BIOMARIN PHARMACEUTICAL INC

FORM 10-Q
(Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data fie required to be submitted and posted pursuant to Rule 405 of the Regulation S-T during the preceding 12 months (or for such greater 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. (Check one):

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the proceeding 12 months (or for such greater 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 ☐

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: 99,986,841 shares common stock, par value $0.001, outstanding as of April 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)	March 31, 2009 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 222,900	$ 214,579
Short-term investments	336,892	337,290
Accounts receivable, net	54,298	61,355
Inventory	73,162	76,423
Other current assets	50,444	23,928
Total current assets	737,696	713,575
Investment in BioMarin/Genzyme LLC	915	367
Long-term investments	1,633	4,011
Property, plant and equipment, net	124,979	142,252
Intangible assets, net	7,626	6,316
Goodwill	21,262	21,262
Other assets	12,584	12,500
Total assets	$ 906,695	$ 900,283
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 59,033	$ 55,877
Acquisition obligation, net of discount	70,741	70,317
Deferred revenue	307	120
Total current liabilities	130,081	126,314
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	2,946
Total liabilities	630,020	626,343
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and March 31, 2009; 99,868,145 and 99,977,953 shares issued and outstanding at December 31, 2008 and March 31, 2009, respectively	100	100
Additional paid-in capital	852,947	862,373
Company common stock held by deferred compensation plan	(882)	(854)
Accumulated other comprehensive income	1,106	2,069
Accumulated deficit	(576,596)	(589,748)
Total stockholders' equity	276,675	273,940
Total liabilities and stockholders' equity	$ 906,695	$ 900,283

(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 Months Ended March 31, 2008 and 2009
(In thousands, except for per share data, unaudited)

	Three Months Ended March 31,	
	2008	2009
Revenues:		
Net product revenues	$ 57,625	$ 71,914
Collaborative agreement revenues	2,465	509
Royalty and license revenues	306	1,557
Total revenues	60,396	73,980
Operating expenses:		
Cost of sales	17,188	14,362
Research and development	17,628	34,358
Selling, general and administrative	23,669	28,568
Amortization of acquired intangible assets	1,093	1,093
Total operating expenses	59,578	78,381
Income (Loss) from operations	818	(4,401)
Equity in the loss of BioMarin/Genzyme LLC	(533)	(547)
Interest income	5,649	2,153
Interest expense	(4,110)	(4,087)
Impairment loss on equity investments	—	(5,853)
Income (Loss) before income taxes	1,824	(12,735)
Provision for income taxes	138	417
Net income (loss)	$ 1,686	$(13,152)
Net income (loss) per share, basic and diluted	$ 0.02	$ (0.13)
Weighted average common shares outstanding, basic	97,647	99,902
Weighted average common shares outstanding, diluted	103,869	99,933

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Three Months Ended March 31, 2008 and 2009
(In thousands, unaudited)

	Three Months Ended March 31,	
	2008	2009
Cash flows from operating activities:		
Net income (loss)	$ 1,686	$ (13,152)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,870	5,103
Amortization of discount on short-term investments	(2,839)	(643)
Imputed interest on acquisition obligation	1,108	1,077
Equity in the loss of BioMarin/Genzyme LLC	533	547
Stock-based compensation	5,210	8,534
Impairment loss on investments	—	5,848
Excess tax benefit from stock option exercises	—	(4)
Unrealized foreign exchange gain (loss) on forward contracts	(161)	1,624
Changes in operating assets and liabilities:		
Accounts receivable, net	(30,277)	(7,057)
Advances to BioMarin/Genzyme LLC	1,764	—
Inventory	4,474	(3,260)
Other current assets	(418)	25,719
Other assets	(143)	(221)
Accounts payable and accrued liabilities	(7,681)	(4,046)
Other liabilities	143	138
Deferred revenue	(448)	(187)
Net cash provided by (used in) operating activities	(23,179)	20,020
Cash flows from investing activities:		
Purchase of property and equipment	(19,889)	(18,737)
Maturities and sales of short-term investments	254,556	110,100
Purchase of short-term investments	(149,025)	(112,801)
Distributions from BioMarin/Genzyme LLC	16,679	—
Investment in La Jolla Pharmaceutical Company	—	(6,250)
Net cash provided by (used in) investing activities	102,321	(27,688)
Cash flows from financing activities:		
Proceeds from ESPP and exercise of stock options	14,255	891
Excess tax benefit from stock option exercises	—	4
Repayment of acquisition obligation	(1,750)	(1,500)
Repayment of capital lease obligations	—	(48)
Net cash provided by (used in) financing activities	12,505	(653)
Net increase (decrease) in cash and cash equivalents	91,647	(8,321)
Cash and cash equivalents:		
Beginning of period	228,343	222,900
End of period	$ 319,990	$ 214,579
Supplemental cash flow disclosures:		
Cash paid for interest	$ 2,155	$ 2,153
Cash paid for income taxes	50	407
Stock-based compensation capitalized into inventory	944	1,303
Depreciation capitalized into inventory	575	650
Supplemental non-cash investing and financing activities disclosures:		
Distribution of inventory resulting from the joint venture restructure	26,780	—
Changes in accrued liabilities related to fixed assets	1,261	1,996
Equipment acquired through capital lease	—	—

See accompanying notes to unaudited consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 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 March 31, 2009, the Company had accumulated losses of approximately $589.7 million. Management believes that the Company's cash, cash equivalents, short-term investments and long-term investments at March 31, 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.

Operating results for the three months ended March 31, 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.

(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 March 31, 2009, the Company had no held-to-maturity investments.

As of March 31, 2009, long-term investments included an equity investment denominated in British Pounds. The equity investment is accounted for under the provisions of Statement of Financial Accounting Standard (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* 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 under the provisions of SFAS No. 52, *Foreign Currency Translation.* 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.

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 pursuant to the terms of the joint venture restructuring (see Note 4 for further information). The inventory distribution was recorded at the historical production cost, which represented the lower of cost or market value.

Stock-based compensation of $0.9 million and $1.3 million was capitalized into inventory for the three months ended March 31, 2008 and 2009, respectively (see Note 6 for further information).

(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 March 31, 2009.

Certain of the Company's operating lease agreements include scheduled rent escalations over the lease term, as well as tenant improvement allowances. The Company accounts for these operating leases in accordance with SFAS No. 13, *Accounting for Leases* , and Financial Accounting Standards Board (FASB) Technical Bulletin No. 85-3, *Accounting for Operating Leases with Scheduled Rent Increases* . Accordingly, the scheduled increases in rent expense are recognized on a straight-line basis over the lease term. The difference between rent expense and rent paid is recorded as deferred rent and included in other liabilities in the accompanying consolidated balance sheets. The tenant improvement allowances 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 and Kuvan, Aldurazyme product transfer and royalty revenues beginning January 1, 2008, 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 (VAT) 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.

The Company began recognizing revenue related to Aldurazyme in the first quarter of 2008, effective with the restructuring of the Company's Aldurazyme joint venture with Genzyme (see Note 4 for further information). According to the terms of the restructuring, 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 March 31, 2009, accounts receivable included $14.3 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. In the E.U., Naglazyme is sold to the Company's authorized distributors or directly to 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 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 March 31, 2009, the Company has experienced no significant bad debts and the recorded allowance for doubtful accounts was insignificant.

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)* .

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Aldurazyme are limited to defective product. Based on these factors, management has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required. The Company maintains a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of March 31, 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. 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 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 first quarter of 2008 included the recognition of $1.5 million of the $25.0 million up-front license fee received from Merck Serono and $1.0 million of reimbursable development costs for Kuvan, compared to the first quarter of 2009, which included $0.5 million 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, primarily the manufacturing and regulatory activities, as well as the rights and responsibilities to deliver the product to Genzyme, the Company elected not to classify the Aldurazyme royalty as other royalty revenues.

Royalty and license revenues in the first quarter of 2009 include $1.4 million of Orapred product royalties, a product the Company acquired in 2004 and sublicensed in 2006, and $0.2 million of Kuvan royalty revenues for product sold in Japan and Europe compared to the first quarter of 2008 which included only included $0.3 million of Orapred 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 Employee Stock Purchase Plan (ESPP), restricted stock and contingent issuances of common stock related to convertible debt and a portion of acquisition costs payable in stock at the Company's option.

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

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

In addition to the stock options included in the above table, options to purchase approximately 0.3 million shares of common stock were outstanding during the first quarter of 2008, but were not included in the computation of diluted earnings per share because they were anti-dilutive during the period using the treasury stock method. These options were anti-dilutive because the fair value of the Company's stock exceeded the assumed proceeds. Additionally, approximately 26.4 million of the underlying shares of the Company's convertible debt were not included in the diluted average common shares outstanding because they were antidilutive during the first quarter of 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 months ended March 31, 2009 (in thousands, except per share data):

	For the Three Months Ended March 31, 2009		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Earnings Per Share:			
Net Loss	$ (13,152)	99,902	$ (0.13)
Effect of dilutive shares:			
Nonqualified Deferred Compensation Plan obligation using the treasury method	(156)	31	
Diluted Earnings Per Share:			
Net Income	$ (13,308)	99,933	$ (0.13)

In addition to the shares of common stock held by the Nonqualified Deferred Compensation Plan included above, the following potential shares of common stock were excluded from the computation as they were anti-dilutive during the period using the treasury stock method (in thousands):

	March 31, 2009
Options to purchase common stock	12,137
Common stock issuable under convertible debt	26,343
Portion of acquisition obligation payable in common stock at the option of the Company	696
Potentially issuable common stock for ESPP purchases	137
Potentially issuable restricted stock	243
Total	39,556

(k) Stock-Based Compensation

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

Expected volatility is based upon proportionate weightings of the historical volatility of the Company's 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.

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 $1.2 million, respectively, of investments held in trust related to our Nonqualified Deferred Compensation Plan for certain employees and directors as of December 31, 2008 and March 31, 2009, respectively. All of the investments held in the Nonqualified Deferred Compensation Plan are classified as trading securities and recorded at fair value in accordance with SFAS No. 115 with changes in the investments' fair values recognized in earnings in the period they occur. In accordance with EITF 97-14, *Accounting for Deferred Compensation Arrangements Where Amounts Earned Are Held in a Rabbi Trust and Invested*, 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 plan is recorded in equity and changes in its fair value are not recognized. 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 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.

(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 income in the period such adjustment was made. During the first quarters of 2008 and 2009, the Company recognized $0.1 million and $0.4 million of income tax expense, respectively, 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 and Accumulated Other Comprehensive Income (Loss)

Comprehensive income 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 first quarters of 2008 and 2009.

Comprehensive loss was approximately $12.2 million for the three months ended March 31, 2009, compared to comprehensive net income of $1.9 million for the three months ended March 31, 2008. The fluctuation in accumulated other comprehensive income (loss) is comprised of the following (in thousands):

	Three Months Ended March 31,	
	2008	2009
Net unrealized gain (loss) on available-for-sale securities	$ 213	$ (632)
Net unrealized gain on foreign currency hedges	—	1,932
Net unrealized loss on equity investments	—	(337)
Net foreign currency translation gain (loss)	(1)	—
Accumulated other comprehensive income	$ 212	$ 963

(q) Restricted Cash

The Company's balance of restricted cash amounted to $7.3 million and $8.9 million at December 31, 2008 and March 31 2009, respectively. The December 31, 2008 and March 31, 2009 balances include $6.2 million and $7.7 million related to cash received for royalties earned pursuant to the Orapred sublicense agreement, respectively, which are restricted from use until August 2009 and are included in other current assets. Restricted cash also includes investments of $0.9 million and $1.2 million held by the Company's Nonqualified Deferred Compensation Plan as of December 31, 2008 and March 31, 2009, respectively, which is included in other assets.

(r) Recent Accounting Pronouncements

In April 2009, the FASB issued FASB Staff Position FAS 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*, or 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 is the second quarter of fiscal 2009. The Company is evaluating the impact this standard will have on its consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position (FSP) FAS 115-2, FAS 124-2, and EITF 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments* , or FSP FAS 115-2, FAS 124-2, and EITF 99-20-2; and 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 is effective for periods ending after June 15, 2009 with early adoption permitted. The Company is currently evaluating the impact this FSP will have on its consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* , or FSP FAS 107-1 and APB 28-1. FSP FAS 107-1 and APB 28-1, amends 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 is the second quarter of fiscal 2009. The Company is currently evaluating the impact this FSP will have on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133* (SFAS No. 161). The standard requires additional quantitative disclosures and qualitative disclosures for derivative instruments. The required disclosures include how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows; relative volume of derivative activity; the objectives and strategies for using derivative instruments; the accounting treatment for those derivative instruments formally designated as the hedging instrument in a hedge relationship; and the existence and nature of credit-related contingent features for derivatives. The Company adopted the provision of SFAS No. 161 on January 1, 2009. As a result of adopting the provision of this standard, the Company has expanded its disclosures regarding derivative instruments and hedging activities within Note 11.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* , (SFAS No. 157). SFAS No. 157 provides enhanced guidance for using fair value to measure assets and liabilities. In February 2008, the FASB issued FSP No. 157-2, which deferred the effective date of SFAS No. 157 for one year relative to certain nonfinancial assets and liabilities. On January 1, 2009, the beginning of our fiscal 2009, the Company adopted the requirements of SFAS No. 157 that had been deferred under FSP 157-2, *Effective Date of FASB Statement No. 157* . The adoption did not have a material impact on the Company's consolidated financial statements during the first quarter of 2009.

In October 2008, the FASB issued Staff Position No. FAS 157-3, *Determining the Fair Value of a Financial Asset in a Market That Is Not Active* (FSP FAS 157-3). FSP FAS 157-3 clarifies the application of FAS No. 157 in a market that is not active and defines additional key criteria in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS 157-3 applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with FAS No. 157. FSP FAS 157-3 was effective upon issuance and the application of FSP FAS 157-3 did not have a material impact on the Company's consolidated financial statements in the first quarter of 2009.

(s) Reclassifications and Adjustments

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

(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 for additional information related to these stock-based compensation plans.

Determining the Fair Value of Stock Options

The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the table below. The expected life of options is based on observed historical exercise patterns. Groups of employees that have similar historical exercise patterns were considered separately for valuation purposes, but none were identified that had distinctly different exercise patterns as of March 31, 2009. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of the Company's stock and the implied volatility of traded options on the Company's stock for fiscal periods in which there is sufficient trading volume in options on the Company's stock. The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that 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 first quarter of 2009, the Company granted 228,750 stock options under the 2006 Share Incentive Plan, with a weighted average fair value of $6.52. The Company also granted 232,324 options under the ESPP with a weighted average fair value of $7.63 during the first quarter of 2009. The assumptions used to estimate the fair value of stock options granted and stock purchase rights granted under the Company's 2006 Share Incentive Plan and ESPP for the three months ended March 31, 2008 and 2009 are as follows:

	Three Months Ended March 31,	
	2008	2009
Stock options:		
Weighted average fair value of common stock	$ 36.78	$ 12.49
Expected life	5.2 years	6.0 years
Volatility	44.7%	54.5%
Risk-free interest rate	2.8%	1.9%
Dividend yield	0%	0%

	Three Months Ended March 31,	
	2008	2009
ESPP:		
Fair market value of common stock	$ 27.18	$ 19.36
Expected life	6 – 24 months	6 – 24 months
Volatility	44.4%	51.4%
Risk-free interest rate	3.8-4.0%	1.1-1.5%
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 underlying the RSU at the date of grant, ratably over the period during which the vesting restrictions lapse. During the first quarter of 2009, the Company granted 20,000 RSUs with a weighted average fair market value of $11.05 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 March 31,	
	2008	2009
Cost of sales	$ 197	$ 564
Research and development expense	1,557	2,475
Selling, general and administrative expense	2,710	4,757
Total stock-based compensation expense	$ 4,464	$ 7,796

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 $0.9 million and $1.3 million was capitalized into inventory during the first quarters of 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. There were no similar upfront inventory shipments in the first quarter of 2009.

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 Years Ending December 31,			December 31, 2008
	2009	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Corporate securities	$ 55,270	$ 55,270	$ (100)	$ 55,170
Commercial paper	33,076	33,076	48	33,124
Equity securities	3,633	3,633	332	3,965
U.S. Government agency securities	220,914	220,914	977	221,891
U.S. Government backed commercial paper	24,370	24,370	5	24,375
Total	$ 337,263	$ 337,263	$ 1,262	$ 338,525

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

	Contractual Maturity Date For the Years Ending December 31,			March 31, 2009	
	2009	2010	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Certificates of deposit	$ 7,234	$2,806	$ 10,040	$ (109)	$ 9,931
Corporate securities	39,602	1,029	40,631	32	40,663
Commercial paper	29,437	—	29,437	34	29,471
Equity securities	4,021	—	4,021	6	4,027
U.S. Government agency securities	256,884	—	256,884	325	257,209
Total	$337,178	$3,835	$341,013	$ 288	$ 341,301

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of March 31, 2009. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized costs.

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

	Less Than 12 Months To Maturity		12 Months or More To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	$ 7,155	$ (78)	$ 2,776	$ (31)	$ 9,931	$ (109)
Corporate securities	15,468	(15)	—	—	15,468	(15)
Commercial paper	4,985	(4)	—	—	4,985	(4)
U.S. Government agency securities	16,518	(15)	—	—	16,518	(15)
Total	$ 44,126	$ (112)	$ 2,776	$ (31)	$ 46,902	$ (143)

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

(6) SUPPLEMENTAL BALANCE SHEET INFORMATION

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

	December 31, 2008	March 31, 2009
Raw materials	$ 10,314	$11,008
Work in process	29,998	29,103
Finished goods	32,850	36,312
Total inventory	$ 73,162	$76,423

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

	December 31, 2008	March 31, 2009
Kuvan European Medicines Agency (EMEA) approval milestone receivable	$ 30,000	$ —
Non-trade receivables	4,828	6,170
Prepaid expenses	3,013	4,359
Deferred cost of goods sold	3,879	2,446
Short-term restricted cash	6,202	7,748
Other	2,522	3,205
Total other current assets	$ 50,444	$23,928

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

	December 31, 2008	March 31, 2009
Accounts payable	$ 922	$ 5,178
Accrued accounts payable	26,214	25,646
Accrued vacation	3,798	4,621
Accrued compensation	11,737	6,270
Accrued interest and taxes	2,684	3,175
Accrued royalties	3,401	3,620
Other accrued expenses	6,094	3,135
Accrued rebates	3,194	3,035
Other	989	1,197
Total accounts payable and accrued liabilities	$ 59,033	$55,877

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

	December 31, 2008	March 31, 2009
Long-term portion of deferred rent	$ 1,176	$ 1,157
Long-term portion of capital lease liability	270	222
Long-term portion of deferred compensation liability	1,410	1,567
Total other long-term liabilities	$ 2,856	$ 2,946

(7) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2008 and March 31, 2009, consisted of (in thousands):

Category	December 31, 2008	March 31, 2009	Estimated Useful Lives
Leasehold improvements	$ 27,544	$ 27,549	Shorter of life of asset or lease term
Building and improvements	61,183	64,356	20 years
Manufacturing and laboratory equipment	26,996	28,347	5 years
Computer hardware and software	13,088	19,900	3 to 5 years
Office furniture and equipment	4,602	4,642	5 years
Land	10,056	10,056	Not applicable
Construction-in-progress	27,589	36,941	Not applicable
Gross property, plant and equipment	$ 171,058	$191,791	
Less: Accumulated depreciation	(46,079)	(49,539)	
Total property, plant and equipment, net	$ 124,979	$142,252	

Depreciation for the first quarters of 2008 and 2009 was $2.4 million and $3.5 million, respectively, of which $0.6 million and $0.7 million was capitalized into inventory, respectively.

Capitalized interest related to the Company’s property, plant and equipment purchases during the first quarters of 2008 and 2009 was insignificant.

In January 2008, the Company purchased its previously leased laboratory/office building located at 300 Bel Marin Keys Drive, Novato, California for approximately $12.0 million. As a result of the purchase, the Company capitalized certain pre-existing deferred rent liabilities of approximately $0.5 million as a reduction to the acquisition cost of the building.

(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 (DMD). The Company paid Summit $7.1 million for an equity investment in Summit shares and licensing rights to SMT C1100. The initial equity investment represents the acquisition of approximately 5.1 million Summit shares with a fair value 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 is 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 License Agreement. 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. 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 March 31, 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 to 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. Based on the current market conditions, the low volume of trading in Summit securities and their current financial condition, the Company determined that its investment in Summit was other-than-temporarily impaired and adjusted the recorded amount of the investment to the stock's market price on March 31, 2009.

(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 an international double blind, placebo controlled randomized Phase III clinical study for lupus nephritis (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 clinical trial 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 have decided to stop the study, unblind all of the data and evaluate all of the clinical results, including the secondary endpoints.

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 holds approximately 10.2 million shares of common stock, or approximately 15.5% La Jolla's outstanding common stock. The Company accounts for the converted La Jolla shares, which are traded on NASDAQ Stock Exchange, under the provisions of SFAS No. 115. 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.

During the first quarter of 2009, the Company has 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 is, 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 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. The investment is included in short-term investments as of March 31, 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 no call provision included and the Company is unable to unilaterally redeem the debt prior to maturity on April 23, 2017. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the April 2007 debt, the Company paid approximately $8.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt. The Company recognized $0.2 million of amortization expense in each of the first quarters of 2008 and 2009.

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 no 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 of amortization expense during each of the first quarters of 2008 and 2009. During the first quarter of 2008, certain note holders voluntarily exchanged an insignificant number of convertible notes for shares of the Company's common stock.

Interest expense in each of the first quarters of 2008 and 2009 was $4.1 million, and included $1.1 million of imputed interest expense related to the Company's acquisition obligation.

(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 our 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 March 31, 2009, the Company had 17 forward contracts outstanding to purchase a total of 30.4 million Euros with expiration dates ranging from April 30, 2009 through February 26, 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 March 31, 2009, the Company had two outstanding foreign currency contracts 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 February 2010. Over the next 12 months, the Company expects to reclassify $1.7 million from accumulated other comprehensive income to earnings as related forecasted revenue transactions occur.

The Company did not enter into any derivative transactions which qualified for hedge accounting under SFAS No. 133, as amended, prior to the second quarter of 2008. For the three months ended March 31, 2009, the Company recognized foreign currency transaction gains of $1.2 million from derivative transactions that qualified for hedge accounting.

At December 31, 2008 and March 31, 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 March 31, 2009		Liability Derivatives March 31, 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	$ 1,437	Other current liabilities	$ —
Total		$ 1,437		$ —
Derivatives not designated as hedging instruments under FAS 133				
Foreign exchange contracts	Other current assets	$ 110	Other current liabilities	$ —
Total		$ 110		$ —
Total derivative contracts		$ 1,547		$ —

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

Derivatives in FAS 133 Hedging Relationships	Amount of Gain/(Loss) Recognized in OCI (Effective Portion)	Location of Gain/(Loss) Reclassified from Accumulated OCI into income (Effective Portion)	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income (Effective Portion)	Location of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded from Effectiveness Testing)	Amount of Gain/(Loss) Recognized in Income on Derivative (Ineffective Portion and Amount Excluded from Effectiveness Testing)
Foreign exchange contracts	$ 1,740	Net product revenues	$ 1,184	Selling, general and administrative	$ 209
Total	$ 1,740		$ 1,184		$ 209

Derivatives Not Designated as Hedging Instruments under Statement 133	Location of Gain/(Loss) Recognized in Income on Derivative	Amount of Gain/(Loss) Recognized in Income on Derivative
Foreign exchange contracts	Selling, general and administrative	$ 1,165
Total		$ 1,165

At December 31, 2008 and March 31, 2009, accumulated other comprehensive income associated with forward contracts qualifying for hedge accounting treatment was a loss of $0.2 million and $1.7 million, respectively.

The Company is exposed to counterparty credit risk on all of our derivative financial instruments. The Company has established and maintained strict counterparty credit guidelines and enter 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 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 March 31, 2009, by SFAS No. 157.

	Fair Value Measurements (in thousands) at March 31, 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)	$ 214,579	$ 17,356	$ 197,223	$ —
Certificates of deposit (6)	9,931	9,931	—	—
Corporate securities (2)	40,663	—	40,663	—
Equity securities (7)	4,027	3,823	204	—
Government agency securities (2)	257,209	—	257,209	—
Commercial paper (2)	29,471	—	29,471	—
Foreign currency derivatives (3)	1,547	—	1,547	—
Total	$ 557,427	$ 31,110	$ 526,317	$ —
Liabilities:				
Deferred compensation liability (4)	$ 1,657	$ —	$ 1,657	$ —
Total	$ 1,657	$ —	$ 1,657	$ —

The fair value of these financial assets and liabilities was determined using the following inputs at December 31, 2008 (in thousands):

	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 (2)	55,170	—	55,170	—
Equity securities (7)	3,965	2,332	1,633	—
Government agency securities (2)	221,891	—	221,891	—
Government backed commercial paper (2)	24,375	—	24,375	—
Commercial paper (2)	33,124	—	33,124	—
Foreign currency derivatives (3)	803	—	803	—
Total	$ 562,228	$ 15,291	$ 546,937	$ —
Liabilities:				
Deferred compensation liability (4)	$ 1,428	$ —	$ 1,428	$ —
Foreign currency derivatives (5)	1,129	—	1,129	—
Total	$ 2,557	$ —	$ 2,557	$ —

(1) Included in cash and cash equivalents investments in the Company's consolidated balance sheet.

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

(3) Included in other current assets on the Company's consolidated balance sheet. Foreign currency derivatives at March 31, 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.

(4) Included in other long-term liabilities on the Company's consolidated balance sheet.

(5) Included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.

(6) 72% and 28% are included in short-term and long-term investments in the Company's consolidated balance sheet, respectively.

(7) Included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2008 and March 31, 2009, 0.5% is included in long-term investments and the remaining balances are included in short-term investments.

(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 months ended March 31, 2008 and 2009.

	Three Months Ended March 31,	
	2008	2009
Region:		
United States	61%	52%
Europe	25%	24%
Latin America	7%	11%
Rest of World	7%	13%
Total Net Product Revenue	100%	100%

As of March 31, 2009, accounts receivable related to net product sales of Naglazyme and Kuvan and Aldurazyme product transfer and royalty revenues. On a consolidated basis, three customers accounted for 51% of our net product revenues during the first quarter of 2009. On a consolidated basis, two customers accounted for 47% and 15% of the March 31, 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

This Form 10-Q contains "forward-looking statements" as defined under securities laws. Many of these statements can be identified by the use of terminology such as "believes," "expects," "anticipates," "plans," "may," "will," "projects," "continues," "estimates," "potential," "opportunity" and similar expressions. These forward-looking statements may be found in "Overview," and other sections of this Form 10-Q. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in "Risk Factors," in our Form 10-K for the year ended December 31, 2008, as well as those discussed elsewhere in this Form 10-Q. You should carefully consider that information before you make an investment decision.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and 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 first quarters of 2008 and 2009 were $27.7 million and $39.4 million, respectively.

Aldurazyme 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. Effective January 2008, we restructured our relationship with Genzyme whereby Genzyme sells Aldurazyme to third parties and we recognize royalty revenue on net sales by Genzyme. 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. 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. Our Aldurazyme net product revenues for the first quarters of 2008 and 2009 were $24.1 million and $17.0 million, respectively.

Kuvan was granted marketing approval in the U.S. in December 2007. Kuvan net product sales for the first quarters of 2008 and 2009 were $5.8 million and $15.5 million, respectively.

We are developing PEG-PAL, an experimental enzyme substitution therapy for the treatment of PKU, for patients that are not responsive to Kuvan. In May 2008, we initiated a Phase I open label clinical trial of PEG-PAL in PKU patients. The primary objective of this study is to assess the safety and tolerability of single subcutaneous injections of PEG-PAL in subjects with PKU. We have completed the dosing of the fifth cohort of patients in the Phase I trial, and are in communications with the FDA regarding the Phase II trial design and expect to initiate the study in the second quarter of 2009. 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 expect to initiate an open label Phase I/II clinical trial of GALNS, an enzyme replacement therapy for the treatment of MPS IVA in April 2009. We expect the results form this trial in the fourth quarter of 2009. 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 months ended March 31, 2008 and 2009 include the following:

	Three Months Ended March 31,	
	2008	2009
Total net product revenues	$ 57,625	$ 71,914
Collaborative agreement revenues	2,465	509
Cost of sales	17,188	14,362
Research and development expense	17,628	34,358
Selling, general and administrative expense	23,669	28,568
Net income (loss)	1,686	(13,152)
Stock-based compensation expense	4,464	7,796

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 $555.9 million as of March 31, 2009, compared to $561.4 million as of December 31, 2008.

Critical Accounting Policies and Estimates

In preparing our condensed consolidated financial statements in accordance with GAAP and pursuant to the rules and regulations of 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 months ended March 31, 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.

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 loss for the three months ended March 31, 2009 was $13.2 million compared to a net income of $1.7 million for the three months ended March 31, 2008, with the change primarily due to the following (in millions).

Net income for the period ended March 31, 2008	$ 1.7
Increased Naglazyme gross profit	8.8
Increased Kuvan gross profit	8.3
Decreased Kuvan license fee revenues	(1.3)
Increased research and development expenses	(16.8)
Increased selling, general and administrative expense	(4.9)
Impairment loss on La Jolla investment	(4.5)
Increased Orapred royalty income	1.1
Decreased interest income	(3.5)
Impairment loss on Summit investment	(1.4)
Other individually insignificant fluctuations	(0.7)
Net loss for the period ended March 31, 2009	$ 13.2

The increase in Naglazyme gross profit in the first quarter of 2009 as compared to the first quarter of 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 first quarter of 2009 compared to the first quarter of 2008 is primarily a result of additional patients initiating therapy in the U.S. The decrease in Kuvan license fee revenues is attributed to us fulfilling all performance obligations relating to the 2005 $25.0 million up-front license payment from Merck Serono in December 2008. The increase in selling, general and administrative expense was primarily due to the continued international expansion of Naglazyme and commercialization of Kuvan in the U.S. The increase in research and development expense was primarily due to increases in development expense for our GALNS program, the up-front costs associated with a product licensed from La Jolla for the treatment of lupus nephritis, 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.

Net Product Revenues, Cost of Sales and Gross Profit

The following table shows a comparison of net product revenues for the three months ended March 31, 2008 and 2009 (in millions):

	Three Months Ended March 31,		
	2008	2009	Change
Naglazyme	$27.7	$39.4	$ 11.7
Kuvan	5.8	15.5	9.7
Aldurazyme	24.1	17.0	(7.1)
Total Net Product Revenues	$57.6	$71.9	$ 14.3

Net product revenue for Naglazyme in the first quarter of 2009 totaled $39.4 million, of which $34.5 million was earned from end-user customers based outside the U.S. The negative impact of foreign currency exchange rates on Naglazyme sales from customers based outside the U.S. was approximately $2.0 million in the first quarter of 2009. Gross profit from Naglazyme in the first quarter of 2009 was approximately $31.3 million, representing gross margins of approximately 80% as compared to $22.2 million in the first quarter of 2008, representing gross margins of approximately 80%. The decrease in gross margins is attributed to the negative foreign currency impact during the first 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 in the U.S. during the first quarter of 2009 was $15.5 million, compared to $5.8 million during the first quarter of 2008. Gross profit from Kuvan in the first quarter of 2009 was approximately $13.1 million, representing gross margins of approximately 84%. During the first quarter of 2008, gross profit from Kuvan was approximately $5.1 million, representing gross margins of 88%. Both periods reflect royalties paid to third parties of 11%. In accordance with our inventory accounting policy, we began capitalizing Kuvan inventory production costs after U.S. regulatory approval was obtained in December 2007. As a result, the product sold in 2008 had an insignificant cost basis. We expect that a significant portion of Kuvan sold during 2009 will be previously expensed product and will have a minimal cost basis. The cost of sales for Kuvan for the first quarters of 2008 and 2009 is primarily comprised of royalties paid to third parties based on Kuvan net sales.

As a result of the restructuring of the BioMarin/Genzyme LLC joint venture, 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 or 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 first quarter of 2009 was $17.0 million, compared to $24.1 million in the first quarter of 2008. Aldurazyme net product revenues in the first quarter of 2009 was comprised of $14.5 million in royalty revenues and incremental net product transfer revenue of $2.5 million. Aldurazyme net product revenue in the first quarter of 2008 was comprised of $14.6 million of royalty revenue and $9.5 million of net product transfer revenue. Royalty revenue from Genzyme is based on 39.5% of net Aldurazyme sales by Genzyme, which totaled $36.8 million in the first quarters of 2009 and 2008. Incremental Aldurazyme net product transfer revenue reflects incremental shipments of Aldurazyme to Genzyme 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 first quarter of 2009, Aldurazyme gross profit was $13.2 million, representing a gross margin of 77%, which reflects the profit earned on royalty revenue and net incremental product transfer revenue. For the same period in 2008, Aldurazyme gross profit was $13.2 million, representing a gross margin of 55%. The increase in gross margins is attributed to a shift in revenue mix between royalty revenue and net product transfer revenues. In the first quarter of 2009, the revenue mix was 85% royalty revenues and 15% net product transfer revenues, compared to the first quarter of 2008, where the revenue mix was 61% royalty revenues and 39% net product transfer revenues. 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 first quarters of 2008 and 2009, was $17.2 million and $14.4 million, respectively. The decrease in cost of sales is primarily due to the Aldurazyme product revenue mix in the first quarter of 2009 compared to the first quarter of 2008 as cost of sales related to Aldurazyme are recorded in the period the product is shipped to Genzyme offset by the increased net product revenues discussed above.

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 or 6R-BH4 successfully complete Phase II clinical trials and Merck Serono exercises its option to co-develop the program. The related costs are included in research and development expenses.

Collaborative agreement revenues in the first quarters of 2008 and 2009 were $2.5 million and $0.5 million, respectively. Collaborative agreement revenues in the first quarter of 2009 were comprised of reimbursable Kuvan development costs, compared to the first quarter of 2008 which included amortization of the $25.0 million up-front license payment received from Merck Serono and reimbursable Kuvan development of $1.5 million and $1.0 million, respectively. Kuvan development costs decreased during the first quarter of 2009 as compared to the first quarter of 2008 due to reductions in Kuvan clinical trial activities.

Royalty and License Revenues

Royalty and license revenue for the first quarter of 2009 totaled $1.6 million, compared to $0.3 million in the first quarter of 2008. Royalty and license revenues for the three months ended March 31, 2009 included royalty revenues from Orapred product sold by the sublicensee of $1.4 million and Kuvan royalty revenues for products sold in Japan and Europe of $0.2 million. Royalty and license revenues for the first quarter of 2008 included royalty revenues from Orapred product sold by the sublicensee of $0.3 million.

Research and Development Expense

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

Research and development expenses increased by $16.8 million to $34.4 million for the three months ended March 31, 2009, from $17.6 million for the three months ended March 31, 2008. The change in research and development expenses for the first quarter of 2009 is primarily as a result of the following (in millions):

Research and development expenses for period ended March 31, 2008	$17.6
License payment related to collaboration with La Jolla Pharmaceutical Company	8.8
Increased GALNS for Morquio Syndrome Type A development expense	2.8
Increased Kuvan development costs	0.7
Increased Prodrug development expenses	0.8
Increased stock-based compensation expense	0.9
Increased Duchene Muscular Dystrophy program development expense	0.3
Decreased 6R-BH4 development costs for indications other than PKU	(0.8)
Decreased research and development expense on early development stage programs	(0.3)
Increase in non-allocated research and development expense and other net changes	3.6
Research and development expenses for the period ended March 31, 2009	$34.4

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, for the treatment of lupus nephritis. 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, as such we do not expect to continue incurring development costs for the licensed product. The increase in GALNS development costs is primarily attributed to an increase in pre-clinical studies and manufacturing costs in preparation for the Phase I/II clinical trial that we initiated in April 2009. The decrease in 6R-BH4 development costs for indications other than PKU is primarily due to a decline in pre-clinical studies in 2009. The increase in Kuvan research and development costs is attributed to long-term clinical activities related to post-approval regulatory commitments. We expect to continue incurring significant Kuvan research and development costs 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 stock-based compensation expense is a result of an increased number of options outstanding due to increased number of employees and a higher average stock price on the related grant date. 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.

Selling, general and administrative expenses increased by $4.9 million, to $28.6 million for the three months ended March 31, 2009, from $23.7 million for the three months ended March 31, 2008. The components of the change for first quarter of 2009 primarily include the following (in millions):

Selling, general and administrative expense for the period ended March 31, 2008	$23.7
Increased Naglazyme sales and marketing expenses	1.2
Increased stock-based compensation expense	2.0
Increased Kuvan commercialization expenses	1.7
Increased foreign exchange losses on un-hedged transactions	(0.2)
Net increase in corporate overhead and other administrative costs	0.2
Selling, general and administrative expenses for the period ended March 31, 2009	$28.6

Naglazyme sales and marketing expenses increased in the first quarter of 2009, primarily due to the expansion of our international commercial activities. We also incurred increased commercialization expenses related to the Kuvan commercial launch. The increase in stock-based compensation expense was the result of an increased number of outstanding stock options and a higher average stock price on the related grant date. 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. The Orapred intangible asset is being amortized over approximately 3.5 years, and is expected to total approximately $1.8 million through the end of its expected useful life in August 2009.

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 goods sold 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 months ended March 31, 2008 and 2009 was $0.1 million and $0.2 million, 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 first quarter of 2009, compared to the first quarter of 2008 at approximately $0.5 million.

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 $2.2 million for the first quarter of 2009, from $5.6 million for the same period in 2008. The reduced interest yields during the first quarter 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 each of the first quarters of 2008 and 2009 was $4.1 million and included $1.1 million of imputed interest. Imputed interest on the outstanding balance will be incurred through August 2009 when payment is due on the Medicis obligation.

Changes in Financial Position

March 31, 2009 Compared to December 31, 2008

From December 31, 2008 to March 31, 2009, our inventory increased by approximately $3.3 million. Our accounts receivable increased by $7.1 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 $26.5 million from December 31, 2008 to March 31, 2009, primarily as a result of the subsequent receipt of the $30.0 million related to the EMEA milestone earned from Merck Serono in December 31, 2008. Our net property, plant and equipment increased by approximately $17.3 million from December 31, 2008 to March 31, 2009, primarily as a result continued expansion and improvements to our facilities practically offset by depreciation expense during the period. We expect property, plant and equipment to increase in future periods, due to several ongoing facility improvement projects.

Liquidity and Capital Resources

Cash and Cash Flow

As of March 31, 2009, our combined cash, cash equivalents, short-term and long-term investments totaled $555.9 million, a decrease of $5.5 million from $561.4 million at December 31, 2008. During the three months ended March 31, 2009, we financed our operations primarily through net product sales and available cash, cash equivalents, short-term and long-term investments and the related interest income earned thereon.

The decrease in our combined balance of cash, cash equivalents, short-term and long-term investments during the first quarter of 2009 was $5.5 million, which was $5.3 million less than the net decrease in cash, cash equivalents and short-term investments during the first quarter of 2008 of $10.8 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)
Decreased capital asset purchases	1.2
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	(13.4)
Net decreased cash used in operating activities, including net payments for working capital, other	12.2
Total decrease in net cash outflow	$ 5.3

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 the " *Results of Operations* " section 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 quarter of 2009 primarily include decreased inventory build of $7.7 million, which excluded the inventory distribution from the joint venture, decreased accounts receivable build of $23.2 million, the receipt of the Merck Serono $30.0 million milestone payment earned in December 2008 related to the EMEA approval of Kuvan, and decreased accounts payable and accrued liabilities build of $3.6 million.

With respect to the restructuring of our joint venture with Genzyme, our liquidity was not materially impacted by the restructuring despite the change in the Aldurazyme transaction structure. We remain responsible for the cash outflows for the investment in inventory and continue to receive the cash inflows from sales of Aldurazyme on a quarterly basis, except we currently receive cash through the royalty from Genzyme instead of cash distributions from the joint venture prior to the restructuring. However, as we now record accounts receivable from Genzyme that include both amounts related to royalty revenue and incremental product transfer revenue, our days sales outstanding has increased as a result of the joint venture restructuring and we expect our days sales outstanding to either remain consistent with the current level or increase modestly in the future. Genzyme is required to pay the royalty due within 45 days of the quarter in which the relevant sales were made, and with respect to the incremental product transfer revenue for unsold Aldurazyme, Genzyme is required to pay within 45 days after the calendar quarter in which the unit was determined to be unsold, which is not determinable until the product is lost, destroyed or expires before a sale to a customer. Further, pursuant to the terms of the restructured joint venture, we received a cash distribution of $16.7 million and an inventory distribution of $26.8 million from the joint venture in the first quarter of 2008.

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, 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.

Funding Commitments

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

Our investment in our product development programs and continued development of our existing commercial products has a major impact on our operating performance. Our research and development expenses for the three months ended March 31, 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 March 31,		Since Program Inception
	2008	2009	
Naglazyme	$ 2.2	$ 2.3	$ 124.9
Kuvan	2.0	2.6	92.4
GALNS for Morquio disease	1.4	4.1	20.5
6R-BH4 for other indications	3.5	3.1	45.2
PEG-PAL	2.3	2.3	33.5
Not allocated to specific major current projects	5.6	8.6	186.5
	$ 17.0	$ 23.0	$ 503.0

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, 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 and at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program;" "—If we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be adversely affected;" and "—If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline."

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

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

- our ability to successfully market and sell Naglazyme and Kuvan;
- Genzyme's ability to successfully market and sell Aldurazyme;
- the progress, timing, scope and results of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;
- the time and cost necessary to develop commercial manufacturing processes, including quality systems and to build or acquire manufacturing capabilities;
- the time and cost necessary to respond to technological and market developments;
- any changes made to or new developments in our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and
- whether our convertible debt is converted to common stock in the future.

Off-Balance Sheet Arrangements

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

Borrowings and Contractual Obligations

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

As a result of the Ascent Pediatrics transaction, we expect to pay Medicis $72.1 million through the end of 2009, of which $8.6 million at our election is payable through the issuance of our common stock.

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of March 31, 2009 is presented below (in thousands).

	Payments Due by Period					
	2009	2010	2011-2012	2013-2014	2015 and Thereafter	Total
Medicis obligations	$ 72,100	$ —	$ —	$ —	$ —	$ 72,100
Convertible debt and related interest	8,246	10,401	20,801	186,544	340,104	566,096
Operating leases	2,832	3,859	6,481	3,423	3,158	19,753
Research and development and purchase commitments	31,218	14,787	5,162	4,820	3,084	59,071
Total	$114,396	$29,047	$32,444	$194,787	$346,346	$717,020

We are also subject to contingent payments related to various development activities totaling approximately $108.0 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 March 31, 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, on file with the Securities and Exchange Commission (SEC).

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) as of the end of the period covered by this report.

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

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

There were no changes, except as noted below, 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.

On January 1, 2009, we implemented a new Enterprise Resource Planning (ERP) system. As appropriate, we have modified the design and operation of our internal controls to supplement the ERP system and complement existing internal controls over financial reporting. Based on management's evaluation, the necessary steps have been taken to monitor and maintain appropriate internal control over financial reporting during this period.

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 Form 10-K for the fiscal year ended December 31, 2008 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.

None.

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Item 5. Other Information.

None.

Item 6. Exhibits.

10.1	Employment Agreement dated March 18, 2009 with Henry J. Fuchs, previously filed with the Commission on March 23, 2009 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated by reference.
10.2+	Development and Commercialization Agreement dated as of January 4, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.29 to the Company's Annual Report on Form 10-K, which is incorporated by reference.
10.3+	Securities Purchase Agreement dated as of January 4, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.30 to the Company's Annual Report on Form 10-K, which is incorporated by reference.
10.4	Amendment No. 1 to the Development and Commercialization Agreement dated as of January 16, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.31 to the Company's Annual Report on Form 10-K, which is incorporated by reference.
10.5	Amendment No. 1 to the Securities Purchase Agreement dated as of January 16, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.32 to the Company's Annual Report on Form 10-K, which is incorporated 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

\+ Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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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: May 1, 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

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* Filed herewith

\+ Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

CERTIFICATION

I, Jean-Jacques Bienaimé, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2009

/s/ JEAN-JACQUES BIENAIMÉ
Jean-Jacques Bienaimé
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Jeffrey H. Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2009

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc. (the "Company") for the quarter ended March 31, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Jean-Jacques Bienaimé and Jeffrey H. Cooper, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JEAN-JACQUES BIENAIMÉ
Jean-Jacques Bienaimé
Chief Executive Officer

May 1, 2009

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

May 1, 2009