	$ 55,270	$ (100)	$ 55,170
Commercial paper	33,076	48	33,124
Equity securities	3,633	332	3,965
U.S. Government agency securities	220,914	977	221,891
U.S. Government backed commercial paper	24,370	5	24,375

Total	$ 337,263	$ 1,262	$ 338,525

At June 30, 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,			June 30, 2009		
	2009	2010	2011	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Certificates of deposit	$ 4,497	$ 24,020	$ 1,449	$ 29,966	$ (131)	$ 29,835
Corporate securities	24,505	56,849	30,940	112,294	(32)	112,262
Commercial paper	11,344	994		12,338	7	12,345
Equity securities	701			701	1,105	1,806
U.S. Government agency securities	88,294	10,222	30,214	128,730	226	128,956
Total	$ 129,341	$ 92,085	$ 62,603	$ 284,029	$ 1,175	$ 285,204

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of June 30, 2009. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized costs.

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At December 31, 2008, the aggregate amount of unrealized losses and related fair value of investments with unrealized losses are presented in the table below follows (in thousands). All investments were classified as available-for-sale at December 31, 2008.

	Less Than 12 Months To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate securities	$ 44,941	$ (147)	$ 44,941	$ (147)
Commercial paper	1,992	(6)	1,992	(6)
U.S. Government agency securities	6,928	(12)	6,928	(12)
U.S. Government back commercial paper	9,947	(31)	9,947	(31)
Total	$ 63,808	$ (196)	$ 63,808	$ (196)

At June 30, 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 June 30, 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	$ 12,736	$ (56)	$ 16,924	$ (74)	$ 29,660	$ (130)
Corporate securities	7,319	(6)	31,994	(185)	39,313	(191)
U.S. Government agency securities			7,963	(9)	7,963	(9)
Total	$ 20,055	$ (62)	$ 56,881	$ (268)	$ 76,936	$ (330)

(6) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2008 and June 30, 2009, inventory consisted of the following (in thousands):

	December 31, 2008	June 30, 2009
Raw materials	$ 10,314	$ 10,928
Work in process	29,998	35,069
Finished goods	32,850	26,839
Total inventory	$ 73,162	$ 72,836

As of December 31, 2008 and June 30, 2009, other current assets consisted of the following (in thousands):

	December 31, 2008	June 30, 2009
Kuvan European Medicines Agency (EMEA) approval milestone receivable	$ 30,000	$
Non-trade receivables	4,828	8,770
Prepaid expenses	3,013	3,494
Deferred cost of goods sold	3,879	2,578

Short-term restricted cash	6,202	97
Other	2,522	239
Total other current assets	$ 50,444	$ 15,178

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As of December 31, 2008 and June 30, 2009, accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31, 2008	June 30, 2009
Accounts payable	$ 922	$ 3,127
Accrued accounts payable	26,214	27,885
Accrued vacation	3,798	4,694
Accrued compensation	11,737	9,580
Accrued interest and taxes	2,684	2,639
Accrued royalties	3,401	3,971
Other accrued expenses	6,094	2,311
Accrued rebates	3,194	4,124
Other	989	773
Total accounts payable and accrued liabilities	$ 59,033	$ 59,104

As of December 31, 2008 and June 30, 2009, other long-term liabilities consisted of the following (in thousands):

	December 31, 2008	June 30, 2009
Long-term portion of deferred rent	$ 1,176	$ 1,108
Long-term portion of capital lease liability	270	179
Long-term portion of deferred compensation liability	1,410	2,600
Total other long-term liabilities	$ 2,856	$ 3,887

(7) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2008 and June 30, 2009 consisted of the following (in thousands):

Category	December 31, 2008	June 30, 2009	Estimated Useful Lives
Leasehold improvements	$ 27,544	$ 34,357	Shorter of life of asset or lease term
Building and improvements	61,183	65,505	20 years
Manufacturing and laboratory equipment	26,996	30,086	5 years
Computer hardware and software	13,088	22,391	3 to 5 years
Office furniture and equipment	4,602	5,024	5 years
Land	10,056	10,056	Not applicable
Construction-in-progress	27,589	45,740	Not applicable
Gross property, plant and equipment	$ 171,058	$ 213,159	
Less: Accumulated depreciation	(46,079)	(53,370)	
Total property, plant and equipment, net	$ 124,979	$ 159,789	

Depreciation for the three and six months ended June 30, 2009 was $4.5 million and $8.6 million, respectively, of which $0.7 million and $1.3 million was capitalized into inventory, respectively. Depreciation for the three and six months ended June 30, 2008 was $2.9 million and $5.3 million, respectively, of which $0.8 million and $1.3 million was capitalized into inventory, respectively.

Capitalized interest related to the Company s property, plant and equipment purchases during the three and six months ended June 30, 2008 and 2009 was insignificant.

(8) 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. The $1.4 million paid in excess of the fair value of the shares acquired was allocated to the license fee using the residual method and expensed under the provisions of SFAS No. 2, *Accounting for Research and Development Costs* (SFAS No. 2), in the third quarter of 2008. Under the terms of the licensing agreement, the Company was obligated to make future development and regulatory milestone payments totaling $51.0 million contingent on future development and regulatory milestones, as well as tiered royalties based on future net sales. All payments pursuant to the Company s investment in, and license from, Summit were denominated in British pounds.

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

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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 under the provisions of SFAS No. 2, in the first quarter of 2009. 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, under the provisions of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The investment is 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 are reported in earnings in the period in which the impairment occurs.

As of June 30, 2009, 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 which may influence their 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.

(9) 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. Riquent was being evaluated by La Jolla in a Phase III clinical study (Phase III ASPEN Study). The Company paid La Jolla $7.5 million for the license rights and $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 under the provisions of SFAS No. 2 in the first quarter of 2009. 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 III ASPEN Study 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 are traded on 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 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 has 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 their 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 their 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.

(10) 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. They are being amortized as interest expense over the life of the debt. The Company recognized $0.2 million and $0.4 million of amortization expense in each of the three and six months ended June 30, 2008 and 2009, respectively.

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 $0.2 million and $0.4 million of amortization expense during each of the three and six months ended June 30, 2008 and 2009, respectively. During the first six months of 2008, certain note holders voluntarily exchanged an insignificant number of convertible notes for shares of the Company s common stock.

Interest expense for the three and six months ended June 30, 2009 was $4.4 million and $8.5 million, respectively, and each period included $1.5 million and $2.6 million, respectively, in imputed interest related to the Company s acquisition obligation. Interest for the three and six months ended June 30, 2008 was $4.1 million and $8.2 million, respectively, and included $1.1 million and $2.2 million of imputed interest expense, respectively.

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(11) 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 forward contract hedges as hedging instruments and enters into some forward contracts that are considered to be economic hedges which 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 revenues designated in currencies other than the U.S. dollar. The fair values of foreign currency agreements are estimated as described in Note 12, 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 June 30, 2009, the Company had 26 forward contracts outstanding to purchase a total of 35.2 million Euros with expiration dates ranging from July 2009 through May 2010. These hedges were entered into to protect against the fluctuations in Euro denominated Naglazyme revenues. The Company has formally designated these contracts as cash flow hedges, and they are expected to be highly effective 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 June 30, 2009, the Company had two outstanding foreign currency contracts to purchase 14.3 million Euros and 5.6 million British Pounds that were not designated as hedges 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 May 2010. Over the next 12 months, the Company expects to reclassify $1.2 million from accumulated other comprehensive income to earnings as related forecasted revenue transactions occur.

Prior to the second quarter of 2008, the Company did not enter into any derivative transactions which qualified for hedge accounting under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended (SFAS No. 133). During the three and six months ended June 30, 2009, the Company recognized foreign currency transaction gains of $0.8 million and $1.9 million, respectively, from derivative transactions that qualified for hedge accounting, compared to the three and six months ended June 30, 2008 when the Company recognized a foreign currency transaction loss of $15,000 in each period.

At December 31, 2008 and June 30, 2009, the fair value carrying amount of the Company s derivative instruments was recorded as follows (in thousands):

	Asset Derivatives December 31, 2008		Liability Derivatives December 31, 2008	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments under FAS 133				
Foreign exchange contracts	Other current assets	$ 754	Other current liabilities	$ 1,129
Total		$ 754		$ 1,129
Derivatives not designated as hedging instruments under FAS 133				
Foreign exchange contracts	Other current assets	$ 49	Other current liabilities	$
Total		$ 49		$
Total derivative contracts		$ 803		$ 1,129

	Asset Derivatives June 30, 2009		Liability Derivatives June 30, 2009	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments under FAS 133				
Foreign exchange contracts	Other current assets	$ 83	Other current liabilities	$ 1,386
Total		$ 83		$ 1,386
Derivatives not designated as hedging instruments under FAS 133				
Foreign exchange contracts	Other current assets	$ 58	Other current liabilities	$
Total		$ 58		$
Total derivative contracts		$ 141		$ 1,386

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The effect of derivative instruments on the consolidated statement of operations for the three and six months ended June 30, 2009, was as follows (in thousands):

	Three Months Ended June 30, 2009	Six Months Ended June 30, 2009
	Foreign Exchange Contracts	Foreign Exchange Contracts
Derivatives in FAS 133 Hedging Relationships		
Net gain (loss) recognized in OCI (1)	$ (2,903)	$ 927
Net gain (loss) reclassified from accumulated OCI into income (2)	761	1,945
Net gain (loss) recognized in income (3)	(54)	(263)
Derivatives Not Designated as Hedging Instruments under Statement 133		
Net gain (loss) recognized in income (4)	(2,179)	(1,073)

(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, 2008 and June 30, 2009, accumulated other comprehensive income associated with forward contracts qualifying for hedge accounting treatment was a loss of $0.2 million and $1.2 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.

(12) FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income and equity securities, other equity securities and foreign currency derivatives. The table below presents the fair value of these certain financial assets and liabilities determined using the inputs defined at December 31, 2008 and June 30, 2009, by SFAS No. 157, *Fair Value Measurements*.

	Fair Value Measurements (in thousands) at December 31, 2008			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market instruments and overnight deposits (1)	$ 222,900	$ 12,959	$ 209,941	$
Corporate securities (3)	55,170		55,170	
Equity securities (4)	3,965	2,332	1,633	
Government agency securities (3)	221,891		221,891	
Government backed commercial paper (3)	24,375		24,375	
Commercial paper (3)	33,124		33,124	
Foreign currency derivatives (5)	803		803	
Total	$ 562,228	$ 15,291	$ 546,937	$

Liabilities:							
Deferred compensation liability (6)	$	1,428	$	$	1,428	$	
Foreign currency derivatives (7)		1,129			1,129		
Total	$	2,557	$	$	2,557	$	

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	Fair Value Measurements (in thousands) at June 30, 2009			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market instruments and overnight deposits (1)	$ 200,050	$ 14,178	$ 185,872	$
Certificates of deposit (2)	29,835		29,835	
Corporate securities (3)	112,262		112,262	
Equity securities (4)	1,806	1,383	423	
Government agency securities (3)	128,956		128,956	
Commercial paper (3)	12,345		12,345	
Deferred compensation asset (8)	1,453		1,453	
Foreign currency derivatives (5)	141		141	
Total	$ 486,848	$ 15,561	$ 471,287	$
Liabilities:				
Deferred compensation liability (6)	$ 2,867	$ 1,415	$ 1,452	$
Foreign currency derivatives (7)	1,386		1,386	
Total	$ 4,253	$ 1,415	$ 2,838	$

(1) These amounts are included in cash and cash equivalents investments in the Company s consolidated balance sheet.
(2) 43% and 57% are included in short-term and long-term investments in the Company s consolidated balance sheet, respectively.
(3) These amounts are included in short-term investments and long-term investments in the Company s consolidated balance sheet. At December 31, 2008, all balances were classified as short-term investments. At June 30, 2009, 72% of corporate securities, 24% government agencies and 8% of commercial paper were included in long-term investments and the remaining balances are included in short-term investments.
(4) These amounts are included in short-term investments and long-term investments in the Company s consolidated balance sheet. At December 31, 2008 and June 30, 2009, 41% and 23%, respectively is included in long-term investments and the remaining balances are included in short-term investments.
(5) These amounts are included in other current assets on the Company s consolidated balance sheet. Foreign currency derivatives at June 30, 2009 include forward foreign exchange contracts for the Euro. Foreign currency derivatives at December 31, 2008 include forward foreign exchange contracts for Euros and British Pounds.
(6) These amounts are included in other long-term 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) These amounts are included in other assets on the Company s consolidated balance sheet.

(13) 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 the three and six months ended June 30, 2008 and 2009.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Region:				
United States	51%	54%	55%	53%

Europe	28%	25%	27%	25%
Latin America	10%	10%	9%	11%
Rest of World	11%	11%	9%	11%
Total Net Product Revenue	100%	100%	100%	100%

As of June 30, 2009, accounts receivable related to net product sales of Naglazyme and Kuvan and Aldurazyme product transfer and royalty revenues. On a consolidated basis, two customers accounted for 47% and 44% of our net product revenues during the three and six months ended June 30, 2009, respectively. On a consolidated basis, two customers accounted for 49% and 17% of the June 30, 2009 accounts receivable balance, respectively. 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.

(14) ASCENT TRANSACTION

In 2004, the Company acquired the Orapred product line from Ascent Pediatrics, a wholly owned subsidiary of Medicis Pharmaceutical Corporation (Medicis). The acquisition was accounted for as a purchase business combination. The amended transaction agreements entered into with Medicis following the settlement of a dispute in January 2005 in the Company s favor, provided for total acquisition payments of $169.0 million payable to Medicis in specified amounts through August 2009. In June 2009, the Company purchased all of the outstanding shares of capital stock of BioMarin Pediatrics II (formerly known as Ascent Pediatrics, Inc. and Medicis

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Pediatrics, Inc.) (Pediatrics) as required by the original transaction agreements from 2004 for $70.6 million in cash. The stock purchase was completed substantially in accordance with the terms of the previously disclosed Securities Purchase Agreement dated May 18, 2004 and amended on January 12, 2005, by and among BioMarin, Medicis and Pediatrics.

Subsequently, on July 1, 2009 the Company transferred all of the North American intellectual property relating to the Orapred product to Scièle Pharma, Inc., a U.S.-based group company of Shionogi & Co., the third party who holds a license to sell and commercialize the Orapred product line in North America. The transfer of the intellectual property was be made in accordance with the terms of the previously disclosed License Agreement dated March 15, 2006 between us and Scièle Pharma, Inc. (formerly Alliant Pharmaceuticals, Inc.). As a result of the completion of the transaction with Medicis, $9.1 million in cash was released from escrow pursuant to the sublicense and was reclassified from restricted cash to cash and cash equivalents by the Company in June 2009.

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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, pote and similar expressions. These forward-looking statements may be found in Overview, 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, 2008, which was filed with the Securities and Exchange Commission (SEC) on February 27, 2009, 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 to reflect the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and 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. Our product portfolio is comprised of three approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme and Kuvan.

Naglazyme received marketing approval in the U.S. in May 2005, in the E.U. in January 2006, and subsequently in other countries. Naglazyme net product revenues for the second quarter and first six months of 2008 were $35.1 million and $62.8 million, respectively, and increased to $42.9 million and $82.3 million in the second quarter and first six months of 2009, respectively.

Aldurazyme, which was developed in collaboration with Genzyme Corporation (Genzyme), has been approved for marketing in the U.S., E.U., and in other countries. Prior to 2008, we developed and commercialized Aldurazyme through a joint venture with Genzyme. 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 and all obligations related to the transfer have been fulfilled at that point and title to, and risk of loss for the product is 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 second quarter and first six months of 2009 were $21.6 million and $38.7 million, respectively, compared to $13.4 million and $37.5 million, in the second quarter and first six months of 2008, respectively.

Kuvan was granted marketing approval in the U.S. and Europe in December 2007 and December 2008, respectively. Kuvan net product revenues for the second quarter and first six months of 2009 were $16.9 million and $32.5 million, respectively, compared to $12.0 million and $17.8 million in the second quarter and first six months of 2008, respectively.

We are developing PEG-PAL, an experimental enzyme substitution therapy for the treatment of phenylketonuria (PKU), for patients that do not respond well to Kuvan. In May 2008, we initiated a Phase I open label clinical trial of PEG-PAL in PKU patients. In June 2009, we released the results of the Phase I open label clinical trial of PEG-PAL. The primary objective of this study was to assess the safety and tolerability of single subcutaneous injections of PEG-PAL in subjects with PKU. We expect to initiate the Phase II clinical trial in the second half of 2009, pending institutional review board approval from the clinical trial sites. In 2007 and early 2008 we devoted substantial resources to the development of 6R-BH4, the active ingredient in Kuvan, for the treatment of certain cardiovascular indications including peripheral arterial disease and sickle cell disease. We released data from several 6R-BH4 trials in early February 2009. We completed enrollment of an open label Phase I/II clinical trial, an enzyme replacement therapy for the treatment of MPS IVA or Morquio Syndrome Type A in July 2009. We expect the results form this trial in mid 2010. We are conducting preclinical development of several other enzyme product candidates for genetic and other diseases, and a small molecule for the treatment of Duchenne Muscular Dystrophy.

Key components of our results of operations for the three and six months ended June 30, 2008 and 2009 include the following (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Total net product revenues	$ 60.5	$ 81.5	$ 118.1	$ 153.4
Collaborative agreement revenues	2.5	0.9	5.0	1.4
Cost of sales	9.6	19.8	26.8	34.2
Research and development expense	23.8	26.3	41.4	60.7
Selling, general and administrative expense	25.2	30.5	48.9	59.1
Net income (loss)	3.8	1.3	5.5	(11.8)
Stock-based compensation expense	5.9	9.0	10.4	16.8

See *Results of Operations* for discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, short-term investments and long-term investments totaled $485.3 million as of June 30, 2009, compared to $561.4 million as of December 31, 2008, primarily due to the early settlement of our Medicis obligation. See *Liquidity and Capital Resources* below for a further discussion of our liquidity and capital resources.

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Critical Accounting Policies and Estimates

In preparing our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. (GAAP) 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 the Board of Directors.

We believe that the assumptions, judgments and estimates involved in the accounting for the impairment of long-lived assets, revenue recognition and related reserves, income taxes, inventory, research and development, and stock-based compensation 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 polices have not differed materially from actual results.

There have been no significant changes in our critical accounting policies and estimates during the three and six months ended June 30, 2009 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, 2008, which was filed with the SEC on February 27, 2009.

Recent Accounting Pronouncements

See Note 2(r) of our accompanying 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.

Results of Operations

Net Income (Loss)

Our net income for the three months ended June 30, 2009 was $1.3 million and our net loss for the six months ended June 30, 2009 was $11.8 million, compared to net income of $3.8 million and $5.5 million for the three and six months ended June 30, 2008, respectively, with the change primarily due to the following (in millions):

	Three Months Ended June 30, 2009	Six Months Ended June 30, 2009
Net income for the period ended June 30, 2008	$ 3.8	$ 5.5
Increased Naglazyme gross profit	5.8	14.9
Increased Kuvan gross profit	3.5	11.6
Increased Aldurazyme gross profit	2.0	1.9
Decreased Kuvan license fee revenues	(1.2)	(2.6)
Decreased Kuvan collaborative agreement revenue	(0.1)	(0.6)
Increased research and development expense	(2.5)	(19.3)
Increased selling, general and administrative expense	(5.3)	(10.2)
Impairment loss on equity investments		(5.8)
Gain on the sale of equity investments	1.6	1.6
Increased (decreased) Orapred royalty revenue	(1.0)	0.1
Decreased interest income	(3.2)	(6.7)
Increased interest expense	(0.4)	(0.4)
Increased amortization of Orapred intangible asset	(0.7)	(0.7)
Other individually insignificant fluctuations	(1.0)	(1.1)
Net income (loss) for the period ended June 30, 2009	$ 1.3	$ (11.8)

The increase in Naglazyme gross profit in the second quarter and first six months of 2009 as compared to the same periods in 2008 is primarily a result of additional patients initiating therapy outside the U.S. and the E.U. The increase in Kuvan gross profit during the second quarter and first six months of 2009 compared to the same periods of 2008 is primarily a result of additional patients initiating therapy in the U.S. The increase in Aldurazyme gross profit in the second quarter and first six months of 2009 as compared to the same periods in 2008 is primarily attributed to increased product transfer revenue resulting from increased shipments to Genzyme. The decrease in Kuvan license fee revenues is attributed to our fulfillment of all performance obligations relating to the 2005 up-front license payment of $25.0 million from Merck Serono in December 2008. The increase in selling, general and administrative expense is primarily due to increased facility and employee related costs and the continued commercialization of Kuvan in the U.S. The increase in research and development expense is primarily due to increases in development expense for our GALNS program for the treatment of MPS IVA, the up-front costs associated with a product licensed from La Jolla Pharmaceutical Company, and other early stage programs. See below for additional information related to the primary net income (loss) fluctuations presented above, including details of our operating expense fluctuations.

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Net Product Revenues, Cost of Sales and Gross Profit

The following table shows a comparison of net product revenues for the three and six months ended June 30, 2008 and 2009 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2008	2009	Change	2008	2009	Change
Naglazyme	$ 35,092	$ 42,929	$ 7,837	$ 62,826	$ 82,281	$ 19,455
Kuvan	12,016	16,940	4,924	17,807	32,452	14,645
Aldurazyme	13,350	21,603	8,253	37,450	38,653	1,203
Total Net Product Revenues	$ 60,458	$ 81,472	$ 21,014	$ 118,083	$ 153,386	$ 35,303

Naglazyme net product revenues earned from customers based outside the U.S. during the second quarter and first six months of 2009 were $37.2 million and $71.5 million, respectively. The negative impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar were approximately $1.7 million and $3.7 million in the second quarter and first six months of 2009, respectively. Gross profit from Naglazyme sales in the second quarter and first six months of 2009 were approximately $34.1 million and $65.5 million, respectively, representing gross margins of 79% and 80%, respectively compared to gross profits of $28.3 million and $50.6 million, in the second quarter and first six months of 2008, respectively, representing gross margins of approximately 81% and 80%, respectively. The slight decrease in gross margins during the second quarter of 2009 as compared to the second quarter of 2008 is attributed to the negative foreign currency impact during the second quarter of 2009.

We received marketing approval for Kuvan in the U.S. in December 2007 and began shipping product that same month. Net product revenue for Kuvan during the second quarter and first six months of 2009 was $16.9 million and $32.5 million, respectively, compared to $12.0 million and $17.8 million, respectively, during the second quarter and first six months of 2008. Gross profit from Kuvan in the second quarter and first six months of 2009 was approximately $13.7 million and $26.7 million, respectively, representing gross margins of approximately 81% and 82%, respectively. During the second quarter and first six months of 2008, gross profit from Kuvan was approximately $10.6 million and $15.7 million, respectively, representing gross margins of 88% for each period. All 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. As a result, the product sold in 2008 had an insignificant cost basis. The cost of sales for Kuvan for the second quarter and first six months of 2008 is primarily comprised of royalties paid to third parties based on Kuvan net sales. We expect U.S. gross margins for Kuvan for the foreseeable future to be in the lower 80% range as the expensed 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.

Aldurazyme net product revenue during the second quarter and first six months of 2009 was $21.6 million and $38.7 million, respectively, compared to $13.4 million and $37.5 million in the second quarter and first six months of 2008, respectively. Aldurazyme net product revenues in the second quarter and first six months of 2009 included royalty revenues of $15.5 million and $30.0 million, respectively, compared to the second quarter and first six months of 2008 which included royalty revenue of $13.4 million and $29.8 million, respectively. Royalty revenue from Genzyme is based on 39.5% of net Aldurazyme sales by Genzyme, which totaled $39.2 million and $76.0 million, respectively, in the second quarter and first six months of 2009, respectively, compared to $38.7 million and $75.5 million in the second quarter and first six months of 2008. Incremental net product transfer revenue in the first six months of 2009 and 2008 was $8.6 million and $7.7 million, respectively. Incremental Aldurazyme net product transfer revenue reflects higher net shipments of Aldurazyme to Genzyme than Genzyme shipments to customers during the period to meet future product demand. In January 2008, we transferred existing finished goods on-hand to Genzyme under the restructured terms of the BioMarin/Genzyme LLC agreements, resulting in the recognition of significant incremental product transfer revenue during 2008. In the future, to the extent that Genzyme Aldurazyme inventory quantities on hand remain flat, we expect that our total Aldurazyme revenues will approximate the 39.5% to 50% royalties on net product sales by Genzyme. In the second quarter and first six months of 2009, Aldurazyme gross profit was $13.9 million and $27.0 million, respectively, representing a gross margin of 64% and 70%, respectively, which reflects the profit earned on royalty revenue and net incremental product transfer revenue. For the same periods in 2008, Aldurazyme gross profit was $11.9 million and $25.1 million, respectively, representing gross margins of 89% and 67%, respectively. The change in gross

margins is attributed to a shift in revenue mix between royalty revenue and net product transfer revenues. During the second quarter of 2008, Aldurazyme net product revenues consisted entirely of royalty revenues, compared to the second quarter of 2009 when the revenue mix was 72% royalty revenues and 28% net product transfer revenues. In the first six months of 2009, the revenue mix was 78% royalty revenues and 22% net product transfer revenues, respectively, compared to the first six months of 2008, where the revenue mix was 79% royalty revenues and 21% net product transfer revenues, respectively. 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 during the second quarter and first six months of 2009, was $19.8 million and $34.2 million, respectively, compared to $9.6 million and $26.8 million in the second quarter and first six months of 2008, respectively. The increase in cost of sales in the second quarter of 2009 compared to the second quarter of 2008 is attributed to an increase in product sales and the Aldurazyme product revenue mix. The increase in cost of sales during the fist six months of 2009 compared to the same period in 2008 is proportional to the increase in net product revenues for the same period.

Collaborative Agreement Revenues

Collaborative agreement revenues include both license revenue and contract research revenue under our agreement with Merck Serono, which was executed in May 2005. License revenues are related to amortization of the $25.0 million up-front license payment received from Merck Serono and contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. Our performance obligations related to the initial $25.0 million up-front license payment were completed in December 2008. Therefore, periods subsequent to December 31, 2008 will not include amortization amounts related to this payment. 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 II clinical trials and Merck Serono chooses to co-develop the PEG-PAL or 6R-BH4 program. The related costs are included in research and development expenses.

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Collaborative agreement revenues in the second quarter and first six months of 2009 were comprised of reimbursable Kuvan development costs and amounted to $0.9 million and $1.4 million, respectively. During the second quarter and first six months of 2008 collaborative revenues were comprised of $1.5 million and $3.0 million of amortization relating to the $25.0 million up-front license payment received from Merck Serono and reimbursable Kuvan development of $1.0 million and $2.0 million, respectively. Kuvan development costs decreased during the second quarter and first six months of 2009 as compared to the same periods of 2008 due to reductions in Kuvan clinical trial activities.

Royalty and License Revenues

Royalty and license revenues for the second quarter and first six months of 2009 totaled $0.4 million and $2.0 million, respectively, compared to $1.2 million and $1.5 million in the second quarter and first six months of 2008, respectively. Royalty and license revenues for the three and six months ended June 30, 2009 included royalty revenues from Orapred product sold by the sublicensee of $0.2 million and $1.6 million, respectively, and 6R-BH4 royalty revenues for related products sold in Japan of $0.3 million and $0.4 million, respectively. Royalty and license revenues for the three and six months ended June 30, 2008 included royalty revenues from Orapred product sold by the sublicensee of $1.2 million and $1.5 million, respectively.

Research and Development Expense

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

Research and development expenses increased by $2.5 million and $19.3 million to $26.3 million and $60.7 million for the three and six months ended June 30, 2009, respectively, from $23.8 million and $41.4 million for the three and six months ended June 30, 2008, respectively. The change in research and development expenses for the second quarter and first six months of 2009 is primarily a result of the following (in millions):

	Three Months Ended June 30, 2009	Six Months Ended June 30, 2009
Research and development expenses for period ended June 30, 2008	$ 23.8	$ 41.4
License payment related to collaboration with La Jolla Pharmaceutical Company		8.8
Increased GALNS for Morquio Syndrome Type A development expense	0.6	3.4
Increased Kuvan development expenses	0.5	1.2
Increased Prodrug development expenses	0.3	1.1
Increased Duchene Muscular Dystrophy program development expense	1.1	1.4
Increased Naglazyme development expenses	0.5	0.5
Increased stock-based compensation expense	0.5	1.5
Decreased 6R-BH4 development expenses for indications other than PKU	(2.8)	(3.6)
Decreased PEG-PAL development expenses	(0.6)	(0.7)
Decreased research and development expenses on early development stage programs		(0.3)
Increase in non-allocated research and development expenses and other net changes	2.4	6.0
Research and development expenses for the period ended June 30, 2009	$ 26.3	$ 60.7

During the first quarter of 2009, we paid La Jolla Pharmaceutical Company an up-front license fee for the rights to develop and commercialize their investigational drug, Riquent. In February 2009, the results of the first interim efficacy analysis for the Phase III ASPEN Study 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 and in March 2009, we terminated the license agreement. As such, there will not be any additional development expense for Riquent. The increase in GALNS development expenses is primarily attributed to an increase in pre-clinical studies and manufacturing costs in preparation for the Phase I/II clinical trial that was initiated in April 2009. The decrease in 6R-BH4 development expense for indications other than PKU is primarily due to a decline in pre-clinical studies in 2009. The increase in Kuvan research and development expense is attributed to long-term clinical activities related to post-approval regulatory commitments. We expect to continue incurring significant research and development expense for the foreseeable future due to long-term clinical activities related to Kuvan post-approval regulatory commitments and spending on our GALNS program for the treatment of Morquio Syndrome Type A and PEG-PAL and Prodrug programs. The increase in Duchene Muscular Dystrophy program development expense is primarily

attributed to increased pre-clinical activities related to the disease. The increase in stock-based compensation expense is a result of an increased number of options outstanding due to increased number of employees. The increase in non-allocated research and development primarily includes increases in facilities costs, general research costs and research and development personnel.

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.

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Selling, general and administrative expenses increased by $5.3 million and $10.2 million, to $30.5 million and $59.1 million for the three and six months ended June 30, 2009, respectively, from $25.2 million and $48.9 million for the three and six months ended June 30, 2008, respectively. The components of the change for second quarter and first six months of 2009 primarily include the following (in millions):

	Three Months Ended June 30,	Six Months Ended June 30,
Selling, general and administrative expense for the period ended June 30, 2008	$ 25.2	$ 48.9
Increased (decreased) Naglazyme sales and marketing expenses	(0.8)	0.2
Increased stock-based compensation expense	1.5	3.6
Increased Kuvan commercialization expenses	0.2	1.9
Increased foreign exchange gains on un-hedged transactions	(0.1)	(0.2)
Absence of sales tax error corrected in the second quarter of 2008	1.2	1.2
Net increase in corporate overhead and other administrative expenses	3.3	3.5
Selling, general and administrative expenses for the period ended June 30, 2009	$ 30.5	$ 59.1

The increase in stock-based compensation expense was the result of an increased number of outstanding stock options due to an increase in the number of employees. We incurred increased Kuvan commercialization expenses as a result of increased commercialization efforts in the U.S. and Canada. The increase in corporate overhead and other administrative costs is comprised of increased employee related costs and increased depreciation expense. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme and the U.S. commercialization activities for Kuvan.

Amortization of Intangible Assets

Amortization of acquired intangible assets includes the current amortization expense of the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology. 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 agreements from 2004 for $70.6 million. Medicis sole substantive asset was the intellectual property related to the Orapred franchise. Subsequently, on July 1, 2009, we transferred the exclusive U.S. intellectual property rights to our sublicense, resulting in revision of the remaining useful life of the Orapred intangible assets from August 2009 to July 1, 2009 when the transfer was completed. Amortization expense for the second quarter and first six months of 2009 was $1.8 million and $2.9 million, respectively, compared to $1.1 million and $2.2 million for the second quarter and first six months of 2008, respectively. The increase in amortization expense in the second quarter and first six months of 2009, is attributed to the revision of the intangible assets useful life.

Kuvan license payments, recorded as intangible assets, made to third parties as a result of the Food and Drug Administration (FDA) approval of Kuvan in December 2007 and the European Medicines Agency (EMEA) approval of Kuvan in December 2008 are being amortized over approximately 7.0 years and 10.0 years, respectively. Amortization of the Kuvan intangible assets is recorded as a component of cost of sales and is expected to approximate $0.6 million annually through 2014 and $0.3 million annually through 2018. Amortization expense related to the Kuvan intangible assets for the three and six months ended June 30, 2009 was $0.2 million and $0.3 million, respectively, compared to $0.1 million and $0.2 million for the three and six months ended June 30, 2008, respectively. The increase in Kuvan related amortization expense is attributed to the EMEA approval milestone paid in December 2008.

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. Effective January 2008, we and Genzyme restructured BioMarin/Genzyme LLC regarding the manufacturing, marketing and sale of Aldurazyme. As of January 1, 2008, BioMarin/Genzyme LLC s operations consist primarily of certain research and development activities and the intellectual property which continues to be managed by the joint venture with costs shared equally by BioMarin and Genzyme.

Equity in the loss of the joint venture remained materially consistent for the second quarter and first six months of 2009, compared to the same periods in 2008 at approximately $0.6 million and $1.1 million, respectively.

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 decreased to $0.9 million and $3.0 million for the second quarter and first six months of 2009, respectively, from $4.1 million and $9.8 million for the same periods in 2008, respectively. The reduced interest yields during the second quarter and first six months of 2009 were due to lower market interest rates and decreased levels of cash and investments. We expect that interest income will decline in future quarters in 2009 as compared to 2008 due to reduced interest yields and lower cash and investment balances.

Interest Expense

We incur interest expense on our convertible debt. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction. Interest expense in the second quarter and first six months of 2009 was $4.4 million and $8.5 million, respectively, and included imputed interest of $1.5 million and $2.6 million, respectively. Interest expense in the second quarter and first six months of 2008 was $4.1 million and $8.2 million, respectively, and included imputed interest of $1.1 million and $2.2 million, respectively. Imputed interest will not be incurred in periods subsequent to June 2009 as the Medicis obligation has been paid in full.

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Changes in Financial Position

June 30, 2009 Compared to December 31, 2008

From December 31, 2008 to June 30, 2009, our cash, cash equivalents, short-term and long term investments decreased by $76.1 million primarily as a result of the early settlement the Medicis obligation. Our accounts receivable increased by $18.3 million due to increased sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. Other current assets decreased approximately $35.3 million from December 31, 2008 to June 30, 2009, primarily as a result of the receipt of the $30.0 million related to the EMEA milestone earned from Merck Serono in December 31, 2008 and paid in January 2009. Our net property, plant and equipment increased by approximately $34.8 million from December 31, 2008 to June 30, 2009, primarily as a result continued expansion and improvements to our facilities during the period. We expect property, plant and equipment to increase in future periods, due to several ongoing facility improvement projects, and we expect depreciation expense to increase as the assets are placed into service.

Liquidity and Capital Resources

Cash and Cash Flow

As of June 30, 2009, our combined cash, cash equivalents, short-term and long-term investments totaled $485.3 million, a decrease of $76.1 million from $561.4 million at December 31, 2008. During the six months ended June 30, 2009, we financed our operations primarily through net product sales and available cash, cash equivalents, short-term and long-term investments.

The decrease in our combined balance of cash, cash equivalents, short-term and long-term investments during the first six months of 2009 was $76.1 million, which was $66.2 million more than the net decrease in cash, cash equivalents and short-term investments during the first six months of 2008 of $9.9 million. The primary items contributing to the increase in net cash outflow in 2009 were as follows (in millions):

Decreased distributions from Genzyme/BioMarin LLC	$ (18.4)
Increased Orapred acquisition payments, primarily the early settlement of the Medicis obligation	(70.1)
Increased capital asset purchases	(8.3)
Investment in La Jolla Pharmaceutical Company	(6.3)
Milestone payment received for Kuvan EMEA approval	30.0
Decreased proceeds from ESPP and stock option exercises	(18.6)
Net proceeds from the sale of equity investments	5.0
Reclassification of previously restricted cash related to Medicis	9.1
Net decreased cash used in operating activities, including net payments for working capital, other	11.4
Total increase in net cash outflow	$ (66.2)

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. Increased capital purchases primarily relate to continued expansion of corporate and manufacturing facilities at our Novato, California campus. Net payments for working capital in the first six months of 2009 primarily include decreased inventory build of $2.9 million, which excluded the inventory distribution from the joint venture, decreased accounts receivable build of $16.9 million, the receipt of the Merck Serono $30.0 million milestone payment earned in December 2008 related to the EMEA approval of Kuvan, and increased accounts payable and accrued liabilities build of $6.8 million.

We purchased all of the outstanding shares of capital stock of BioMarin Pediatrics II (formerly known as Ascent Pediatrics, Inc. and Medicis Pediatrics, Inc.) (Pediatrics) a wholly-owned subsidiary of Medicis Pharmaceutical Corporation (Medicis) as required by the original transaction agreements from 2004 for $70.6 million in cash. Pediatrics sole substantial asset was the intellectual property related to the Orapred franchise. The stock purchase was substantially completed in accordance with the terms of the previously disclosed Securities Purchase Agreement dated May 18, 2004 and amended on January 12, 2005, by and among BioMarin, Medicis and Pediatrics. As a result of the completion of the transaction with Medicis, $9.1 million in cash was released from escrow pursuant to the sublicense and was reclassified from restricted cash to cash and cash equivalents in June 2009.

We expect that our net cash outflow in the remainder of 2009 related to capital asset purchases will increase significantly compared to 2008. The expected increase in capital asset purchases primarily includes: expansion of our manufacturing facility, increased spending on manufacturing and lab equipment, expansion of our corporate campus, including leasehold improvements and the continued development of information technology systems upgrades.

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 the remainder of 2009, 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.

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Funding Commitments

We expect to fund our operations with our net product revenues from Naglazyme, Aldurazyme and Kuvan; 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 June 30, 2008 and 2009 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 June 30,		Six Months Ended June 30,		Since Program Inception
	2008	2009	2008	2009	
Naglazyme	$ 2.3	$ 2.8	$ 4.5	$ 5.1	$ 127.7
Kuvan	2.7	3.2	4.7	5.8	95.6
GALNS for Morquio Syndrome Type A	3.2	3.8	4.6	7.9	24.3
6R-BH4 for indications other than PKU	4.4	1.4	7.9	3.6	45.7
PEG-PAL	3.0	2.4	5.3	4.7	35.9
Not allocated to specific major current projects	7.8	8.4	13.4	17.0	203.5
	$ 23.4	$ 22.0	$ 40.4	$ 44.1	$ 532.7

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, 2008, which was filed with the SEC on February 27, 2009, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in our Form 10-K If we fail to maintain regulatory approval to commercially market 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 time frames we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.

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

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

- our ability to successfully market and sell Naglazyme and Kuvan;
- Genzyme s ability to successfully market and sell Aldurazyme;

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

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

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

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

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

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

Off-Balance Sheet Arrangements

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

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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 June 30, 2009 is presented below (in thousands).

	Payments Due by Period					
	Remainder of 2009	2010	2011-2012	2013-2014	2015 and Thereafter	Total
Convertible debt and related interest	$ 5,200	$ 10,401	$ 20,801	$ 186,544	$ 340,104	$ 563,050
Operating leases	1,895	3,859	6,481	3,423	3,158	18,816
Research and development and purchase commitments	12,333	6,655	5,026	3,565	3,979	31,558
Total	$ 19,428	$ 20,915	$ 32,308	$ 193,532	$ 347,241	$ 613,424

We are also subject to contingent payments related to various development activities totaling approximately $109.0 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our market risks at June 30, 2009 have not changed significantly from those in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2008, which was filed with the SEC on February 27, 2009, and Part II, Item 3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 which was filed with the SEC on May 1, 2009.

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, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this report.

Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC s rules and instructions for Form 10-Q.

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

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

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.
None.

Item 1A. Risk Factors
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, 2008, which was filed with the SEC on February 27, 2009, and Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, which was filed with the SEC on May 1, 2009, have remained substantially unchanged.

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

Item 3. Defaults upon Senior Securities.
None.

Item 4. Submission of Matters to a Vote of Security Holders.
We held our 2009 Annual Meeting of Stockholders (the Annual Meeting) on May 12, 2009 at the Inn of Marin, 250 Entrada Drive, Novato, California 94949. At the Annual Meeting, the following actions were taken:

a) The following directors were elected to serve until the Company s next annual meeting of stockholders and until their successors are elected:

Director Elected	Vote For	Withheld
Jean-Jacques Bienaimé	83,339,782	481,221
Michael Grey	73,376,278	10,444,725
Elaine J Heron Ph. D.	83,623,887	197,116
Joseph Klein, III	81,579,895	2,241,108
Pierre Lapalme	83,611,316	209,687
V. Bryan Lawlis, Ph. D.	73,776,254	10,044,749
Alan J. Lewis, Ph. D.	74,290,441	9,530,562
Richard A. Meier	83,656,463	164,540

b) The selection of KPMG LLP as independent registered public accounting firm for the year ending December 31, 2009 was ratified by a vote of 83,759,526 shares in favor; 34,592 shares against; and 26,885 shares abstained.

Item 5. Other Information.
None.

Item 6. Exhibits.

10.1*	Amended and Restated Severance Plan and Summary Plan Description as originally adopted on January 27, 2004 and amended and restated on May 12, 2009.
10.2	Severance Agreement between the Company and Dr. Emil D. Kakkis, dated May 28, 2009, previously filed with the SEC on June 3, 2009 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.3	Consulting Agreement between the Company and Dr. Emil D. Kakkis, dated July 1, 2009, previously filed with the SEC on June 3, 2009 as Exhibit 10.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.

* Filed herewith
Management contract or compensatory plan or arrangement

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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: July 31, 2009

By /s/ JEFFREY H. COOPER
Jeffrey H. Cooper,

Senior Vice President, Chief Financial Officer
(On behalf of the registrant and as principal financial officer)

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Exhibit Index

10.1*	Amended and Restated Severance Plan and Summary Plan Description as originally adopted on January 27, 2004 and amended and restated on May 12, 2009.
10.2	Severance Agreement with Dr. Emil D. Kakkis, dated May 28, 2009, previously filed with the SEC on June 3 2009 as Exhibit 10.1 to the Company Current Report on Form 8-K, which is incorporated herein by reference.
10.3	Consulting Agreement between the Company and Dr. Emil D. Kakkis, dated July 1, 2009, previously filed with the SEC on June 3, 2009 as Exhibit 10.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.

* Filed herewith
Management contract or compensatory plan or arrangement