

# BIOMARIN PHARMACEUTICAL INC

## FORM 10-Q (Quarterly Report)

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

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**Form 10-Q**

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

For the quarterly period ended September 30, 2008

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 000-26727

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**BioMarin Pharmaceutical Inc.**

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

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**Delaware**  
(State of other jurisdiction  
of Incorporation or organization)

**105 Digital Drive, Novato, California**  
(Address of principal executive offices)

**68-0397820**  
(I.R.S. Employer  
Identification No.)

**94949**  
(Zip Code)

**Registrant's telephone number: (415) 506-6700**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See 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       Smaller reporting company   
(Do not check if a smaller reporting company)

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

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

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

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 99,826,284 shares common stock, par value \$0.001, outstanding as of October 31, 2008.

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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, <u>2007 (1)</u>	September 30, <u>2008</u> (unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 228,343	\$ 271,217
Short-term investments	357,251	291,752
Accounts receivable, net	16,976	51,135
Advances to BioMarin/Genzyme LLC	2,087	206
Inventory	32,445	68,094
Other current assets	7,195	14,609
Total current assets	<u>644,297</u>	<u>697,013</u>
Investment in BioMarin/Genzyme LLC	44,881	343
Other investments	—	4,659
Property, plant and equipment, net	76,818	110,716
Intangible assets, net	9,596	6,068
Goodwill	21,262	21,262
Restricted cash	2,889	6,219
Other assets	15,536	12,758
Total assets	<u>\$ 815,279</u>	<u>\$ 859,038</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 49,907	\$ 47,982
Current portion of acquisition obligation, net of discount	6,309	71,158
Deferred revenue	5,327	1,443
Other current liabilities	—	152
Total current liabilities	<u>61,543</u>	<u>120,735</u>
Convertible debt	497,375	497,240
Long-term portion of acquisition obligation, net of discount	66,553	—
Other long-term liabilities	2,082	3,162
Total liabilities	<u>627,553</u>	<u>621,137</u>
Stockholders' equity:		
Common stock, \$0.001 par value: 250,000,000 shares authorized at December 31, 2007 and September 30, 2008; 97,114,159 and 99,691,581 shares issued and outstanding at December 31, 2007 and September 30, 2008, respectively	97	100
Additional paid-in capital	794,917	841,657
Company common stock held by deferred compensation plan	—	(936)
Accumulated other comprehensive income (loss)	139	(1,818)
Accumulated deficit	(607,427)	(601,102)
Total stockholders' equity	<u>187,726</u>	<u>237,901</u>
Total liabilities and stockholders' equity	<u>\$ 815,279</u>	<u>\$ 859,038</u>

(1) December 31, 2007 balances were derived from the audited consolidated financial statements.

See accompanying notes to unaudited consolidated financial statements.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**For the Three and Nine Months Ended September 30, 2007 and 2008**  
(In thousands, except for per share data, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2008	2007	2008
<b>Revenues:</b>				
Net product revenues	\$ 21,325	\$ 67,812	\$ 60,600	\$185,895
Collaborative agreement revenues	3,107	2,414	10,758	7,389
Royalty and license revenues	574	2,420	5,369	3,933
<b>Total revenues</b>	<b>25,006</b>	<b>72,646</b>	<b>76,727</b>	<b>197,217</b>
<b>Operating expenses:</b>				
Cost of sales	4,460	14,063	13,135	40,844
Research and development	17,241	26,175	54,585	67,559
Selling, general and administrative	19,521	28,964	53,075	77,836
Amortization of acquired intangible assets	1,093	1,093	3,278	3,278
<b>Total operating expenses</b>	<b>42,315</b>	<b>70,295</b>	<b>124,073</b>	<b>189,517</b>
Income (Loss) from operations	(17,309)	2,351	(47,346)	7,700
Equity in the income (loss) of BioMarin/Genzyme LLC	8,446	(572)	21,159	(1,692)
Interest income	7,948	3,407	18,549	13,157
Interest expense	(4,109)	(4,105)	(10,163)	(12,297)
Income (Loss) before income taxes	(5,024)	1,081	(17,801)	6,868
Provision for income taxes	192	252	572	543
Net income (loss)	\$ (5,216)	\$ 829	\$ (18,373)	\$ 6,325
Net income (loss) per share, basic	\$ (0.05)	\$ 0.01	\$ (0.19)	\$ 0.06
Net income (loss) per share, diluted	\$ (0.05)	\$ 0.01	\$ (0.19)	\$ 0.06
Weighted average common shares outstanding, basic	96,199	99,537	95,523	98,705
Weighted average common shares outstanding, diluted	96,199	103,403	95,523	103,916

See accompanying notes to unaudited consolidated financial statements.

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**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For the Nine Months Ended September 30, 2007 and 2008**  
**(In thousands, unaudited)**

	<u>Nine Months Ended September 30,</u>	
	<u>2007</u>	<u>2008</u>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (18,373)	\$ 6,325
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	9,941	12,874
Amortization of discount on short-term investments	(9,008)	(5,469)
Imputed interest on acquisition obligation	3,410	3,295
Equity in the (income) loss of BioMarin/Genzyme LLC	(21,159)	1,692
Stock-based compensation	13,871	20,108
Unrealized foreign exchange gain on forward contracts	(86)	(404)
Other	9	149
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,298)	(34,159)
Advances to BioMarin/Genzyme LLC	(357)	1,881
Inventory	(6,476)	(8,869)
Other current assets	(1,040)	(6,628)
Other assets	(1,999)	(2,286)
Accounts payable and accrued liabilities	451	947
Other liabilities	774	1,286
Deferred revenue	(5,202)	(3,884)
Net cash used in operating activities	<u>(36,542)</u>	<u>(13,142)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(12,476)	(44,445)
Maturities and sales of short-term investments	501,301	600,254
Purchase of short-term investments	(587,419)	(531,400)
Investments in BioMarin/Genzyme LLC	—	(600)
Distributions from BioMarin/Genzyme LLC	17,100	16,683
Investment Summit Corporation plc	—	(5,689)
Settlement of forward contracts	(565)	818
Net cash provided by (used in) investing activities	<u>(82,059)</u>	<u>35,621</u>
<b>Cash flows from financing activities:</b>		
Proceeds from ESPP and exercise of stock options	10,174	25,395
Net proceeds from convertible debt offering	316,340	—
Repayment of acquisition obligation	(5,250)	(5,000)
Net cash provided by financing activities	<u>321,264</u>	<u>20,395</u>
Net increase in cash and cash equivalents	<u>\$ 202,663</u>	<u>\$ 42,874</u>
Cash and cash equivalents:		
Beginning of period	<u>\$ 89,162</u>	<u>\$ 228,343</u>
End of period	<u>\$ 291,825</u>	<u>\$ 271,217</u>
<b>Supplemental cash flow disclosures:</b>		
Cash paid for interest	\$ 4,313	\$ 7,356
Cash paid for income taxes	430	248
Stock-based compensation capitalized into inventory	1,469	3,317
Depreciation capitalized into inventory	1,422	2,068
<b>Supplemental non-cash investing and financing activities disclosures:</b>		
Conversion of convertible notes	\$ 51,440	\$ 135
Distribution of inventory resulting from the joint venture restructure	—	26,780
Deferred offering costs reclassified to additional paid in capital as a result of convertible notes	512	4
Changes in accrued liabilities related to fixed assets	3,908	(2,871)
Equipment acquired through capital lease	—	456

See accompanying notes to unaudited consolidated financial statements.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2008**  
**(Unaudited)**

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

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

Through September 30, 2008, the Company had accumulated losses of approximately \$601.1 million. Management believes that the Company's cash, cash equivalents and short-term investments at September 30, 2008 will be sufficient to meet the Company's obligations for the foreseeable future based on management's current long-term business plans and assuming that the Company achieves its long-term goals. If the Company elects to increase its spending on development programs significantly above current long-term plans or enter into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance net future cash needs primarily through its current cash, cash equivalents and short-term investments, milestone payments from third parties, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners. In April 2007, the Company raised approximately \$316.4 million in net proceeds from a public offering of senior subordinated convertible debt due in 2017.

The Company is subject to a number of risks, including the financial performance of Naglazyme, Kuvan, and Aldurazyme; the potential need for additional financings; risks related to the manufacturing of its products; 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 and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. 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, 2007.

*(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.

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### *(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 records its investments in debt and equity securities as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investments are recorded at fair market value, with unrealized gains or losses being included in accumulated other comprehensive income/loss. Short-term investments are comprised mainly of corporate securities, commercial paper, U.S. federal government agency securities, U.S. treasury bills and money market funds. As of September 30, 2008, the Company had no held-to-maturity investments.

Other investments are comprised of 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 value are reported as a component of accumulated other comprehensive income, 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. Translation gains/losses on this 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*.

### *(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.

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

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

Stock-based compensation of \$1.3 million and \$3.3 million was capitalized into inventory for the three and nine months ended September 30, 2008, respectively, compared to \$0.5 million and \$1.5 million capitalized into inventory for the three and nine months ended September 30, 2007, respectively.

See Note 5 for further information on inventory balances as of December 31, 2007 and September 30, 2008.

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

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

### *(g) Property, Plant and Equipment*

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the related estimated useful lives, except for leasehold improvements, which are depreciated over the shorter of the useful life of the asset or the lease term. Significant additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Property and equipment purchased for specific research and development projects with no alternative uses are expensed as incurred. See Note 6 for further information on property, plant and equipment balances as of December 31, 2007 and September 30, 2008.

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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 from Aldurazyme, Naglazyme and Kuvan when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Product sales transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) related to Naglazyme sales in foreign jurisdictions, are presented on a net basis in the Company's statements of operations, in 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 revenue 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. 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 September 30, 2008, accounts receivable included \$13.1 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 European distributors or directly to hospitals, which act as the end-users. Additionally, the Company receives revenue from sales of Naglazyme in other countries, which are generally made to distributors or directly to hospitals. Because of the pricing of Naglazyme and Kuvan, the limited number of patients and the customers' limited return rights, Naglazyme and Kuvan customers and retailers generally carry a limited inventory. Accordingly, the Company expects the sales related to Naglazyme and Kuvan will be closely tied to end-user demand.

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

The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including market exclusivity of the products based on their orphan drug status, the patient population, the customers' limited return rights and the Company's experience with returns. 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 generally limited to defective product or product that does not meet applicable regulatory specification at the time of delivery. Based on these factors, management has concluded that product

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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 September 30, 2008, 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 estimates that its performance obligation related to the \$25.0 million up-front payment from Merck Serono will end in the fourth quarter of 2008. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related 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 three and nine months ended September 30, 2008 include \$1.5 million and \$4.5 million, respectively, of the up-front license fee received from Merck Serono recognized as revenue and \$0.9 million and \$2.9 million of reimbursable Kuvan development costs incurred during the three and nine months ended September 30, 2008, respectively. Collaborative agreement revenues during the three and nine months ended September 30, 2007 include \$1.7 million and \$5.3 million, respectively, of the up-front license fee received from Merck Serono recognized as revenue and \$1.4 million and \$5.5 million of reimbursable Kuvan development costs incurred during the three and nine months ended September 30, 2007, respectively. Amortization of the up-front license fee received from Merck Serono and recognized as revenue decreased during the third quarter and first nine months of 2008 compared to the same period in 2007 due primarily to the changes in the amortization period.

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

Royalty and license revenues include royalty revenues from Orapred product sold by Sciele Pharma, Inc. (Sciele), the sublicensee of the Orapred product line, of \$0.8 million and \$2.3 million for the three and nine months ended September 30, 2008, respectively. Royalty and license revenues for the three and nine months ended September 30, 2007, included \$0.4 million and \$1.2 million from Orapred products sold by Sciele. During the third quarter of 2008, the Company earned a \$1.5 million milestone payment related to the Japanese approval of Kuvan in July 2008. There is no cost of sales associated with the royalty and license revenues recorded during the periods and no related costs are expected in future periods.

The Company recognized the \$4.0 million milestone in the second quarter of 2007 as a result of the one year anniversary of the receipt of approval from the Food and Drug Administration (FDA) for the marketing application of Orapred ODT. Although the receipt of the \$4.0 million payment was based solely on the passage of time from the FDA approval, the Company did not recognize the payment during the twelve-month period following approval because the fee was not considered to be fixed or determinable until it became due and payable. In making this determination, management considered the extended one-year payment term, the related uncertain future product sales, and the Company's lack of experience with Sciele. 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.

### (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 receipt of goods or as services are performed. The accounting for amounts due under arrangements that include up-front payments and payments upon the completion of milestones are evaluated based on the nature of the underlying service and whether there is an alternative future use in other research and development projects. When non-refundable amounts are paid in advance of future services, the cost is capitalized and expensed as the services are performed. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the activities.

### (j) *Net Income (Loss) Per Share*

Basic net income (loss) per share is calculated by dividing net income/loss by the weighted average shares of common stock outstanding during the period. Diluted net income (loss) per share reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock; however, potential common equivalent shares are

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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. For the three and nine months ended September 30, 2007, such potential shares of common stock were excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Potentially dilutive securities for the three and nine months ended September 30, 2007 include (in thousands):

	September 30, 2007
Options to purchase common stock	11,626
Common stock issuable under convertible debt	26,361
Portion of acquisition obligation payable in common stock at the option of the Company	345
Potentially issuable common stock for ESPP purchases	379
Potentially issuable restricted stock	117
Total	<u>38,828</u>

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

	For the Three Months Ended September 30, 2008			For the Nine Months Ended September 30, 2008		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
<b>Basic Earnings Per Share:</b>						
Net Income	\$ 829	99,537	\$ 0.01	\$ 6,325	98,705	\$ 0.06
<b>Effect of dilutive shares:</b>						
Stock options using the treasury method		3,317			4,629	
Portion of acquisition obligation payable in common stock at the option of the Company		325			325	
Potentially issuable restricted stock		—			19	
Potentially issuable common stock for ESPP		190			204	
Company common stock held in the Deferred Compensation Plan	(29)	34		(29)	34	
<b>Diluted Earnings Per Share:</b>						
Net Income	<u>\$ 800</u>	<u>103,403</u>	<u>\$ 0.01</u>	<u>\$ 6,296</u>	<u>103,916</u>	<u>\$ 0.06</u>

In addition to the options included in the above table, options to purchase approximately 3.2 million and 1.7 million shares of common stock were outstanding during the three and nine months ended September 30, 2008, respectively, 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 26.3 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 both the three and nine months ended September 30, 2008 using the "if-converted" method whereby the related interest expense on the convertible debt is added to net income for the period.

### (k) Stock-Based Compensation

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

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

As stock-based compensation expense recognized in the consolidated 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 discussion of the Company's accounting for stock-based compensation.

### *(l) Income Taxes*

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred taxes are determined based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded to reduce deferred tax assets to the amount that is more likely than not to be realized. There was a full valuation allowance against net deferred tax assets of \$294.4 million at December 31, 2007. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease income in the period such adjustment was made. For the three and nine months ended September 30, 2008, the Company recognized \$0.3 million and \$0.5 million of income tax expense, respectively, related to income earned in the U.S. and certain of the Company's international subsidiaries, respectively, compared to \$0.2 million and \$0.6 million in the three and nine months ended September 30, 2007, respectively. The Company has recorded an insignificant amount of net current U.S. Federal and state income tax expense, primarily because the Company expects to utilize net operating loss carry forwards and research and development credits to offset most of its 2008 taxable income. However, the Company has not released any incremental valuation allowance against net deferred tax assets beyond the amount of deferred tax assets expected to be used for 2008 taxable income.

### *(m) Recent Accounting Pronouncements*

In December 2007, the FASB released SFAS No. 141(R), *Business Combinations*. This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which would impact the Company for business combinations completed after January 1, 2009. The objective of this Statement is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. The effect of this statement on the Company's consolidated financial position, results of operations or cash flows will depend on the potential future business combinations entered into by the Company that will be subject to the statement.

In December 2007, the FASB released SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51*. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, which for the Company is the year ending December 31, 2009, and the interim periods within that fiscal year. The Company does not expect the adoption of SFAS No. 160 to have a material effect on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, an amendment to SFAS No. 133 (SFAS No. 161), which changes the disclosure requirements for derivative instruments and hedging activities. SFAS No. 161 requires enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This statement's disclosure requirements are effective for the Company as of January 1, 2009. Because the statement only requires additional disclosures relating to the Company's derivative instruments, the adoption will not impact the Company's consolidated balance sheets, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles. SFAS No. 162 becomes effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to Statement on Auditing Standards No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*, for periods completed after January 1, 2009. The Company does not expect that the adoption of SFAS No. 162 to have a material effect on its consolidated financial statements.

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In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3), which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Asset*. FSP FAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. This Statement is effective for fiscal years beginning on or after December 15, 2008, which for the Company is the year ending December 31, 2009. The Company is currently evaluating the potential impact the adoption of FSP FAS 142-3 will have on its consolidated financial statements.

### (n) Accumulated Other Comprehensive Income (Loss)

Comprehensive income/loss includes net income/loss and certain changes in stockholders' equity that are excluded from net income/loss, such as changes in unrealized gains and losses on the Company's available-for-sale securities, unrealized gains and 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 third quarters or first nine months of 2007 or 2008.

Comprehensive loss was approximately \$0.4 million for the three months ended September 30, 2008 and comprehensive income was approximately \$4.4 million for the nine months ended September 30, 2008, compared to comprehensive loss of \$5.1 million and \$18.2 million for the three and nine months ended September 30, 2007, respectively. Comprehensive income (loss) included the following changes in accumulated other comprehensive income (loss) (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2008	2007	2008
Net unrealized gain (loss) on available-for-sale securities	\$ 34	\$ (1,792)	\$ 50	\$ (2,113)
Net unrealized loss on other investments	—	(1,030)	—	(1,030)
Net unrealized gain on foreign currency hedges	—	1,592	—	1,200
Net foreign currency translation gain (loss)	101	(12)	103	(14)
Other comprehensive income (loss)	<u>\$ 135</u>	<u>\$ (1,242)</u>	<u>\$ 153</u>	<u>\$ (1,957)</u>

### (o) Reclassifications and Adjustments

In the second quarter of 2008, the Company recorded an out of period adjustment to correct inventory and property, plant and equipment balances for sales taxes associated with purchases made between April 2007 and March 2008 that were erroneously expensed at the time of purchase. The correction reduced operating expenses by \$1.2 million during the second quarter of 2008. The amounts capitalized into inventory will be recognized into cost of goods sold as the inventory is sold and the amounts capitalized into property, plant and equipment will be depreciated over the assets' respective estimated useful lives. The Company determined that the impact of the adjustment was not material to prior periods or to the expected results for the year ended December 31, 2008, and as such the adjustment was recorded in the second quarter of 2008 under the provisions of Accounting Principles Board Opinion (APB) No. 28, *Interim Financial Reporting*. The adjustment did not affect the consolidated statement of operations for the three months ended September 30, 2008, and the adjustment increased net income for the nine months ended September 30, 2008 by \$0.8 million.

During the third quarter of 2008, the Company recorded a \$0.6 million reserve for an estimated value added tax (VAT) liability in Europe that resulted from professional tax advice received during the third quarter of 2008 that conflicted with professional tax advice received in 2006. The Company is continuing to evaluate the conflicting advice and possible mitigation strategies. The Company determined that the amounts that related to prior periods, which totaled \$0.5 million, were immaterial to all prior periods and therefore recognized the expense during the third quarter of 2008.

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. Readers should refer to Note 3 of the Company's consolidated financial statements in the Annual Report on Form 10-K for the fiscal year ended December 31, 2007, 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 September 30, 2008. 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 nine months of 2008, the Company granted approximately

2.8 million stock options under the 2006 Share Incentive Plan, with a weighted average fair value of \$37.98. The Company also granted approximately 63,000 options under the ESPP with a weighted average fair value of \$13.87 during the first nine months of 2008. 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 and nine months ended September 30, 2007 and 2008 are as follows:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2008	2007	2008
<b>Stock options:</b>				
Weighted average fair value of common stock	\$ 20.66	\$ 27.79	\$ 17.69	\$ 37.98
Expected life	5.5 years	5.6 years	5.2 - 5.5 years	5.2 - 5.6 years
Volatility	51%	45%	48 - 51%	45 - 47%
Risk-free interest rate	4.4%	3.1%	4.4 - 5.1%	2.8-3.2%
Dividend yield	0%	0%	0%	0%

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	Three and Nine Months Ended September 30,	
	2007	2008
<b>ESPP:</b>		
Fair market value of common stock	\$ 16.41	\$ 37.61
Expected life	6 – 24 months	6 – 24 months
Volatility	49.3%	47.4%
Risk-free interest rate	5.0%	1.7 – 2.4%
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 nine months ended September 30, 2007, the Company granted 116,625 RSUs with a weighted average fair market value of \$17.39 per share. During the nine months ended September 30, 2008, the Company granted 158,255 RSUs with a weighted average fair market value of \$38.45 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 September 30,		Nine Months Ended September 30,	
	2007	2008	2007	2008
Cost of sales	\$ 136	\$ 430	\$ 416	\$ 1,019
Selling, general and administrative expense	3,001	4,468	7,635	10,674
Research and development	1,864	2,501	4,767	6,118
Total stock-based compensation expense	<u>\$ 5,001</u>	<u>\$ 7,399</u>	<u>\$12,818</u>	<u>\$17,811</u>

Stock-based compensation of \$1.5 million and \$3.3 million was capitalized into inventory for the nine months ended September 30, 2007 and 2008, 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.

As of January 1, 2008, instead of sharing all costs and profits equally through the 50/50 joint venture, Genzyme records sales of Aldurazyme to third party customers and pays 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. 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 generally limited to defective product or product that does not meet applicable regulatory specification at the time of delivery. 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.

In the first quarter of 2008, BioMarin transferred inventory on-hand to Genzyme, resulting in the recognition of product transfer revenue of \$14.0 million. A portion of that inventory representing \$4.5 million of the related product transfer revenue was also sold by Genzyme during the first quarter of 2008, which resulted in a royalty due to the Company totaling \$14.6 million.

The Company presents the related cost of sales and its Aldurazyme-related operating expenses as operating expenses in the consolidated statements of operations. Equity in the income (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. The results of the joint venture's operations for the three and nine months ended September 30, 2007 and 2008 are presented in the table below (in thousands).

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2008	2007	2008
Net product sales	\$32,322	\$ —	\$88,270	\$ —
Cost of goods sold	6,894	—	19,778	—
Gross profit	25,428	—	68,492	—
Operating expenses	8,754	1,149	26,706	3,577
Income (loss) from operations	16,674	(1,149)	41,786	(3,577)
Other income	218	5	531	193
Net income (loss)	<u>\$16,892</u>	<u>\$(1,144)</u>	<u>\$42,317</u>	<u>\$(3,384)</u>
Equity in the income (loss) of BioMarin/Genzyme LLC	<u>\$ 8,446</u>	<u>\$ (572)</u>	<u>\$21,159</u>	<u>\$(1,692)</u>

At December 31, 2007 and September 30, 2008, the summarized assets and liabilities of the joint venture and the components of the Company's investment in the joint venture are as follows (in thousands):

	December 31, 2007	September 30, 2008
Assets	\$ 98,340	\$ 1,423
Liabilities	(8,577)	(736)
Net equity	\$ 89,763	\$ 687
Investment in BioMarin/Genzyme LLC (50% share of net equity)	<u>\$ 44,881</u>	<u>\$ 343</u>

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

### (5) SHORT-TERM INVESTMENTS

At December 31, 2007, the principal amounts of short-term investments by contractual maturity are summarized in the table below (in thousands).

	Contractual Maturity Date For the Years Ending December 31,			December 31, 2007	
	Total Book			Unrealized Gain (Loss)	Aggregate Fair Value
	2008	2009	Value		
Corporate securities	\$ 88,324	\$ —	\$ 88,324	\$ (99)	\$ 88,225
Commercial paper	259,067	—	259,067	155	259,222
U.S. Government treasuries	9,798	—	9,798	6	9,804
Total	<u>\$357,189</u>	<u>\$ —</u>	<u>\$357,189</u>	<u>\$ 62</u>	<u>\$ 357,251</u>

At September 30, 2008, the principal amounts of short-term investments by contractual maturity are summarized in the table below (in thousands).

	Contractual Maturity Date For the Years Ending December 31,			September 30, 2008	
	Total Book			Unrealized Gain (Loss)	Aggregate Fair Value
	2008	2009	Value		
Corporate securities	\$ 10,000	\$ 55,377	\$ 65,377	\$ (1,709)	\$ 63,668
Commercial paper	78,094	30,853	108,947	(118)	108,829
U.S. Government agency securities	46,810	50,635	97,445	(159)	97,286
U.S. Government treasuries	19,928	1,989	21,917	52	21,969
Total	<u>\$154,832</u>	<u>\$138,854</u>	<u>\$293,686</u>	<u>\$ (1,934)</u>	<u>\$ 291,752</u>

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The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of September 30, 2008. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized costs.

At September 30, 2008, the aggregate amounts of unrealized losses related to fair value of investments with unrealized losses were as follows (in thousands). All short-term investments were classified as available-for-sale at September 30, 2008.

	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
Corporate securities	\$ 63,668	\$ (1,709)	\$ —	\$ —	\$ 63,668	\$ (1,709)
Commercial paper	108,829	(118)	—	—	108,829	(118)
U.S. Government agency securities	50,462	(173)	—	—	50,462	(173)
Total	<u>\$ 222,959</u>	<u>\$ (2,000)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 222,959</u>	<u>\$ (2,000)</u>

At December 31, 2007, the aggregate amount of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands):

	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
Corporate securities	\$ 44,826	\$ (135)	\$ —	\$ —	\$ 44,826	\$ (135)
Commercial paper	4,948	(1)	—	—	4,948	(1)
Total	<u>\$ 49,774</u>	<u>\$ (136)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 49,774</u>	<u>\$ (136)</u>

## (6) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2007 and September 30, 2008, inventory consisted of the following (in thousands):

	December 31, 2007	September 30, 2008
Raw materials	\$ 5,695	\$ 10,632
Work in process	14,458	6,102
Finished goods	12,292	51,360
Total inventory	<u>\$ 32,445</u>	<u>\$ 68,094</u>

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As of December 31, 2007 and September 30, 2008, accounts payable and accrued liabilities consisted of the following (in thousands):

	<u>December 31, 2007</u>	<u>September 30, 2008</u>
Accounts payable	\$ 1,169	\$ 2,029
Accrued accounts payable	27,377	20,521
Accrued vacation	2,820	3,590
Accrued compensation	9,931	10,524
Accrued interest and taxes	2,533	2,901
Accrued royalties	1,329	3,166
Other accrued expenses	1,154	1,786
Accrued rebates	1,816	2,705
Acquired rebates and returns reserve	743	621
Short-term portion of deferred compensation liability	859	—
Other	176	139
Total accounts payable and accrued liabilities	<u>\$ 49,907</u>	<u>\$ 47,982</u>

As of December 31, 2007 and September 30, 2008, other long-term liabilities consisted of the following (in thousands):

	<u>December 31, 2007</u>	<u>September 30, 2008</u>
Long-term portion of deferred rent	\$ 1,635	\$ 253
Long-term portion of capital lease liability	—	1,205
Long-term portion of deferred compensation liability	447	1,704
Total other long-term liabilities	<u>\$ 2,082</u>	<u>\$ 3,162</u>

## (7) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2007 and September 30, 2008, consisted of (in thousands):

<u>Category</u>	<u>December 31,</u> <u>2007</u>	<u>September 30,</u> <u>2008</u>	<u>Estimated Useful Lives</u>
Leasehold improvements			Shorter of life of asset or
	\$ 33,583	\$ 27,198	lease term
Building and improvements	26,784	61,106	20 years
Manufacturing and laboratory equipment	19,403	26,083	5 years
Computer hardware and software	9,657	12,730	3 years
Office furniture and equipment	3,991	4,488	5 years
Land	4,259	10,056	Not applicable
Construction-in-progress	13,952	11,992	Not applicable
Gross property, plant and equipment	<u>\$ 111,629</u>	<u>\$ 153,653</u>	
Less: Accumulated depreciation	<u>(34,811)</u>	<u>(42,937)</u>	
Total property, plant and equipment, net	<u>\$ 76,818</u>	<u>\$ 110,716</u>	

Depreciation for the three and nine months ended September 30, 2008 was \$3.0 million and \$8.3 million, respectively, of which \$0.8 million and \$2.1 million was capitalized into inventory, respectively. Depreciation for the three and nine months ended September 30, 2007 was \$2.0 million and \$5.6 million, respectively, of which \$0.2 million and \$1.0 million was capitalized into inventory, respectively.

Capitalized interest related to the Company's property, plant and equipment purchases during the three and nine months ended September 30, 2007 and 2008 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.

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### **(8) 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 and \$0.6 million of amortization expense during the three and nine months ended September 30, 2008, respectively. Amortization expense was \$0.2 million and \$0.4 million during the three and nine months ended September 30, 2007.

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 and \$0.6 million of amortization expense during the three and nine months ended September 30, 2008, respectively. Amortization expense was \$0.2 million and \$0.6 million during the three and nine months ended September 30, 2007, respectively. During the first nine months of 2008, certain note holders voluntarily exchanged an insignificant number of convertible notes for shares of the Company's common stock.

Interest expense for the three and nine months ended September 30, 2008 was \$4.1 million and \$12.3 million, respectively, and each period included \$1.1 million and \$3.3 million, respectively, in imputed interest expense related to the Company's acquisition obligation. Interest expense for the three and nine months ended September 30, 2007 was \$4.1 million and \$10.2 million, respectively, and included \$1.1 million and \$3.4 million in imputed interest expense, respectively.

### **(9) DERIVATIVE FINANCIAL INSTRUMENTS**

#### *Foreign Currency and Other Hedging Instruments*

The Company follows the provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended. SFAS No. 133 establishes accounting and reporting standards for derivative instruments and hedging activities and requires the Company to recognize these as either assets or liabilities on the balance sheet and measure them at fair value. The accounting for gains and losses resulting from changes in fair value is dependent on the use of the derivative and whether it is designated and qualifies for hedge accounting.

#### *Economic and Accounting Hedging—Hedges of Forecasted Transactions*

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. These foreign exchange contracts have durations of six months or less and are entered into in the normal course of business; as such they are not speculative.

All hedging relationships are formally documented at the inception of the hedge and must meet the definition of highly effective in offsetting changes to future cash flows within the meaning of SFAS No. 133 to be a qualifying hedge. The effectiveness of the qualifying hedge contract, excluding the time value of money, is assessed quarterly using regression analysis. The Company records changes in the fair value of the derivative instruments designated as qualifying hedges of forecasted non-U.S. dollar revenue from product sales in other current assets and other current liabilities. Gains or losses resulting from changes in the fair value of qualifying hedges is initially reported as a component of accumulated other comprehensive income/loss in stockholders' equity, until the forecasted transaction occurs. When the forecasted transaction occurs this amount is reclassified into revenue. As of September 30, 2008, the Company expects the entire amount in other comprehensive income to be reclassified to earnings within twelve months. Any non-qualifying portion of the gains or losses resulting from changes in fair value, if any, is reported in the Company's consolidated statement of operations in operating expenses.

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In the event the underlying forecasted transaction does not occur, or it becomes remote that it will occur, the gain or loss on the related hedge is reclassified from accumulated other comprehensive income/loss to other income on the consolidated statement of income at that time. During the quarter, there were no such net gains or losses recognized.

As of September 30, 2008, the Company had open contracts totaling \$29.4 million that qualified for hedge accounting, \$1.2 million in other comprehensive income representing the anticipated gain to be reclassified to revenue over the next twelve months as the forecasted transactions occur. During both the three and nine months ended September 30, 2008, the Company recognized a net gain of \$0.3 million in revenue relating to hedged transactions which occurred. The ineffective portion of the gains or losses resulting from changes in fair value was insignificant. The loss representing time value excluded from the assessment of the hedge effectiveness was immaterial and is included in operating expense on the Company's consolidated statement of operations.

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.

### (10) FAIR VALUE MEASUREMENTS

In January 2008, the Company adopted SFAS No. 157, "Fair Value Measurements" for financial assets and liabilities. SFAS No. 157 utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. Level 1 involves observable inputs such as unadjusted quoted prices in active markets for identical assets or liabilities. Level 2 involves inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly, which include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active. Level 3 involves unobservable inputs that reflect the reporting entity's own assumptions. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income and equity securities, other equity securities and foreign currency derivatives. The table below presents the fair value of these certain financial assets and liabilities determined using the inputs defined at September 30, 2008, by SFAS No. 157.

In February 2008, the FASB issued FASB FSP 157-2, which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements at least annually, until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The partial adoption of SFAS No. 157 for financial assets and liabilities did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

	Fair Value Measurements (in thousands) at Reporting Date Using:			
	Total	Quoted Price in Active	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		Markets for Identical Assets (Level 1)		
<b>Assets:</b>				
Money market funds and overnight deposits <sup>(1)</sup>	\$ 256,113	\$ 15,104	\$ 241,009	\$ —
Corporate equity securities <sup>(2)</sup>	68,327	4,659	63,668	—
Government agency securities <sup>(2)</sup>	119,255	—	119,255	—
Commercial paper <sup>(2)</sup>	108,829	—	108,829	—
Foreign currency derivatives <sup>(3)</sup>	1,042	—	1,042	—
<b>Total</b>	<b>\$ 553,566</b>	<b>\$ 19,763</b>	<b>\$ 533,803</b>	<b>\$ —</b>

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

<sup>(2)</sup> 93% and 7% included in short-term investments and other investments, respectively, in the Company's consolidated balance sheet.

<sup>(3)</sup> Included in other current assets on the Company's consolidated balance sheet. Foreign currency derivatives include forward foreign exchange contracts for the Euro and British Pound.

### (11) 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 by region for the three and nine months ended September 30, 2007 and 2008.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2008	2007	2008
Region:				
United States	18%	58%	21%	56%
Europe	58%	24%	62%	26%
Latin America	9%	10%	6%	9%
Rest of World	15%	8%	11%	9%
Total Net Product Revenue	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

As of September 30, 2008, accounts receivable related to net product sales of Naglazyme and Kuvan and Aldurazyme product transfer and royalty revenues. On a consolidated basis, two customers accounted for 55% and 18% of the September 30, 2008, accounts receivable balance. The Company does not require collateral from its customers, but performs periodic credit evaluations of its customers' financial condition and requires immediate payment in certain circumstances.

### (12) INVESTMENT IN SUMMIT CORPORATION PLC

On July 21, 2008, the Company entered into an exclusive worldwide licensing agreement with Summit Corporation plc (Summit) related to Summit's preclinical candidate SMT C1100 and follow-on molecules, 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. The \$1.4 million paid in excess of the fair value of the shares acquired was allocated to the license fee and expensed under the provisions of SFAS No. 2, *Accounting for Research and Development Costs*, in the third quarter of 2008. The Company is also obligated to make future development and regulatory milestone payments totaling \$51.0 million based on future 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. Changes in the value of the investment which is a nonmonetary asset, arising from fluctuations in foreign exchange rates are included in accumulated other comprehensive income under the provisions of SFAS No. 52, *Foreign Currency Translation*.

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### 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, 2007 as well as those discussed elsewhere in this Form 10-Q. You should carefully consider that information before you make an investment decision.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and 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 sales for the third quarter and first nine months of 2007 totaled \$21.3 million and \$60.6 million, respectively, and increased to \$33.3 million and \$96.2 million in the third quarter and first nine months of 2008, 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 revenue for the third quarter and first nine months of 2008 totaled \$20.7 million and \$58.1 million, respectively.

Kuvan was granted marketing approval in the U.S. in December 2007. Kuvan net product sales for the third quarter and first nine months of 2008 were \$13.8 million and \$31.6 million, respectively.

We are developing PEG-PAL, an enzyme substitution therapy candidate for the treatment of PKU, for patients that are not responsive to Kuvan. In May 2008, we initiated a Phase 1 clinical trial of PEG-PAL in PKU patients. We expect to complete this 35 patient, open label study in the first half of 2009. 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 are developing 6R-BH4, the active ingredient in Kuvan, for the treatment of certain cardiovascular indications including peripheral arterial disease. We expect to release data from several 6R-BH4 trials in early 2009. We also have several preclinical product candidates including: GALNS for the treatment of Morquio Syndrome Type A (MPS IV A), a lysosomal storage disease, and a small molecule for the treatment of Duchenne muscular dystrophy.

Key components of our results of operations for the three and nine months ended September 30, 2007 and 2008, include the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2008	2007	2008
Total net product revenue	\$ 21,325	\$ 67,812	\$ 60,600	\$185,895
Research and development expense	17,241	26,175	54,585	67,559
Selling, general and administrative expense	19,521	28,964	53,075	77,836
Net income (loss)	(5,216)	829	(18,373)	6,325
Stock-based compensation expense	5,001	7,399	12,818	17,811

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See “*Results of Operations*” for a discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, and short-term investments totaled \$563.0 million as of September 30, 2008 compared to \$585.6 million as of December 31, 2007.

### Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates” in our Form 10-K for the year ended December 31, 2007. Additional information regarding updates to our policies for Aldurazyme Revenue Recognition are included below. Other than discussed below, there have been no significant changes to our critical accounting policies or estimates since December 31, 2007.

### Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin No. 104 (SAB 104): *Revenue Recognition*, and Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Our revenues consist of net product revenues from Naglazyme and Kuvan product sales during 2007 and 2008, Aldurazyme product transfer and royalty revenues starting January 1, 2008, revenues from our 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 we have no future performance obligations related to the payment.

We began recognizing revenue related to Aldurazyme in the first quarter of 2008 effective with the restructuring of our joint venture with Genzyme (see Note 4 to the accompanying consolidated financial statements for further information). According to the terms of the joint venture restructuring, we receive a 39.5 to 50% royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenue in the consolidated statements of operations. We recognize a portion of this amount as product transfer revenue when product is released to Genzyme and all of our obligations have been fulfilled at this point. Genzyme’s return rights for Aldurazyme are limited to defective product or product that does not meet applicable regulatory specifications at the time of delivery. 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 amount earned when the product is sold by Genzyme. We record the Aldurazyme royalty revenue based on net sales information provided by Genzyme and recognize product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with SAB 104 and the terms of the related agreements with Genzyme. In periods where BioMarin shipments of Aldurazyme to Genzyme exceed quantities sold to third parties by Genzyme, we will report incremental product transfer revenue. In periods where Genzyme sales to third parties exceed quantities released by BioMarin to Genzyme, we will report net product revenue representing the royalty from Genzyme related to current period sales by Genzyme less the previously recognized product transfer revenue related to the net decrease in Aldurazyme quantities at Genzyme.

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

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

### Recent Accounting Pronouncements

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

### Results of Operations

#### Net Income (Loss)

Our net income for the three and nine months ended September 30, 2008 was \$0.8 million and \$6.3 million, respectively, as compared to a net loss of \$5.2 million and \$18.4 million for the three and nine months ended September 30, 2007, respectively. Net income for the three and nine months ended September 30, 2008 increased \$6.0 million and \$24.7 million, respectively, primarily as a result of the following (in millions):

	Three Months Ended	Nine Months Ended
	September 30,	September 30,
Net loss for the period ended 2007	\$ (5.2)	\$ (18.4)
Increased Naglazyme gross profit	10.2	30.1
Increased Kuvan gross profit	13.6	29.3
Increased Aldurazyme gross profit	14.8	39.8
Increased research and development expense	(8.9)	(13.3)
Increased selling, general and administrative expenses	(8.8)	(24.7)
Increased losses from BioMarin/Genzyme LLC	(9.0)	(22.9)
Decreased collaborative agreement revenues	(0.7)	(3.4)
Absence of Orapred milestone revenue	—	(4.0)
Increased Orapred gross profit	0.4	1.1
Decreased interest income	(4.5)	(5.4)
Sales tax error correction recorded in Q2 2008	—	0.8
Increased interest expense	—	(2.1)
Estimated value added tax reserve	(0.6)	(0.6)
Other, net	(0.5)	—
Net income for the period ended 2008	<u>\$ 0.8</u>	<u>\$ 6.3</u>

The increase in Naglazyme gross profit during the third quarter and first nine months of 2008 as compared to the same periods of 2007 is the result of additional patients initiating Naglazyme therapy, primarily outside of the U.S., as well as the favorable impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. The increase in Kuvan gross profit during the third quarter and first nine months of 2008 as compared to the same periods in 2007 is due to the December 2007 marketing approval for Kuvan in the U.S. The increase in Aldurazyme gross profit during the third quarter and first nine months of 2008 as compared to the same periods of 2007 is the result of the restructuring of the joint venture with Genzyme and is partially offset by increased losses from BioMarin/Genzyme LLC, also due to the restructuring. The year-to-date decrease in collaborative agreement revenues primarily relates to lower reimbursable Kuvan development expenses. The increase in selling, general and administrative expense was primarily due to the continued international expansion of Naglazyme and commercialization of Kuvan in the U.S. The increase in research and development expense was primarily due to increases in development expenses for GALNS, a licensed product for the treatment of Duchenne Muscular Dystrophy, and other early stage programs. See below for additional information related to the primary net loss fluctuations presented above, including details of our operating expense fluctuations.

The sales tax error correction recorded during the second quarter of 2008 relates to the out of period adjustment to correct inventory and property, plant and equipment balances for sales taxes associated with purchases made between April 2007 and March 2008 that were erroneously expensed at the time of purchase. The correction of the error, which was discovered in May 2008, reduced operating expenses by \$1.2 million during the second quarter of 2008, and also increased net income for the period by the same amount. The adjustment reduced operating expenses for the six months ended June 30, 2008 by \$0.8 million and increased net income for the period by the same amount. The adjustment did not affect the consolidated statement of operations for the three months ended September 30, 2008, and increased net income during the nine months ended September 30, 2008 by \$0.8 million. We believe that the adjustment is immaterial to the results of operations for the second quarter of 2008 when considering the \$64.2 million of total revenues and \$59.6 million of total operating expenses that contributed to the net income for the second quarter of 2008. For similar reasons, we believe that it is immaterial for the nine months ended September 30, 2008. Further, we determined that the impact of the adjustment was not material to prior periods or to the expected results for the year ending

December 31, 2008, and as such the adjustment was recorded in the second quarter of 2008 under the provisions of Accounting Principles Board Opinion (APB) No. 28, Interim Financial Reporting.

During the third quarter of 2008, we recorded a \$0.6 million reserve for an estimated value added tax (VAT) liability in Europe that resulted from professional tax advice received during the third quarter of 2008 that conflicted with professional tax advice received in 2006. We are continuing to evaluate the conflicting advice and possible mitigation strategies. We determined that the amounts that related to prior periods, which totaled \$0.5 million, were immaterial to all prior periods and therefore recognized the expense during the third quarter of 2008.

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### Net Product Revenues and Gross Profit

The following table shows a comparison of net product revenues for the three and nine months ended September 30, 2007 and 2008 (in millions):

	Three Months Ended September 30,			Nine Month Ended September 30,		
	2007	2008	Change	2007	2008	Change
Naglazyme	\$ 21.3	\$ 33.3	\$ 12.0	\$ 60.6	\$ 96.2	\$ 35.6
Kuvan	—	13.8	13.8	—	31.6	31.6
Aldurazyme	—	20.7	20.7	—	58.1	58.1
Total Net Product Revenues	<u>\$ 21.3</u>	<u>\$ 67.8</u>	<u>\$ 46.5</u>	<u>\$ 60.6</u>	<u>\$ 185.9</u>	<u>\$ 125.3</u>

Net product revenues for Naglazyme in the third quarter of 2008 were \$33.3 million, of which \$28.2 million was from customers based outside of the U.S. The positive impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. was approximately \$1.1 million in the third quarter of 2008. Gross profit from Naglazyme in the third quarter of 2008 was approximately \$27.0 million, representing gross margins of approximately 81% as compared to \$16.9 million in the third quarter of 2007, representing gross margins of approximately 79%. The increase in gross margin is attributable to both foreign currency exchange benefits and improved manufacturing yields.

Net product revenues for Naglazyme in the first nine months of 2008 were \$96.2 million, of which \$80.8 million was from customers based outside of the U.S. The positive impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. was approximately \$4.9 million in the first nine months of 2008. Gross profit from Naglazyme in the first nine months of 2008 was approximately \$77.6 million, representing gross margins of approximately 81% as compared to \$47.5 million in the first nine months of 2007, representing gross margins of approximately 78%. The increase in gross margin is attributable to both foreign currency benefits and improved manufacturing yields.

Prior to the restructuring of BioMarin/Genzyme LLC effective January 2008, we did not record Aldurazyme revenue and instead recorded our share of the net profits from the joint venture. As a result of the restructuring of the joint venture, we record a 39.5 to 50% royalty on worldwide net product sales of Aldurazyme. In addition, we 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 that does not meet applicable regulatory specifications at the time of delivery. 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 revenues of \$20.7 million and \$58.1 million for the third quarter and first nine months of 2008 represent \$15.1 million and \$44.9 million of royalty revenue on net Aldurazyme sales by Genzyme, respectively. Royalty revenue from Genzyme is based on 39.5% of net Aldurazyme sales by Genzyme, which totaled \$38.2 million and \$113.7 million for the third quarter and first nine months of 2008, respectively. Incremental Aldurazyme net product transfer revenue of \$5.6 million and \$13.2 million for the third quarter and first nine months of 2008, respectively, reflect 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 the first nine months of 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 third quarter and first nine months of 2008, Aldurazyme gross profit was \$14.8 million and \$39.8 million, representing a gross margin of 71% and 69%, respectively, which primarily reflects the profit earned on royalty revenue and net product transfer revenue. Our Aldurazyme gross margins may fluctuate depending on the mix of royalty revenue, from which we earn higher gross profit, and product transfer revenue, from which we earn a lower gross profit.

We received marketing approval for Kuvan in the U.S. in December 2007 and began shipping product that same month. Net product sales for Kuvan in the third quarter and first nine months of 2008 were \$13.8 million and \$31.6 million, respectively, all of which were from customers based in the U.S. Gross profit from Kuvan in the third quarter and first nine months of 2008 was approximately \$12.0 million and \$27.7 million, respectively, representing gross margins of approximately 88% for each period, which 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, all of the product sold in the first nine months of 2008 had an insignificant cost basis. We expect that the majority of Kuvan through the first quarter of 2009 will be previously expensed product and will have a minimal cost basis. The cost of goods for Kuvan for the three and nine months ended September 30, 2008 is principally royalties paid to third parties based on Kuvan net sales.

Total cost of goods sold during the three and nine months ended September 30, 2008, were \$14.1 million and \$40.8 million, respectively, which increased significantly compared to \$4.5 million and \$13.1 million during the three and nine months ended September 30, 2007, respectively. The increase is primarily due to the increased net product revenues discussed above, as well as the restructuring of the joint venture with Genzyme, prior to which we did not recognize Aldurazyme net product revenues and the related cost of goods sold that were recognized by the joint venture.

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### *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. 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 2 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 third quarter and first nine months of 2008 were \$2.4 million and \$7.4 million, respectively, and include the amortization of \$1.5 million and \$4.5 million of the up-front license fee received from Merck Serono and recognized as revenue during each period, respectively, and \$0.9 million and \$2.9 million of reimbursable Kuvan development costs incurred during each period, respectively. Collaborative agreement revenues of \$3.1 million and \$10.8 million for the third quarter and first nine months of 2007, respectively, includes the amortization of \$1.7 million and \$5.3 million of the up-front license fee received from Serono and recognized as revenue during each period, respectively, and \$1.4 million and \$5.5 million of reimbursable Kuvan development costs incurred during each period, respectively. Reimbursable Kuvan development costs decreased during the third quarter and first nine months of 2008 compared to the same periods in 2007 due primarily to reductions in Kuvan clinical trial activities subsequent to the FDA approval received in December 2007. Amortization of the up-front license fee received from Merck Serono and recognized as revenue decreased during the third quarter and first nine months of 2008 compared to the same period in 2007 due primarily to the changes in the amortization period.

### *Royalty and License Revenues*

Royalty and license revenues in the third quarter and first nine months of 2008 were \$2.4 million and \$3.9 million, respectively, compared to \$0.6 million and \$5.4 million in the third quarter and first nine months of 2007, respectively. Royalty and license revenues during the third quarter of 2008, included royalty revenues from Orapred product sold by the sublicensee of \$0.8 million, Kuvan royalty revenues for products sold in Japan of \$0.1 million and a \$1.5 million milestone payment related to the Japanese approval of Kuvan in July 2008. Royalty and license revenues in the third quarter of 2007, included royalty revenues from Orapred product sold by the sublicensee of \$0.4 million and a \$4.0 million milestone payment related to the one-year anniversary of FDA approval of the marketing application for Orapred ODT. Royalty and license revenues in the first nine months of 2008 included \$0.1 million of Kuvan royalty revenue, a \$1.5 million one-time approval milestone related to the Japanese approval of Kuvan, and \$2.3 million in Orapred royalty revenue for product sold by the sublicensee, compared to the first nine months of 2007 that included \$1.2 million of Orapred royalty revenue and a \$4.0 million milestone payment related to the one-year anniversary of FDA approval of the marketing application for Orapred ODT.

### *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 \$9.0 million and \$13.0 million to \$26.2 million and \$67.6 million for the three and nine months ended September 30, 2008, respectively. Research and development expenses for the same periods in 2007 were \$17.2 million and \$54.6 million, respectively. The change in research and development expenses for the third quarter and first nine months of 2008 is primarily a result of the following (in millions):

	Three Months Ended	Nine Months Ended
	September 30,	September 30,
Research and development expenses for the period ended 2007	\$ 17.2	\$ 54.6
Increased GALNS for Morquio disease development expenses	3.7	7.8
Decreased Kuvan clinical trial and manufacturing costs	(1.1)	(6.1)
Increased stock-based compensation expense	0.6	1.1
Increased Aldurazyme development expenses	0.3	1.1
License payment related to collaboration with Summit Corporation plc	1.4	1.4
Increase in research and development expense on other early stage programs	1.0	4.6
Increased Naglazyme development costs	0.4	0.3
Decreased 6R-BH4 development costs for indications other than PKU	—	(0.6)
Increased (decreased) PEG-PAL development costs	0.9	(0.7)
Increase in non-allocated research and development expense and other net changes	1.8	4.1
Research and development expenses for the period ended 2008	<u>\$ 26.2</u>	<u>\$ 67.6</u>

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The decrease in year-to-date 6R-BH4 development costs is related to decreases in the ongoing pre-clinical study activities of 6R-BH4 in indications other than PKU, including indications associated with endothelial dysfunction, and costs related to conducting Phase 2 clinical trials in peripheral arterial disease and hypertension, offset by increases in spending related to sickle cell disease. The year-to-date decrease in PEG-PAL development costs is related to decreases in pre-clinical study activities and manufacturing costs. The increase in GALNS for Morquio disease development costs is related to increases in pre-clinical study activities and manufacturing costs. The decrease in Kuvan clinical trial and manufacturing costs is primarily due to decreased clinical trial and manufacturing expenses now that Kuvan has received regulatory approval in the U.S. However, we expect to continue incurring significant Kuvan research and development costs for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments. The increase in stock-based compensation expense is the result of an increased number of options outstanding due to increased headcount and a higher average stock price on the related grant date. The increase in research and development on other programs primarily includes increases in facilities costs, general research costs and research and development personnel. We expect research and development expense to increase in future periods, primarily as a result of spending on our development programs.

### *Selling, General and Administrative Expense*

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to administratively 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 fees and legal fees.

Selling, general and administrative expenses increased \$9.5 million and \$24.7 million, to \$29.0 million and \$77.8 million for the three and nine months ended September 30, 2008, respectively. Selling, general and administrative expenses for the same periods in 2007 were \$19.5 million and \$53.1 million, respectively. The components of the change for the third quarter and first nine months of 2008 primarily include the following (in millions):

	Three Months Ended	Nine Months Ended
	September 30,	September 30,
Selling, general and administrative expense for the period ended 2007	\$ 19.5	\$ 53.1
Increased Naglazyme sales and marketing expenses	3.0	7.7
Increased Kuvan commercialization expenses	2.7	8.8
Increased stock-based compensation expense	1.4	3.0
Net increase in corporate overhead and other administrative costs	2.4	5.2
Selling, general and administrative expense for the period ended 2008	<u>\$ 29.0</u>	<u>\$ 77.8</u>

Naglazyme sales and marketing expenses increased during the three and nine months ended September 30, 2008 primarily due to the expansion of our international commercial activities. We also incurred increased commercialization expenses related to Kuvan commercial launch. The increase in stock-based compensation expense is the result of an increased number of options outstanding due to increased headcount and a higher average stock price on the related grant date. The year-to-date increase in corporate overhead and other administrative costs is primarily related to increases in salaries and benefits due to growth in administrative headcount, consulting fees, travel, facilities and non-income tax expense. We expect selling, general and administrative expense to increase in future periods as a result of the international expansion of Naglazyme and the U.S. commercialization activities for Kuvan.

### *Amortization of Acquired Intangible Assets*

Amortization of acquired intangible assets includes the current amortization expense of the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology. The acquired intangible assets are being amortized over approximately 3.5 years and the amortization expense for the third quarter and first nine months of both 2007 and 2008 was \$1.1 million and \$3.3 million, respectively. Following our expected purchase of the common stock of Ascent Pediatrics from Medicis in August 2009, the underlying intellectual property will be transferred to Sciele. We expect that the annual amortization expense associated with the intangible assets will be approximately \$4.4 million in all of 2008 and \$2.9 million through the end of the expected useful life in August 2009.

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

Equity in the income (loss) of BioMarin/Genzyme LLC includes our 50% share of the joint venture's income or loss for the period. Effective January 2008, we and Genzyme restructured BioMarin/Genzyme LLC regarding the manufacturing, marketing and sale of Aldurazyme. Under the revised structure, the operational responsibilities for us and Genzyme did not significantly change, as Genzyme will continue to globally market and sell Aldurazyme and we will continue to manufacture Aldurazyme. 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, we 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.

As of January 1, 2008, instead of sharing all costs and profits equally through the 50/50 joint venture, BioMarin/Genzyme LLC's operations will consist primarily of certain research and development activities and intellectual property will continue to be managed in the joint venture with the costs shared equally by BioMarin and Genzyme. In the first quarter of 2008, we transferred inventory on-hand to Genzyme, resulting in the recognition of product transfer revenue of \$14.0 million. A portion of that inventory 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 us totaling \$14.6 million.

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Equity in the loss of BioMarin/Genzyme LLC was \$0.6 million and \$1.7 million for the three and nine months ended September 30, 2008, respectively, compared to equity in the income of BioMarin/Genzyme LLC of \$8.4 million and \$21.2 million for the three and nine months ended September 30, 2007, respectively. The decrease in profit from BioMarin/Genzyme LLC in the third quarter and first nine months of 2008 was due to the restructuring of the joint venture, whereby the joint venture no longer records the sales and related commercial operations of Aldurazyme. Under the restructured terms of the joint venture, BioMarin/Genzyme LLC incurred \$1.1 million and \$3.6 million of primarily clinical trial costs during the third quarter and first nine months of 2008, respectively.

Equity in the income of the joint venture was \$8.4 million and \$21.2 million for the third quarter and first nine months of 2007, respectively, and was primarily attributable to \$32.3 million and \$88.3 million of net product sales in the respective periods. Gross profit was \$25.4 million and \$68.5 million for the third quarter and first nine months of 2007, with gross margins approximating 78% in both periods. During the third quarter and first nine months of 2007, respectively, operating costs included the costs associated with the development and commercial support of Aldurazyme and totaled \$8.8 million and \$26.7 million, respectively. Operating expenses in the third quarter and first nine months of 2007, included \$5.5 million and \$17.9 million of selling, general and administrative expenses associated with the commercial efforts of Aldurazyme, respectively, and \$3.2 million and \$8.9 million of research and development expenses, primarily clinical trial costs, respectively.

### ***Interest Income***

We invest our cash and short-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income decreased to \$3.4 million for the third quarter of 2008, from \$7.9 million for the same period in 2007 and decreased to \$13.2 million for the first nine months of 2008, from \$18.5 million for the same period in 2007. The reduced interest yields during the third quarter and first nine months of 2008 were due to lower market interest rates and were partially offset by increased levels of cash and investments. We expect that interest income will decline in future quarters in 2008 as compared to 2007 due to reduced interest yields.

### ***Interest Expense***

We incur interest expense on our convertible debt. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction that occurred in May 2004. Interest expense for the three months ended September 30, 2007 and 2008 remained consistent at \$4.1 million while interest expense for the nine months ended September 30, 2008 increased \$2.1 million from \$10.2 million in 2007 to \$12.3 million in 2008. The increase in the first nine months of 2008 is primarily due to the April 2007 convertible debt issuance of approximately \$324.9 million of 1.875% Senior Subordinated Convertible Notes due in 2017.

Imputed interest expense totaled \$1.1 million and \$3.3 million for the third quarter and first nine months of 2008, respectively, compared to \$1.1 million and \$3.4 million for the third quarter and first nine months of 2007, respectively.

## **Changes in Financial Position**

### ***September 30, 2008 Compared to December 31, 2007***

From December 31, 2007 to September 30, 2008, our inventory increased by approximately \$35.6 million. The increase in inventory was primarily attributable to the distribution of Aldurazyme inventory from the joint venture and the capitalization of Kuvan inventory costs as a result of the FDA approval in December 2007. Our accounts receivable increased by \$34.2 million due to increased sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. In the first quarter of 2008, we received distributions of \$16.7 million of cash and \$26.8 million of inventory from BioMarin/Genzyme LLC as a result of the restructuring of the joint venture. Our net property, plant and equipment increased by approximately \$33.9 million from December 31, 2007 to September 30, 2008, primarily as a result of the purchase of our facility at 300 Bel Marin Keys, Novato, California, capital equipment and improvements to our other facilities, partially offset by depreciation expense during the period. We expect net property, plant and equipment to continue to increase in future periods, due to several ongoing facility improvement projects. Our total current liabilities increased by approximately \$59.2 million in the first nine months of 2008 primarily due to the reclassification of \$66.6 million due to Medicis from non-current acquisition obligation to current portion of acquisition obligation.

## **Liquidity and Capital Resources**

### ***Cash and Cash Flow***

As of September 30, 2008, our combined cash, cash equivalents and short-term investments totaled \$563.0 million, a decrease of \$22.6 million compared to \$585.6 million at December 31, 2007. During the nine months ended September 30, 2008, we financed our operations primarily through net product sales and available cash, cash equivalents and short-term investments and the related interest income earned thereon.

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The decrease in cash, cash equivalents and short-term investments during the first nine months of 2008 was \$22.6 million, which was \$4.2 million more than the net decrease in cash, cash equivalents and short-term investments during the first nine months of 2007 of \$18.4 million, excluding net offering proceeds of \$316.4 million. The primary items contributing to the decrease in net cash outflow in the first nine months of 2008 were as follows (in millions):

Net decrease in cash and short-term investments for the first nine months of 2007	\$(18.4)
Net decrease in operating spend	17.5
Increased capital asset purchases	(32.0)
Increased cash flows from BioMarin/Genzyme LLC	1.2
Investment in Summit Corporation plc	(5.7)
Cash received from settlement of foreign currency forward contracts	1.4
Increased proceeds from stock option exercises and ESPP	15.2
Other	(1.8)
Net decrease in cash and short-term investments for the first nine months of 2008	<u>\$(22.6)</u>

The decreased net operating spend includes increases in cash receipts from net revenues offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, as discussed in “*Results of Operations*” above. Increased capital asset purchases include the purchase of our facility at 300 Bel Marin Keys Drive, Novato, California. Increased cash flows from BioMarin/Genzyme LLC include the cash distribution resulting from the restructure of the joint venture of \$16.7 million. Net payments for working capital in the first nine months of 2008 include increased inventory build of \$2.4 million, which excluded the inventory distribution from the joint venture, and decreased accounts payable and accrued liabilities build of \$0.5 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.

Pursuant to our settlement of a dispute with Medicis in January 2005, Medicis made available to us a convertible note of up to \$25.0 million beginning July 1, 2005 based on certain terms and conditions and provided that we do not experience a change of control. Money advanced under the convertible note is convertible into our common stock, at Medicis’ option, according to the terms of the convertible note. As of September 30, 2008, we have not made any draws on the note. We do not anticipate that we will draw funds from this note.

### Funding Commitments

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

Our investment in our product development programs has a major impact on our operating performance. Our research and development expenses for the three and nine months ended September 30, 2007 and 2008 and for the period since inception (March 1997) include the following (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Program Inception
	2007	2008	2007	2008	
GALNS for Morquio disease	\$ 0.3	\$ 4.0	\$ 0.7	\$ 8.6	\$ 12.4
6R-BH4 for indications other than PKU, including indications associated with endothelial dysfunction	3.5	3.6	10.8	11.5	38.9
PEG-PAL	2.3	3.2	9.3	8.5	28.7
Not allocated to specific major current development stage projects	4.6	9.7	12.8	24.1	176.9
Total	<u>\$ 10.7</u>	<u>\$ 20.5</u>	<u>\$ 33.6</u>	<u>\$ 52.7</u>	<u>\$ 256.9</u>

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

Form 10-K “—If we fail to maintain regulatory approval to commercially market or sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating

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*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 timeframes we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline. “*

We may elect to increase our spending above our current long-term plans and may be unable to achieve our long-term goals. This could increase our capital requirements, including: costs associated with the commercialization of our products; additional clinical trials and the manufacturing of Naglazyme, Aldurazyme 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 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, 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 \$497.2 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 \$75.1 million through 2009, of which \$1.5 million is payable during the remainder of 2008. At our option, we may elect to pay Medicis \$8.6 million of the amounts due in 2009 through the issuance of our common stock.

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of September 30, 2008 is presented below (in thousands).

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	Payments Due by Period					Total
	Remainder of 2008	2009	2010-2011	2012-2013	2014 and Thereafter	
Medicis obligations	\$ 1,500	\$73,600	\$ —	\$ —	\$ —	\$ 75,100
Convertible debt and related interest	3,046	10,404	20,808	191,077	346,195	571,530
Operating leases	835	3,534	6,868	4,783	40	16,060
Research and development and purchase commitments	9,865	7,048	5,785	2,213	2,526	27,437
Total	<u>\$ 15,246</u>	<u>\$94,586</u>	<u>\$33,461</u>	<u>\$198,073</u>	<u>\$348,761</u>	<u>\$690,127</u>

We are also subject to contingent payments related to various development activities totaling \$113.2 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

Other than those discussed below, our market risks at September 30, 2008 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007.

#### *Foreign Currency Hedging Instruments*

We transact business in various foreign currencies, primarily in certain European countries. Accordingly, we are subject to exposure from movements in foreign currency exchange rates, primarily related to Euro and British Pound revenue from sales of our products in Europe. Our operating expenses in the United Kingdom and other European countries are in British Pounds and Euros, respectively. Both serve to mitigate a portion of the exposure related to the above-mentioned revenue in both markets.

We hedge a portion of our net position in assets and liabilities denominated in Euros and British Pounds using primarily forward contracts. We also hedge a percentage of our forecasted international revenue with forward contracts. Our hedging policy is designed to reduce the impact of foreign currency exchange rate movements.

In the second quarter of 2008, we commenced hedging a portion of our forecasted Euro-based revenue to help mitigate short term exposure to fluctuations of the currency by entering foreign exchange forward rate contracts. These contracts have maturities of less than 12 months.

Our hedging programs are expected to reduce, but do not entirely eliminate, the short-term impact of currency exchange rate movements in operating expenses. As of September 30, 2008, we had foreign currency forward contracts to sell approximately \$45.3 million in Euros and \$7.4 million in British Pounds. As of September 30, 2008, our outstanding foreign currency forward contracts had a fair value of \$1.0 million, which is included in other current assets.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exposure in a manner that entirely offsets the effects of changes in foreign exchange rates. The counterparty to these forward contracts is a creditworthy multinational commercial bank, which minimizes the risk of counterparty nonperformance. We currently do not use financial instruments to hedge local currency operating expenses in Europe. Instead, we believe that a natural hedge exists, in that local currency revenue substantially offsets the local currency operating expenses. We regularly review our hedging program and may, as part of this review, make changes to the program.

Based on our overall currency rate exposures at September 30, 2008, we expect that a near-term 10% fluctuation of the U.S. dollar could result in the potential change in the fair value of our foreign currency sensitive assets and investments by approximately \$2.9 million. We expect to enter into new transactions based in foreign currencies that could be impacted by changes in exchange rates.

### Item 4. Controls and Procedures

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

Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls are 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 Securities and Exchange Commission's rules and instructions for Form 10-Q. There was no change in our internal control over financial reporting that occurred during the period covered by this Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

As discussed in our Form 10-Q for the quarters ended March 31, 2008 and June 30, 2008, in April 2008, the U.S. Environmental Protection Agency (EPA) notified us that it intends to file an administrative complaint against us for certain violations of the Clean Water Act. Specifically, over the last several years, on numerous instances, the pH level of the waste water discharged into the City of Novato sanitary sewer was outside of the levels specified in our waste water discharge permit. These excursions were all very short in duration and small in quantity. On January 31, 2008, we completed construction of a pH neutralization system to avoid future excursions. On September 3, 2008, we finalized a settlement agreement with the EPA for approximately \$120,000 and agreed to support an unrelated wetland restoration project.

**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, 2007 and Part II, Item 1A of our Form 10-Q for the quarters ended March 31 and June 30, 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.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

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

\* Filed herewith

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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: November 7, 2008

By /s/ JEFFREY H. COOPER

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

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**Exhibit Index**

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

\* Filed herewith

**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: November 7, 2008

/s/ JEAN-JACQUES BIENAIMÉ

Jean-Jacques Bienaimé  
Chief Executive Officer

**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: November 7, 2008

/s/ JEFFREY H. COOPER

Jeffrey H. Cooper  
Senior Vice President, Chief Financial Officer

**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 September 30, 2008, 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

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Jean-Jacques Bienaimé  
Chief Executive Officer

November 7, 2008

/s/ JEFFREY H. COOPER

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Jeffrey H. Cooper  
Senior Vice President, Chief Financial Officer

November 7, 2008