BIOMARIN PHARMACEUTICAL INC
Form 10-Q
November 05, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2007

Or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to_____.

Commission file number: 000-26727

BioMarin Pharmaceutical Inc.

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

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

Registrant s telephone number: (415) 506-6700

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

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

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

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

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

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

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

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 96,817,004 shares common stock, par value $0.001, outstanding as of October 26, 2007.

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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, 2006 (1)	September 30, 2007 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 89,162	$ 291,825
Short-term investments	199,685	294,861
Accounts receivable, net	14,670	15,968
Advances to BioMarin/Genzyme LLC	1,596	1,953
Inventory	25,075	31,551
Other current assets	4,036	5,076
Total current assets	334,224	641,234
Investment in BioMarin/Genzyme LLC	31,457	35,516
Property, plant and equipment, net	55,466	66,249
Acquired intangible assets, net	11,655	8,377
Goodwill	21,262	21,262
Restricted cash	1,731	3,632
Other assets	7,641	14,786
Total assets	$ 463,436	$ 791,056
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 32,166	$ 35,874
Current portion of acquisition obligation, net of discount	6,787	6,549
Current portion of deferred revenue	7,092	6,639
Total current liabilities	46,045	49,062
Convertible debt	223,940	497,375
Long-term portion of acquisition obligation, net of discount	68,548	66,946
Deferred revenue, net of current portion	5,023	274
Other long-term liabilities	2,078	2,854
Total liabilities	345,634	616,511
Stockholders equity:		
Common stock, $0.001 par value: 150,000,000 and 250,000,000 shares authorized at December 31, 2006 and September 30, 2007, respectively; 91,725,528 and 96,644,549 shares issued and outstanding at December 31, 2006 and September 30, 2007, respectively	92	97
Additional paid-in capital	709,359	784,317
Accumulated other comprehensive loss	(25)	128

Accumulated deficit	(591,624)	(609,997)
Total stockholders equity	117,802	174,545
Total liabilities and stockholders equity	$ 463,436	$ 791,056

(1) December 31, 2006 balances were derived from the audited consolidated financial statements.

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

For the Three and Nine Months Ended, September 30, 2006 and 2007

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2007	2006	2007
Revenues:				
Net product sales	$ 14,660	$ 21,325	$ 33,297	$ 60,600
Collaborative agreement revenues	4,908	3,107	13,857	10,758
Royalty and license revenues	5,359	574	15,036	5,369
Total revenues	24,927	25,006	62,190	76,727
Operating expenses:				
Cost of sales	2,612	4,460	5,124	13,135
Research and development	18,105	17,241	46,163	54,585
Selling, general and administrative	12,292	19,713	35,059	53,647
Amortization of acquired intangible assets	1,093	1,093	2,558	3,278
Total operating expenses	34,102	42,507	88,904	124,645
Loss from operations	(9,175)	(17,501)	(26,714)	(47,918)
Equity in the income of BioMarin/Genzyme LLC	5,059	8,446	13,604	21,159
Interest income	4,003	7,948	8,738	18,549
Interest expense	(3,608)	(4,109)	(10,455)	(10,163)
Debt conversion expense	(3,315)		(3,315)	
Net loss	$ (7,036)	$ (5,216)	$ (18,142)	$ (18,373)
Net loss per share, basic and diluted	$ (0.08)	$ (0.05)	$ (0.22)	$ (0.19)
Weighted average common shares outstanding, basic and diluted	86,269	96,199	82,232	95,523

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2006 and 2007

(In thousands, unaudited)

	Nine Months Ended September 30,	
	2006	2007
Cash flows from operating activities		
Net loss	$ (18,142)	$ (18,373)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,397	9,838
Amortization of discount on short-term investments	(336)	(9,008)
Imputed interest on acquisition obligation	3,530	3,410
Loss on disposals of property and equipment		9
Equity in the income of BioMarin/Genzyme LLC	(13,604)	(21,159)
Stock-based compensation	7,366	13,871
Changes in operating assets and liabilities:		
Accounts receivable	(7,140)	(1,298)
Advances to BioMarin/Genzyme LLC	(490)	(357)
Inventory	(14,864)	(6,476)
Other current assets	(1,823)	(1,040)
Other assets	(1,074)	(1,999)
Accounts payable and accrued liabilities	7,679	451
Other liabilities	(5,029)	774
Deferred revenue	(5,883)	(5,202)
Net cash used in operating activities	(40,413)	(36,559)
Cash flows from investing activities		
Purchase of property, plant and equipment	(20,647)	(12,476)
Sale of short-term investments	24,906	501,301
Purchase of short-term investments	(116,988)	(587,419)
Distributions from BioMarin/Genzyme LLC	12,000	17,100
Net settlement of foreign currency forward contracts		(651)
Net cash used in investing activities	(100,729)	(82,145)
Cash flows from financing activities		
Proceeds from ESPP and exercise of stock options	10,240	10,174
Decrease in cash balances related to long-term debt	17,049	
Repayment of equipment and facility loans	(20,909)	
Repayment of acquisition obligation	(5,950)	(5,250)
Proceeds from public offering of common stock, net	127,431	
Proceeds from convertible debt offering, net	166,979	316,340
Net cash provided by financing activities	294,840	321,264
Effect of foreign currency translation on cash	(8)	103
Net increase in cash	153,690	202,663

Cash and cash equivalents:		
Beginning of period	38,092	89,162
End of period	$ 191,782	$ 291,825

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2007

(Unaudited)

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin received marketing approval for Naglazyme® (galsulfase) in the U.S. in May 2005, and in the E.U. in January 2006. Aldurazyme® (laronidase) has been approved in the U.S and E.U. and is marketed by its joint venture partner, Genzyme Corporation (Genzyme). In May 2004, BioMarin acquired the Ascent Pediatrics business, for which, in March 2006, BioMarin sublicensed the North American rights to Alliant Pharmaceuticals, Inc., which was recently acquired by Sciele Pharma, Inc. (Sciele). The May 2004 transaction included the exclusive marketing and development rights to Orapred® (prednisolone sodium phosphate oral solution). See Note 4 for further discussion of the sublicense in 2006. The Company is incorporated in the state of Delaware.

Through September 30, 2007, the Company had accumulated losses of approximately $610.0 million. Management believes that the Company s cash, cash equivalents and short-term investments at September 30, 2007 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 invest in new technologies or other business development activities, the Company may need additional capital. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance net future cash needs primarily through its current cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners. In April 2007, the Company raised approximately $316.3 million in net proceeds from a public offering of senior subordinated convertible debt due in 2017. The proceeds are intended to fund future business development transactions and for general corporate purposes.

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

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

Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. These consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2006, included in the Company s Annual Report on Form 10-K.

(b) Use of Estimates

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

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(Unaudited)

(c) Inventory

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

Regulatory approval for Naglazyme was received in the U.S. in May 2005, and costs related to the manufacturing of Naglazyme 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 Naglazyme prior to regulatory approval were not capitalized as inventory. When regulatory approval was obtained in the U.S. in May 2005, the Company began capitalizing Naglazyme inventory at the lower of cost or fair market value. As of September 30, 2007, Naglazyme inventory includes a small amount of pre-approval manufactured finished goods, which have an insignificant cost basis. The majority of the previously expensed inventory has been sold or used in clinical trials as of September 30, 2007. Stock-based compensation of $0.5 million and $1.5 million was capitalized into Naglazyme inventory in three and nine months ended September 30, 2007, respectively, compared to $0.2 million and $0.9 million of stock-based compensation being capitalized into Naglazyme inventory in the three and nine months ended September 30, 2006, respectively. See Note 7 for further information on inventory balances as of December 31, 2006 and September 30, 2007.

(d) Goodwill, Acquired Intangible Assets and Impairment of Long-Lived Assets

The Company records goodwill in a business combination when the total consideration exceeds the fair value of the net tangible and identifiable intangible assets acquired. In accordance with Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets* , goodwill and intangible assets with indefinite lives are not amortized. Intangible assets with definite lives are amortized over their useful lives on a straight-line basis.

The Company reviews long-lived assets for impairment annually and whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. If it is determined that the full carrying amount of an asset is not recoverable, an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. See Note 5 for further discussion of the Company s intangible asset and goodwill impairment analyses.

The Company currently operates in one business segment, the biopharmaceutical development and commercialization segment. When reviewing goodwill for impairment, SFAS No. 142 requires that the Company assess whether goodwill should be allocated to operating levels lower than its single operating segment for which discrete financial information is available and reviewed for decision-making purposes. These lower levels are referred to as reporting units. As of September 30, 2007, the Company has only one reporting unit. The Company performs an annual impairment test in the fourth quarter of each fiscal year by assessing the fair value and recoverability of its goodwill, unless facts and circumstances warrant a review of goodwill for impairment before that time. No triggering events were identified during the first nine months of 2007. The Company determines the fair value of its reporting units using a combination of discounted cash flow models, quoted market prices when available and independent appraisals.

The recoverability of the carrying value of buildings and leasehold improvements for the Company s facilities will depend on the successful execution of the Company s business plan and the Company s ability to earn sufficient returns on its approved products and product candidates. Based on management s current estimates, the Company expects to recover the carrying value of such assets.

(e) Revenue Recognition

The Company recognizes revenue in accordance with the provisions of SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, and Emerging Issues Task Force Issue (EITF) No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*.

The Company s revenues consist of Naglazyme product sales, Orapred product sales through March 2006, revenues from its collaborative agreement with Merck Serono and revenues from its sublicense agreement with Sciele for North American Orapred rights (see Note 4). All Aldurazyme sales are reported by BioMarin/Genzyme LLC and are included in the results of the joint venture (see Note 6).

Naglazyme product sales The Company recognizes revenue from Naglazyme 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. Naglazyme product sales transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from

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September 30, 2007

(Unaudited)

customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company s statements of operations, in that taxes billed to customers are not included as a component of net product sales, as per EITF No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* .

In the U.S., Naglazyme is generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. In the E.U., Naglazyme is generally sold to the Company s authorized European distributors or directly to hospitals, which act as the end users. Additionally, the Company receives revenue from named patient sales of Naglazyme in other countries, which are generally made to local distributors. Because of the pricing of Naglazyme, the limited number of patients and the customers limited return rights, Naglazyme customers and retailers generally carry a very limited amount of inventory. Accordingly, the Company expects that sales related to Naglazyme 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 Naglazyme 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 of Naglazyme is required, including market exclusivity of the product based on its orphan drug status, the patient population, the customers limited return rights and the Company s joint venture s experience of returns for Aldurazyme, which is a similar product. Based on these factors, management has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required. The Company maintains a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of its Naglazyme customers to make required payments. As of September 30, 2007, the Company has experienced no bad debts and had no allowance for doubtful accounts.

Orapred product sales The Company does not expect to report Orapred product sales in future periods because of the sublicense of North American rights to the product to Sciele in March 2006. The Company recognized revenue from Orapred product sales when persuasive evidence of an arrangement existed, the product had been shipped, title and risk of loss passed to the customer, the price to the buyer was fixed or determinable and collection from the customer was reasonably assured. Orapred product sales transactions were evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

The Company established and maintained rebate reserves for amounts payable to managed care organizations and state Medicaid programs for the reimbursement of a portion of the retail price of prescriptions filled that are covered by the respective plans. The amounts estimated to be paid relating to products sold are recognized as revenue reductions and as additions to accrued expenses at the time of the original sale. The rebate reserves were generally based on the Company s best estimate of the expected prescription fill rate to these managed care organizations and state Medicaid patients. The estimates were developed using the product s rebate history adjusted to reflect known and forecasted changes in the factors that impact such reserves. During the first nine months of 2006, the Company reduced its Orapred rebate reserves, which increased net revenues by $1.3 million for rebates related to product sold by the Company. The reduction was due to the sublicense of North American Orapred rights to Sciele, which reduced the Company s liability for certain rebates. No significant adjustments were made in the three or nine months ended September 30, 2007.

Provisions for sales discounts and estimates for chargebacks and product returns were established as a reduction of product sales at the time such revenues were recognized. These revenue reductions were established by the Company s management as its best estimate at the time of the original sale based on the product s historical experience adjusted to reflect known and forecasted changes in the factors that impact such reserves. These revenue reductions were generally reflected either as a direct reduction to gross sales and accounts receivable through an

allowance or as an addition to accrued expenses. The Company generally permits product returns only if the product is damaged or if it is returned near or after expiration. During the third quarter of 2006, the Company adjusted estimates of return liabilities primarily due to retail product demand realized in excess of previous estimates and the early settlement of product returns with a customer for an amount less than the previous estimate. This adjustment resulted in reserve reductions of approximately $1.0 million, which was recorded as an increase in revenue of $0.7 million for returns of product sold by the Company and $0.3 million of reduced expense for returns of product sold by the previous owner.

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Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue. Nonrefundable up-front license fees where the Company has continuing involvement through research and development collaboration are initially deferred and recognized as collaborative agreement license revenue over the estimated period for which the Company continues to have a performance obligation. The Company estimates that its performance obligation related to the $25.0 million upfront payment from Merck Serono will end in the fourth quarter of 2008. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono s share of Kuvan (sapropterin dihydrochloride) 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, 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, respectively. Collaborative agreement revenues during the three and nine months ended September 30, 2006 include $1.8 million and $5.6 million, respectively, of the up-front license fee received from Merck Serono recognized as revenue and $3.1 million and $8.3 million of reimbursable Kuvan development costs incurred during the three and nine months ended September 30, 2006, respectively.

Royalty and license revenues Royalty revenue is recognized based on sublicensee sales of Orapred liquid and Orapred ODT (Oral Disintegrating Tablets) subsequent to the execution of the sublicense of Orapred North American rights in March 2006. 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.

The timing of customer purchases and the resulting product shipments have a significant impact on the amount of royalty revenue that the Company recognizes in a particular period. The majority of Orapred sales are made to wholesalers, which, in turn, resell the product to retail outlets. Inventory in the distribution channel consists of inventory held by wholesalers, who are the principal customers for Orapred, and inventory held by retailers. Royalty revenues from Orapred sales in a particular period will be impacted by increases or decreases in wholesaler inventory levels. If wholesaler inventories substantially exceed retail demand, the Company could experience reduced royalty revenue from sales in subsequent periods.

The up-front license fee of $2.5 million received from Sciele in March 2006 was deferred and was recognized as revenue on a straight-line basis over approximately 5 months, which represented the best estimate of the time from inception of the agreement until commercial launch of Orapred ODT in August 2006, at which point the Company s performance obligations ended. Royalty and license revenues include royalty revenues from Orapred product sold by the sublicensee of $0.4 million and $1.2 million for the three and nine months ended September 30, 2007, respectively, and was $0.8 million and $0.9 million for the three and nine months ended September 30, 2006, respectively. Royalty and license revenue during the three and nine months ended September 30, 2006 also includes $0.6 million and $2.5 million of the up-front license fee received from Sciele that was recognized as revenue, respectively. There are 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 $4.0 million in milestone revenue during the second quarter of 2007 as a result of the one-year anniversary of FDA approval for the marketing application of Orapred ODT, and recognized $7.5 million in the second quarter of 2006 related to the initial FDA approval, which was received in June 2006. The Company recognized $4.0 million in milestone revenue during the third quarter of 2006 as a result of the sublicensee s commercial launch of Orapred ODT. 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.

(f) 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 generally expensed upon the earlier of when non-refundable amounts are due or as services are performed, unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the activities.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

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September 30, 2007

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

(g) Net Loss Per Share

Net loss per share is calculated by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing net loss by the weighted average shares of common stock outstanding and potential shares of common stock during the period. Potential shares of common stock include dilutive shares issuable upon the exercise of outstanding common stock options, contingent issuances of common stock related to convertible debt, acquisition payable and purchases under the Employee Stock Purchase Plan. For all periods presented, 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 include (in thousands):

	September 30,	
	2006	2007
Options to purchase common stock	8,354	11,626
Common stock issuable under convertible debt	14,075	26,361
Portion of acquisition payable in common stock at the option of the Company	604	345
Restricted share units		117
Potentially issuable common stock for ESPP purchases	549	379
Total	23,582	38,828

(h) 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, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating future stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and results of operations could be materially impacted.

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

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

(i) Derivative Instruments

The Company utilizes derivative financial instruments, including foreign exchange forward contracts, to manage its exposure to foreign currency exchange rate fluctuation risks. The Company does not hold or issue financial instruments for speculative or trading purposes, but rather for the intent of economic hedging.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

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(Unaudited)

The Company has transactions denominated in foreign currencies and, as a result, is exposed to changes in foreign currency exchange rates. The Company manages some of these exposures on a consolidated basis, which results in the netting of certain exposures to take advantage of natural offsets. Forward exchange contracts are used to hedge a portion of the net exposures. Gains or losses on net foreign currency hedges are intended to offset losses or gains on the underlying net exposures in an effort to reduce the earnings and cash flow volatility resulting from fluctuating foreign currency exchange rates. The resulting losses or gains from these instruments are included as a component of selling, general and administrative expenses on the Company s consolidated statements of operations. See Note 10 for further discussion of the Company s derivative instruments.

(j) Fair Value of Financial Instruments

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

The carrying amounts of all cash equivalents and forward exchange contracts approximate fair value based upon quoted market prices. The fair value of trade accounts receivable, accounts payable and other financial instruments approximates carrying value due to their short-term nature.

(k) Comprehensive Loss and Accumulated Other Comprehensive Loss

Comprehensive loss was approximately $5.1 million and $18.2 million for the three and nine months ended September 30, 2007, respectively, and included $0.1 million and $0.2 million of other comprehensive income in each of those periods, respectively. Comprehensive loss was approximately $7.0 million and $18.2 million for the three and nine months ended September 30, 2006, respectively, and included $25,000 of other comprehensive income and $8,000 of other comprehensive loss during the periods, respectively. Other comprehensive income/loss includes unrealized gains and losses on short-term investments designated as available-for-sale and foreign currency translation adjustments, of which each were individually insignificant for the periods presented. There were no tax effects related to any components of other comprehensive income during the three and nine months ended September 30, 2006 and 2007.

Comprehensive loss was approximately $187.8 million, $73.9 million, $28.5 million for the years ended December 31, 2004, 2005 and 2006, respectively, and included $0.3 million of other comprehensive loss, $0.3 million of other comprehensive income and $9,000 of other comprehensive loss, respectively. Other comprehensive income/loss includes unrealized gains and losses on short-term investments designated as available-for-sale and foreign currency translation adjustments. There were no tax effects related to any components of other comprehensive income/loss during the years ended December 31, 2004, 2005 and 2006.

(l) Restricted Cash

Restricted cash of $1.7 million and $3.6 million as of December 31, 2006 and September 30, 2007, respectively, includes $0.9 million and $2.4 million related to cash received for royalties pursuant to the Orapred sublicense agreement, respectively, which are restricted until August 2009, upon the stock purchase of Ascent Pediatrics from Medicis (see Note 4). Restricted cash also includes investments of $0.8 million and $1.2 million held by the Company s Nonqualified Deferred Compensation Plan as of December 31, 2006 and September 30, 2007, respectively (see Note 13).

(m) Other Significant Accounting Policies

For all other significant accounting policies, please refer to the Company s Annual Report on Form 10-K for the year ended December 31, 2006.

(n) Recent Accounting Pronouncements

In June 2007, the Financial Accounting Standards Board (FASB) ratified the EITF consensus reached in EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which provides guidance for prepayments for goods or services that will be used or rendered for future research and development activities and directs that such payments should be deferred and capitalized. Such amounts should be recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective for interim and annual reporting periods beginning after December 15, 2007. Management does not expect the adoption of EITF No. 07-3 to have a material effect on the Company s consolidated financial position, results of operations or cash flows.

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In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* . SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement provides entities the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply the hedge accounting provisions as prescribed by SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* . This statement is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. Management is currently evaluating the impact of adopting this statement.

Effective January 1, 2007, the Company adopted FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes* . FIN 48 prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. As of January 1, 2007 and September 30, 2007, the Company did not have any unrecognized tax benefits. There was no effect on the Company s consolidated financial position, results of operations or cash flows as a result of adopting FIN 48. The Company s policy is to recognize accrued interest and penalties for unrecognized tax benefits as a component of tax expense. As of January 1, 2007 and September 30, 2007, there was no accrued interest and penalties for unrecognized tax benefits. For the three and nine months ended September 30, 2007, there was no interest or penalties included as a component of tax expense for unrecognized tax benefits.

The Company and its subsidiaries file income tax returns in their relevant U.S. federal, various state and foreign jurisdictions. For income tax returns filed by the Company, the Company is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for tax years before 2002, although carryforward tax attributes that were generated prior to 2002 may still be adjusted upon examination by tax authorities if they either have been or will be utilized.

(o) Reclassifications

The Company s equity in the income of the BioMarin/Genzyme LLC joint venture has been presented as non-operating income in the consolidated statements of operations. During the first quarter of 2007, management determined that the significance of the joint ventures operations with respect to the Company has decreased on a relative basis compared to the Company s other activities and that presenting the equity in the income of the joint venture as a non-operating income item was now more representative of the Company s operations as a whole. Changes to the proportionate significance of the operating nature of the joint venture to the Company s total operations include the continued world-wide commercialization of Naglazyme, the planned commercial launch of Kuvan pending FDA approval, and the increasing requirements of the Company s ongoing research and development programs. Prior periods have been reclassified to conform to the current presentation for consistency.

Additionally, approximately $1.7 million was reclassified from Other Assets to Restricted Cash on the consolidated balance sheet as of December 31, 2006. Certain other items in the 2006 consolidated financial statements have been reclassified to conform to the 2007 presentation.

(3) STOCK-BASED COMPENSATION

Effective January 1, 2006, BioMarin began recording compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123R, *Share Based Payment* , as interpreted by SAB No. 107. Prior to January 1, 2006, the Company accounted for stock options according to the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* , and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. BioMarin adopted the modified prospective transition method provided for under SFAS No. 123R, and consequently has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (1) quarterly amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123; and (2) quarterly amortization related to all restricted stock and stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with

the provisions of SFAS No. 123R. In addition, the Company records expense related to shares issued under its employee stock purchase plan over the offering period.

The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the requisite service period of the options using the straight-line method. Prior to adoption of SFAS No. 123R, benefits of tax deductions in excess of recognized compensation costs were required to be reported as operating cash flows. SFAS No. 123R requires that they be recorded as a financing cash inflow rather than as a reduction of taxes paid. For the nine months ended September 30, 2007, no net excess tax benefits were generated from option exercises. The Company evaluated the need to record a cumulative effect adjustment

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for estimated forfeitures upon the adoption of SFAS No. 123R and determined the amount to be insignificant. Pursuant to the income tax provisions included in SFAS 123R, the Company has elected the long method of computing its hypothetical additional paid-in capital pool. The Company is in the process of computing the hypothetical excess tax benefits in additional paid-in capital as of the date of adoption of SFAS No. 123R. This analysis is not expected to result in a material change to BioMarin s financial statements.

Stock-based compensation expense for the three months ended September 30, 2007 totaled $5.0 million, of which $3.0 million was included in selling, general and administrative expense, $1.9 million was included in research and development expense and $0.1 million of stock-based compensation was included in cost of goods sold. Stock-based compensation expense for the three months ended September 30, 2006 totaled $2.7 million, of which $1.6 million was included in selling, general and administrative expense, $1.1 million was included in research and development expense and $0 was included in cost of goods sold. Stock-based compensation of $0.2 million and $0.5 million was capitalized into Naglazyme inventory for the three months ended September 30, 2006 and 2007, respectively, and will be recognized as cost of goods sold when the related product is sold.

Stock-based compensation expense for the nine months ended September 30, 2007 totaled $12.8 million, of which $7.6 million was included in selling, general and administrative expense, $4.8 million was included in research and development expense and $0.4 million of stock-based compensation was included in cost of goods sold. Stock-based compensation expense for the nine months ended September 30, 2006 totaled $6.5 million, of which, $3.6 million was included in selling, general and administrative expense, $2.9 million was included in research and development expense and $0 was included in cost of goods sold. Stock-based compensation of $0.9 million and $1.5 million was capitalized into Naglazyme inventory for the nine months ended September 30, 2006 and 2007, respectively, and will be recognized as cost of goods sold when the related product is sold.

Share Incentive Plan

BioMarin s 2006 Share Incentive Plan, which was approved in June 2006 and replaces the Company s previous stock option plans, provides for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date, as well as other forms of equity compensation. As of September 30, 2007, awards issued under the 2006 Share Incentive Plan include both stock options and restricted stock units. Stock option awards generally vest over a four-year period on a cliff basis six months after the grant date and then monthly thereafter. The term of the outstanding options is generally ten years. Options assumed under past business acquisitions generally vest over periods ranging from immediately upon grant to five years from the original grant date and have terms ranging from two to ten years. Restricted stock units granted to employees generally vest in a straight-line, annually over a four-year period after the grant date. Restricted stock units granted to directors generally vest in full one year after the grant date.

The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the table below. The expected life of options is based on observed historical exercise patterns. Groups of employees that have similar historical exercise patterns were considered separately for valuation purposes, but none were identified that had distinctly different exercise patterns as of September 30, 2007. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of BioMarin stock and the implied volatility of traded options on the Company s stock for fiscal periods in which there is sufficient trading volume in options on the Company s stock. The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that BioMarin has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

	Three Months Ended September 30,		Nine Months Ended September 30,	
Stock Option Valuation Assumptions	**2006**	**2007**	**2006**	**2007**

Expected volatility	52.2%	50.83%	52.2-57.87 %	48.28	50.83 %
Dividend yield	0.0%	0.0%	0.0%		0.0%
Expected life	4.9 years	5.5 years	4.9-5.0 years	5.2	5.5 years
Risk-free interest rate	4.6%	4.4%	4.4-5.1%	4.4	5.1%

The Company recorded $5.0 million and $12.8 million of compensation expense related to current period vesting of stock options for the three and nine months ended September 30, 2007, respectively, recognized in accordance with SFAS No. 123R, and recorded $2.6 million and $6.9 million of compensation expense related to stock options for the three and nine months ended September 30, 2006. As of September 30, 2007, there was $49.3 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 2.9 years.

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A summary of stock option activity under all plans, including plans that were suspended upon adoption of the 2006 Share Incentive Plan, for the nine months ended September 30, 2007 is presented as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Options Granted	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2006	10,374,194	$ 11.75			
Granted	2,691,275	$ 17.69	$ 8.98		
Exercised	(1,102,895)	$ 8.42			$ 13,026
Expired and forfeited	(336,589)	$ 14.50			
Balance as of September 30, 2007	11,625,985	$ 13.36		7.8	$ 155,291
Options expected to vest at September 30, 2007	5,407,252	$ 15.13		9.0	$ 52,808
Exercisable as of September 30, 2007	4,935,498	$ 10.95		6.2	$ 54,039

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of our common stock as of the end of the period. There were 11.6 million options that were in-the-money at September 30, 2007. The aggregate intrinsic value of options exercised was determined as of the date of option exercise. The total intrinsic value of options exercised during the three and nine months ended September 30, 2007 was $9.3 million and $13.0 million, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2006 was $4.1 million and $7.6 million, respectively. The weighted-average grant-date fair value of stock options granted during the three and nine months ended September 30, 2007 was $10.64 and $8.98, respectively. The weighted-average grant-date fair value of stock options granted during the three and nine months ended September 30, 2006 was $7.44 and $6.54, respectively.

An initial option is granted to each new outside member of BioMarin s Board of Directors to purchase 30,000 shares of common stock at the fair value on the date of the grant. Until January 2007, on each anniversary date of becoming a director, each outside member was granted options to purchase 30,000 shares of common stock at the fair market value on such date. Effective June 7, 2007, on the date of each annual meeting of stockholders, other than newly elected directors, each outside director is granted options for the purchase of 15,000 shares of common stock and 2,500 restricted stock units. The options vest over one year and have a term of ten years. The restricted stock units vest on the one-year anniversary of the date of grant.

As of September 30, 2007, the options outstanding consisted of the following:

	Options Outstanding			Options Exercisable	
Range of exercise prices	Number of Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options Exercisable	Weighted Average Exercise Price

$ 3.50 to 7.00	1,617,358	6.15	$ 5.93	1,120,762	$ 5.83
7.01 to 10.50	1,808,661	6.09	8.73	1,474,867	8.67
10.51 to 14.00	2,670,143	7.65	12.22	1,280,613	12.23
14.01 to 17.50	2,815,069	9.30	16.88	394,802	15.95
17.51 to 21.00	2,362,954	9.06	17.75	454,454	17.90
21.01 to 24.50	351,800	5.57	22.23	210,000	22.00
	11,625,985			4,935,498	

A summary of non-vested restricted stock unit activity under the plan for the nine months ended September 30, 2007 is presented as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested units as of December 31, 2006		$
Granted	116,625	17.39
Vested		
Forfeited		
Non-vested units as of September 30, 2007	116,625	$ 17.39

The Company recorded $0.1 million and $0.2 million of compensation expense related to restricted stock units for the three and nine months ended September 30, 2007, respectively, recognized in accordance with SFAS No. 123R. There were no restricted stock unit grants prior to the second quarter of 2007 and therefore no compensation expense was recognized related to restricted stock units in previous periods. As of September 30, 2007, there was $1.8 million of total unrecognized compensation cost related to unvested restricted stock units. These costs are expected to be recognized over a weighted average period of 3.5 years.

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At September 30, 2007, an aggregate of approximately 11.8 million unissued shares were authorized for future issuance under the Company s stock plans, which include shares issuable under the Company s 2006 Share Incentive Plan and the Company s Employee Stock Purchase Plan. Awards under the 2006 Share Incentive Plan that expire or are cancelled without delivery of shares generally become available for issuance under the plan. Awards that expire or are cancelled under the Company s suspended 1997 Stock Plan or 1998 Director Option Plan may not be reissued.

Employee Stock Purchase Plan

Under BioMarin s Employee Stock Purchase Plan, which was approved in June 2006 and replaces the Company s previous plan, employees meeting specific employment qualifications are eligible to participate and can purchase shares on established dates semi-annually through payroll deductions at the lower of 85% of the fair market value of the stock at the commencement or each purchase date of the offering period. Each offering period will span up to two (2) years. The Employee Stock Purchase Plan permits eligible employees to purchase common stock through payroll deductions for up to 10% of qualified compensation, up to an annual limit of $25,000. The Employee Stock Purchase Plan has been treated as a compensatory plan. The Company recorded compensation expense of $0.3 million and $1.1 million related to the Employee Stock Purchase Plan in the three and nine months ended September 30, 2007, and recorded $0.3 million and $0.5 million of compensation expense in the three and nine months ended September 30, 2006.

The fair value of each award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the table below. The expected volatility of Employee Stock Purchase Plan shares is based on the implied volatility of traded options on the Company s stock for periods in which there is sufficient trading volume in those options. Otherwise, historical volatility is utilized. The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that BioMarin has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

	Three and Nine Months Ended September 30,	
Employee Stock Purchase Plan	**2006**	**2007**
Expected volatility	44% to 54%	44% to 54%
Dividend yield	0.0%	0.0%
Expected life	6-24 months	6-24 months
Risk-free interest rate	2.7% to 4.9%	4.3% to 5.2%

(4) SUBLICENSE OF NORTH AMERICAN ORAPRED RIGHTS

In March 2006, the Company entered into a license agreement with Sciele for the continued sale and commercialization of Orapred and other Orapred formulations then under development, including Orapred ODT. Through the agreement, Sciele acquired exclusive rights to market these products in North America, and BioMarin retained exclusive rights to market these products outside of North America. BioMarin and Sciele are individually responsible for the costs of commercializing the products within their respective territories. Sciele will also pay BioMarin royalties on its net sales of these products. BioMarin will also transfer the North American intellectual property to Sciele in August 2009, following the planned purchase of the stock of Ascent Pediatrics from Medicis.

Pursuant to the agreement, Sciele paid BioMarin $2.5 million as consideration for executing the agreement, and agreed to make additional milestone payments of $15.5 million based on the approval and successful commercial launch of Orapred ODT, of which $11.5 million was received during the nine months ended September 30, 2006, with $4.0 million received during the three months ended September 30, 2006. An additional milestone of $4.0 million was received in June 2007 related to the one-year anniversary of FDA approval of Orapred ODT. During the

three and nine months ended September 30, 2007, the Company recognized $0.4 million and $1.2 million, respectively, in royalty revenues from Orapred products sold by the sublicense, and recognized $0.8 million and $0.9 million in royalty revenues during the three and nine months ended September 30, 2006, respectively.

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(5) ACQUIRED INTANGIBLE ASSETS AND GOODWILL

(a) Acquired Intangible Assets

Acquired intangible assets relate to the Ascent Pediatrics transaction completed during May 2004 and consist of the Orapred product technology as of September 30, 2007. The gross and net carrying value of the Orapred product technology as of September 30, 2007 were as follows (in thousands):

Gross value	$ 20,437
Accumulated amortization	(12,060)
Net carrying value	$ 8,377

Upon execution of the sublicense of the North American rights of Orapred in March 2006, which was determined to be a triggering event according to SFAS No. 144, the Company performed an impairment test and determined that no impairment of intangible assets existed as of March 31, 2006. No triggering events were identified during the first nine months of 2007.

The Orapred product technology is being amortized on a straight-line basis over its revised estimated useful life of 3.5 years. The estimated useful life was revised from 15 years following the execution of the sublicense for the North American rights to Orapred, which includes an asset transfer of the underlying intangible assets in August 2009, representing the revised useful life of the asset. The estimated amortization expense associated with the revised estimated useful life of the Orapred product technology for each of the succeeding three years is as follows (in thousands):

	As of September 30, 2007
Remainder of 2007	$ 1,092
2008	4,371
2009	2,914
Total	$ 8,377

Amortization expense for the three and nine months ended September 30, 2007 was $1.1 million and $3.3 million, respectively, and was $1.1 million and $2.6 million, respectively, for the three and nine months ended September 30, 2006.

(b) Goodwill

Goodwill as of September 30, 2007 relates to the Ascent Pediatrics transaction completed during May 2004. The aggregate amount of goodwill acquired in the transaction was approximately $21.3 million. Using the reporting unit basis required by SFAS No. 142, *Goodwill and Other Intangible Assets*, the Company completed an impairment test during March 2006, upon execution of the sublicense of North American rights, which was determined to be a triggering event according to SFAS No. 142. The Company determined that no impairment of goodwill existed as

of March 2006. Following the sublicense of North American rights of Orapred in March 2006, the Company has concluded it only has one reporting unit. Whether or not goodwill will be impaired in the future is dependent upon the future estimated fair value of the Company. No triggering events were identified during the first nine months of 2007.

(6) JOINT VENTURE

(a) Joint Venture Financial Data

The results of the joint venture s operations for the three and nine months ended September 30, 2006 and 2007, are presented in the table below (in thousands). Equity in the Income of BioMarin/Genzyme LLC represents the Company s 50% share of the joint venture s income. The joint venture s results and summarized assets and liabilities as presented below give effect to the difference in inventory cost basis between the Company and the joint venture. The difference in basis primarily represents the difference in inventory capitalization policies between the joint venture and the Company. The Company began capitalizing Aldurazyme inventory costs in May 2003 after regulatory approval was obtained. The joint venture began capitalizing Aldurazyme inventory costs in January 2002 when inventory production for commercial sale began. The difference in inventory capitalization policies resulted in greater operating expense recognized by the Company prior to regulatory approval compared to the joint venture. Correspondingly, this results in less cost of goods sold recognized by the Company when the previously expensed product is sold by the joint venture and less operating expenses when this previously expensed product is used in clinical trials. The difference will be eliminated when all of the product produced prior to obtaining regulatory approval has been sold or used in clinical trials. The majority of the difference has been eliminated as of September 30, 2007.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2007	2006	2007
Net product sales	$ 25,029	$ 32,322	$ 69,891	$ 88,270
Cost of goods sold	6,037	6,894	17,044	19,778
Gross profit	18,992	25,428	52,847	68,492
Operating expenses	9,063	8,754	26,129	26,706
Income from operations	9,929	16,674	26,718	41,786
Other income	188	218	489	531
Net income	$ 10,117	$ 16,892	$ 27,207	$ 42,317
Equity in the income of BioMarin/Genzyme LLC	$ 5,059	$ 8,446	$ 13,604	$ 21,159

At September 30, 2007, 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, 2006	September 30, 2007
Assets	$ 71,192	$ 78,117
Liabilities	(8,278)	(7,086)
Net equity	$ 62,914	$ 71,031
Investment in BioMarin/Genzyme LLC (50% share of net equity)	$ 31,457	$ 35,516

(b) Joint Venture Critical Accounting Policies

Revenue recognition BioMarin/Genzyme LLC recognizes revenue from 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. Revenue transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

The timing of product shipment and receipts can have a significant impact on the amount of revenue that BioMarin/Genzyme LLC recognizes in a particular period. Also, Aldurazyme is sold in part through distributors. Inventory in the distribution channel consists of inventory held by distributors, who are BioMarin/Genzyme LLC s customers, and inventory held by retailers, such as pharmacies and hospitals. BioMarin/Genzyme LLC s revenue in a particular period can be impacted by increases or decreases in distributor inventories. If distributor inventories increased to excessive levels, BioMarin/Genzyme LLC could experience reduced purchases in subsequent periods. To determine the amount of Aldurazyme inventory in the joint venture s U.S. distribution channel, BioMarin/Genzyme LLC receives data on sales and inventory levels directly from its primary distributors for the product.

BioMarin/Genzyme LLC records reserves for rebates payable under Medicaid and third-party payer contracts, such as managed care organizations, as a reduction of revenue at the time product sales are recorded.

Certain components of the BioMarin/Genzyme LLC rebate reserves are calculated based on the amount of inventory in the distribution channel, and are impacted by BioMarin/Genzyme LLC s assessment of distribution channel inventory. BioMarin/Genzyme LLC s calculation also requires other estimates, including estimates of sales mix, to determine which sales will be subject to rebates and the amount of such rebates. BioMarin/Genzyme LLC updates its estimates and assumptions each period, and records any necessary adjustments to its reserves.

BioMarin/Genzyme LLC 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 the nature of Aldurazyme and its patient population, the customers limited return rights, Genzyme s experience of returns for similar products and BioMarin/Genzyme LLC s estimate of distribution channel inventory, based on sales and inventory level information provided by the primary distributors for Aldurazyme, as described above. Based on these factors, BioMarin/Genzyme LLC has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

Inventory BioMarin/Genzyme LLC values inventories at the lower of cost or fair value. BioMarin/Genzyme LLC determines the cost of raw materials using the average cost method and the cost of work in process and finished goods using the specific identification method. BioMarin/Genzyme LLC analyzes its inventory levels quarterly and writes down to its net realizable value

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inventory that has expired, become obsolete, has a cost basis in excess of its expected net realizable value, or is in excess of expected requirements. If actual market conditions are less favorable than those projected by the joint venture, additional inventory write-offs may be required.

BioMarin/Genzyme LLC capitalizes inventory produced for commercial sale. Refer to Note 6(a) above for discussion of the difference in inventory cost basis between the Company and BioMarin/Genzyme LLC.

(7) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2006 and September 30, 2007, accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31, 2006	September 30, 2007
Accounts payable	$ 2,285	$ 1,313
Accrued accounts payable	13,901	16,604
Accrued vacation	2,109	2,556
Accrued compensation	6,302	6,603
Accrued interest and taxes	1,305	2,803
Accrued Naglazyme royalties	819	1,048
Other accrued expenses	996	1,637
Accrued rebates	819	1,606
Acquired rebates and returns reserve	906	666
Returns reserves	2,633	930
Current portion of deferred rent	91	108
	$ 32,166	$ 35,874

As of December 31, 2006 and September 30, 2007, other long-term liabilities consisted of the following (in thousands):

	December 31, 2006	September 30, 2007
Long-term portion of deferred rent	$ 1,234	$ 1,612
Deferred compensation liability	844	1,242
Total other long-term liabilities	$ 2,078	$ 2,854

As of December 31, 2006 and September 30, 2007, inventory consisted of the following (in thousands):

	December 31, 2006	September 30, 2007
Naglazyme raw materials	$ 2,747	$ 2,535
Naglazyme work in process	13,305	16,861
Naglazyme finished goods	9,023	12,155
Total inventory	$ 25,075	$ 31,551

As of December 31, 2006 and September 30, 2007, short-term investments consisted of the following (in thousands):

	December 31, 2006	September 30, 2007
Corporate securities	$ 27,212	$ 70,060
Commercial paper	157,563	224,801
U.S. Government agency securities	14,910	
Total short-term investments	$ 199,685	$ 294,861

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(8) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2006 and September 30, 2007, consisted of (in thousands):

Category	December 31, 2006	September 30, 2007	Estimated Useful Lives
Leasehold improvements	$ 24,733	$ 26,359	Shorter of life of asset or lease term
Building and improvements	22,604	26,742	20 years
Manufacturing and laboratory equipment	16,045	18,130	5 years
Computer hardware and software	6,484	9,130	3 years
Office furniture and equipment	3,617	3,888	5 years
Land	4,259	4,259	
Construction-in-progress	4,777	10,366	
	$ 82,519	$ 98,874	
Less: Accumulated depreciation	(27,053)	(32,625)	
Total property, plant and equipment, net	$ 55,466	$ 66,249	

Depreciation for the three and nine months ended September 30, 2007 was $2.0 million and $5.6 million, respectively, of which $0.2 and $1.0 million was capitalized into inventory, respectively. Depreciation for the three and nine months ended September 30, 2006 was $1.6 million and $5.1 million, respectively, of which $0.2 and $1.4 million was capitalized into inventory, respectively.

(9) CONVERTIBLE DEBT

In April 2007, the Company sold approximately $324.9 million of senior subordinated convertible notes due on April 23, 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of 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 the common stock.

In connection with the placement of the April 2007 debt, the Company paid approximately $8.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt, and the Company recognized $0.2 million and $0.4 million of amortization expense during the three and nine months ended September 30, 2007, respectively.

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

In connection with the placement of the 2006 debt, the Company paid approximately $5.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt, and the Company recognized $0.2 million and $0.6 million of amortization expense during the three and nine months ended September 30, 2007, respectively. Amortization expense was $0.2 million and $0.4 million for the three and nine months ended September 30, 2006, respectively.

In June 2003, the Company sold $125 million of convertible notes due on June 15, 2008. In September 2006, certain holders of the Company s 3.50% Convertible Senior Subordinated Notes due in 2008 agreed to convert $73.6 million in aggregate principal amount of the notes to approximately 5.25 million shares of common stock. The Company agreed to make a cash payment to the holders, comprised of accrued interest through the date of conversion of $0.7 million and an inducement for the holders to convert of approximately $3.3 million. The inducement payment of $3.3 million was recognized as additional expense during the third quarter. Also as a result of the conversion, approximately $0.9 million in previously capitalized debt offering costs were reclassified to additional paid in capital. As of December 31, 2006, the Company had an outstanding balance of $51.4 million of the Company s 3.5% Senior Subordinated Convertible Notes due 2008, which was converted into approximately 3.7 million shares of common stock in January 2007. As a result of this conversion, approximately $0.5 million in previously capitalized debt offering costs were reclassified to additional paid in capital.

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. Imputed interest expense relates to the amortization of the discount on the Company s Ascent Pediatrics acquisition obligation. Interest expense for the three and nine months ended September 30, 2006 was $3.6 million and $10.5 million, respectively, and included $1.2 million and $3.5 million in imputed interest expense, respectively. Interest paid for the three and nine months ended September 30, 2007 was $2.2 and $4.3 million, respectively, and was $2.8 million and $5.0 million for the three and nine months ended September 30, 2006, respectively. Capitalized interest related to the Company s fixed asset purchases during the three and nine months ended September 30, 2006 and 2007 was insignificant.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2007

(Unaudited)

(10) DERIVATIVE FINANCIAL INSTRUMENTS

The Company periodically enters into foreign currency forward contracts, which have a maturity of less than one year. At September 30, 2007, the Company had net outstanding foreign exchange forward contracts to sell $13.3 million of foreign currencies, comprised of sell contracts of $9.6 million of equivalent Euros and $3.7 million of equivalent British Pounds, both of which have a term of less than 3 months.

None of the Company s forward exchange contracts are designated as hedges under SFAS No. 133. As a result, the fair value changes of all contracts are reported in earnings as foreign exchange gain or loss. For the three and nine months ended September 30, 2007, foreign exchange gain of approximately $0.5 million and $0.7 million has been included in the Company s consolidated statement of operations with respect to the Company s forward exchange contracts. The Company did not utilize any foreign currency forward contracts during the three and nine months ended September 30, 2006.

(11) SUPPLEMENTAL CASH FLOW INFORMATION

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

	Nine Months Ended September 30,	
	2006	2007
Conversion of 3.5% convertible debt due 2008	$ 73,560	$ 51,440
Deferred offering costs reclassified to additional paid in capital as a result of the conversion of the remaining debt due 2008	868	512
Change in accrued payables related to fixed asset additions	719	3,908
Stock-based compensation capitalized into inventory	864	1,469

(12) FINANCIAL INSTRUMENTS CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. All cash, cash equivalents, and short-term investments are placed in financial institutions with strong credit ratings, which minimizes the risk of loss due to nonpayment. Trade accounts receivable as of September 30, 2007 related to net product sales of Naglazyme. A significant portion of net product sales are made to a limited number of financially viable specialty pharmacies and distributors. The Company s largest customer is one of its authorized European distributors and accounted for 48% and 58% of the Company s total net product sales of Naglazyme for the nine months ended September 30, 2006 and 2007, respectively. For the three and nine months ended September 30, 2007, net product sales of Naglazyme were $3.8 million and $12.7 million from customers based in the U.S., respectively, and $17.5 million and $47.9 million from customers based outside of the U.S., respectively. For the three and nine months ended September 30, 2006, net product sales of Naglazyme were $4.2 million and $11.2 million from customers based in the U.S., respectively, and $8.7 million and $19.0 million from customers based outside of the U.S., respectively.

The Company does not require collateral from its customers, but performs periodic credit evaluations of its customers financial condition and requires immediate payment in certain circumstances. The Company has not experienced any significant losses related to its financial instruments and management does not believe a significant credit risk existed at September 30, 2007.

(13) DEFERRED COMPENSATION PLAN

In December 2005, the Company adopted the BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan (the Deferred Compensation Plan). The Deferred Compensation Plan allows eligible employees, including management and certain highly-compensated employees as designated by the Plan s Administrative Committee, and members of the Board the opportunity to make voluntary deferrals of compensation to specified future dates, retirement or death. Participants are permitted to defer portions of their salary, annual cash bonus and restricted stock. The Company may not make additional direct contributions to the Deferred Compensation Plan on behalf of the participants without further action by the Board. Deferred compensation is held in trust and generally invested to match the investment benchmarks selected by participants. The recorded cost of any investments will approximate fair value. Investments of $0.7 million and $1.2 million and the related deferred compensation liability of $0.7 million and $1.2 million were recorded as of December 31, 2006 and September 30, 2007, respectively. The change in market value was a gain of $44,000 and $0.2 million for the three and nine months ended September 30, 2007, and was insignificant for the three and nine months ended September 30, 2006.

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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 a 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, 2006 as well as those discussed elsewhere in this Form 10-Q. You should carefully consider that information before you make an investment decision.

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

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

Overview

We develop and commercialize innovative biopharmaceuticals for serious diseases and medical conditions. We select product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market. Our product portfolio is comprised of two approved products and multiple investigational product candidates. Approved products include Naglazyme (galsulfase) and Aldurazyme (laronidase). Additionally, we have rights to receive payments and royalties related to Orapred (prednisolone sodium phosphate) and Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets) subsequent to the sublicense of North American rights in March 2006.

Naglazyme is a recombinant form of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) indicated for patients with mucopolysaccharidosis VI (MPS VI). MPS VI is a debilitating life-threatening genetic disease for which no other drug treatment currently exists and is caused by the deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B), an enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). Patients with MPS VI typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body.

Naglazyme was granted marketing approval in the U.S. in May 2005 and in the E.U. in January 2006. We market Naglazyme in the U.S. and E.U. using our own sales force and commercial organization. We have launched the product in the major markets of the E.U. and are continuing launch efforts on a country-by-country basis in the other E.U. countries. Additionally, we are receiving revenue from named patient sales of Naglazyme in other countries. We initiated commercial operations in South America, with headquarters in Brazil, during 2006 and are currently evaluating commercialization options in other countries, including the use of local distributors of Naglazyme. Naglazyme net product sales for the third quarter and first nine months of 2006 totaled $12.9 million and $30.2 million, respectively, and increased to $21.3 million and $60.6 million for the third quarter and first nine months of 2007, respectively.

Aldurazyme has been approved for marketing in the U.S., E.U., Japan and other countries for patients with mucopolysaccharidosis I (MPS I), for which no other drug treatment currently exists. MPS I is a progressive and debilitating life-threatening genetic disease that is caused by the deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of GAGs. Patients with MPS I typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body.

We have developed Aldurazyme through a 50/50 joint venture with Genzyme Corporation. We are responsible for product development, manufacturing and U.S. regulatory submissions. Genzyme is responsible for sales, marketing, distribution, obtaining reimbursement for Aldurazyme worldwide and international regulatory submissions. See *Management s Discussion and Analysis of Financial Condition and Results of Operations BioMarin/Genzyme LLC* for discussion of the financial results of Aldurazyme. Aldurazyme net revenue recorded by our joint venture for the third quarter and first nine months of 2007 increased to $32.3 million and $88.3 million, respectively, from $25.0 million and $69.9 million for the third quarter and first nine months of 2006, respectively.

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In May 2004, we completed the transaction to acquire the Orapred product line from Ascent Pediatrics, a wholly owned subsidiary of Medicis. In March 2006, we entered into an agreement with Alliant Pharmaceuticals, Inc., which was recently acquired by Sciele Pharma Inc. (Sciele), for the continued sale and commercialization of the Orapred product line. Through the sublicense agreement, Sciele acquired exclusive rights to market these products in North America. Sciele is responsible for the costs of commercializing the products in North America. In June 2006, the FDA granted marketing approval for Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets), the first orally disintegrating tablet form of prednisolone available in the United States.

In May 2005, we entered into an agreement with Merck Serono for the further development and commercialization of Kuvan and Phenylase for PKU and 6R-BH4 (BH4), the active ingredient in Kuvan, for other diseases such as cardiovascular indications, including those associated with endothelial dysfunction. Through the agreement, Merck Serono acquired exclusive rights to market these products in all territories outside the U.S. and Japan, and we retained exclusive rights to market these products in the U.S. Merck Serono and we will generally share equally all development costs following successful completion of Phase 2 clinical trials for each product candidate in each indication. Merck Serono and we are individually responsible for the costs of commercializing the products within our respective territories. Merck Serono will also pay us royalties on its net sales of these products and milestone payments for the successful completion of certain development and approval milestones.

PKU is an inherited metabolic disease that we estimate affects at least 50,000 diagnosed patients under the age of 40 in the developed world. We believe that 30% to 50% of those with PKU could benefit from treatment with Kuvan, if approved. PKU is caused by a deficiency of activity of an enzyme, phenylalanine hydroxylase (PAH), which is required for the metabolism of Phe. Phe is an essential amino acid found in all protein-containing foods. Without sufficient quantity or activity of PAH, Phe accumulates to abnormally high levels in the blood resulting in a variety of serious neurological complications, including severe mental retardation and brain damage, mental illness, seizures and other cognitive problems. Kuvan, our lead product candidate for the treatment of PKU, is a proprietary synthetic oral form of 6R-BH4, a naturally occurring enzyme co-factor for PAH. If approved, Kuvan could become the first drug for the treatment of PKU.

In March 2006, we announced positive results from the Phase 3 clinical trial, which was a six-week, multi-center international, double-blind placebo-controlled study of Kuvan. In December 2006, we announced positive results from the Phase 3 extension study, and in January 2007, we announced positive results from the Phase 3 diet study. We have received orphan drug designation for Kuvan for the treatment of PKU in both the U.S. and E.U. If Kuvan is the first approved drug for PKU, it will have seven years of market exclusivity in the U.S. and 10 years of market exclusivity in the E.U. In January 2006, the FDA designated Kuvan as a fast track product for the treatment of PKU. In May 2007, we filed the New Drug Application (NDA) for Kuvan with the FDA. On July 25, 2007, we announced that the FDA granted priority review status to the NDA for Kuvan. Under the Prescription Drug User Fee Act (PDUFA), the FDA was expected to take action on the application by November 25, 2007. On Tuesday, October 30, 2007, the FDA notified us that, solely due to an unanticipated staffing constraint at the FDA and not due to any identified issues in the NDA, the action date has been moved to December 14, 2007.

We are also developing BH4 for the treatment of other indications, including sickle cell disease and indications associated with endothelial dysfunction. Endothelial dysfunction has been associated with many cardiovascular diseases, such as peripheral arterial disease. Endothelial dysfunction is a condition characterized by the inability of the endothelium (the single cell layer lining of the blood vessels) to respond to physiological changes correctly. In preclinical and investigator-sponsored studies, administration of BH4 has improved vascular endothelial function in animal models and in patients with diabetes and other cardiovascular diseases. BH4 is a naturally occurring enzyme cofactor required for the production of nitric oxide, a molecule that is key to the regulation of dilation and constriction of blood vessels. Data from preclinical and clinical trials suggest that treatment with BH4 is generally safe and well tolerated.

In January 2007, we announced the initiation of a Phase 2 clinical trial of BH4 for peripheral arterial disease, which is a 24-week, multi-center, double-blind, placebo-controlled study. We expect results from the Phase 2 clinical trial in the second half of 2008, depending on trial enrollment rates. We have initiated several additional preclinical and clinical studies of BH4 for other indications, including those related to endothelial dysfunction, and expect results from these studies in 2008.

Phenylase is an investigational enzyme substitution therapy currently in preclinical development. It is being developed as a subcutaneous injection and is intended for those who suffer from classic PKU and for those who do not respond to Kuvan. In preclinical models, Phenylase produced a rapid, dose-dependent reduction in blood Phe levels. We expect to file an Investigational New Drug application for Phenylase with the FDA in late 2007.

Key components of our results of operations for the nine months ended September 30, 2006 and 2007, include the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2007	2006	2007
Total net product sales	$ 14,660	$ 21,325	$ 33,297	$ 60,600
Research and development expense	18,105	17,241	46,163	54,585
Selling, general and administrative expense	12,292	19,713	35,059	53,647
Net loss	(7,036)	(5,216)	(18,142)	(18,373)
Stock-based compensation expense	2,653	5,001	6,489	12,818

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Our cash, cash equivalents and short-term investments totaled $586.7 million as of September 30, 2007 compared to $288.8 million as of December 31, 2006.

Critical Accounting Policies and Estimates

In preparing our consolidated financial statements, we make assumptions, judgments and estimates that can have a significant impact on our net loss, as well as on the value of certain assets and liabilities on our consolidated balance sheets. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates and make changes accordingly. Unless otherwise noted below, there have not been any recent changes to our assumptions, judgments or estimates included in our critical accounting policies. We believe that the assumptions, judgments and estimates involved in the accounting for the impairment of long-lived assets, revenue recognition and related reserves, income taxes, inventory, research and development, clinical trial accruals and stock option plans have the greatest potential impact on our consolidated financial statements, so we consider these to be our critical accounting policies. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results. For further information on our critical and other accounting policies, see Note 2 to the accompanying consolidated financial statements.

Impairment of Long-Lived Assets

Our long-lived assets primarily include our investment in BioMarin/Genzyme LLC, property, plant and equipment, the acquired Orapred intangible assets and goodwill. We regularly review long-lived assets for impairment. The recoverability of long-lived assets, other than goodwill and our investment in BioMarin/Genzyme LLC, is measured by comparing the asset s carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. If the carrying amount of the asset is not recoverable, an impairment loss is recorded for the amount that the carrying value of the asset exceeds its fair value. No significant impairments were recognized for the year ended December 31, 2006 or the nine months ended September 30, 2007.

We currently operate in one business segment, the biopharmaceutical development and commercialization segment. When reviewing goodwill for impairment, we assess whether goodwill should be allocated to operating levels lower than our single operating segment for which discrete financial information is available and reviewed for decision-making purposes. These lower levels are referred to as reporting units. Currently, we have identified only one reporting unit as per SFAS No. 142, *Goodwill and Other Intangible Assets* . The amount of our goodwill originated from the acquisition of the Orapred business in 2004. No triggering events occurred during the first nine months of 2007 that required an impairment test. We also perform an annual impairment test in the fourth quarter of each fiscal year by assessing the fair value and recoverability of our goodwill by comparing the carrying value of the reporting unit to its fair value as determined by available market value, a discounted cash flow model or appraisals, unless facts and circumstances warrant a review of goodwill for impairment before that time.

Determining whether an impairment has occurred typically requires various estimates and assumptions, including determining which cash flows are directly related to the potentially impaired asset, the useful life over which cash flows will occur, their amount, and the asset s residual value, if any. In turn, measurement of an impairment loss requires a determination of fair value, which is based on the best information available. We use internal cash flow estimates, quoted market prices when available and independent appraisals as appropriate to determine fair value. We derive the required cash flow estimates from our historical experience and our internal business plans and apply an appropriate discount rate.

We believe that our investment in the joint venture will be recovered because we project that the joint venture will maintain sustained positive earnings and cash flows in the future. The joint venture recorded net income of $16.9 million and $42.3 million during the third quarter and first nine months of 2007, respectively. We and our joint venture partner maintain the ability and intent to fund the joint venture s operations, if necessary.

The recoverability of the carrying value of buildings and leasehold improvements for our facilities will depend on the successful execution of our business initiatives and our ability to earn sufficient returns on our approved products and product candidates. Based on management s current estimates, we expect to recover the carrying value of such assets.

Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104: *Revenue Recognition* , and Emerging Issues Task Force Issue (EITF) No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* . Our revenues consist of Naglazyme product sales during 2006 and 2007, Orapred product sales through March 2006, revenues from our collaborative agreement with Merck Serono and revenues from our Orapred sublicense agreement.

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Naglazyme product sales We recognize revenue from Naglazyme 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. Naglazyme 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) in foreign jurisdictions, are presented on a net basis in our income statement, in that taxes billed to customers are not included as a component of net product sales, as per EITF Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* .

In the U.S., Naglazyme is generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. In the E.U., Naglazyme is generally sold to our authorized European distributor and also to hospitals, which act as end-users. Additionally, we also receive revenue from named patient sales of Naglazyme in other countries, which are generally made to local distributors. Because of the pricing of Naglazyme, the limited number of patients and the customers limited return rights, Naglazyme customers and retailers generally carry a very limited inventory. We also sell Naglazyme to certain larger pharmaceutical wholesalers, which, with respect to Naglazyme, act as intermediaries between us and end-users and generally do not stock significant quantities of Naglazyme. Accordingly, we expect that sales related to Naglazyme will be closely tied to end-user demand.

We record reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product sales are recorded. Our reserve calculations require estimates, including estimates of sales mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period, and record any necessary adjustments to our reserves. To the extent actual rebates differ from our estimates, additional reserves may be required or reserves may need to be reversed.

We record 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 product based on its orphan drug status, the patient population, the customers limited return rights and our joint venture s experience of returns for Aldurazyme, which is a similar product. Based on these factors, management has concluded that Naglazyme product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

As Naglazyme was approved for commercial sale in the U.S. during the second quarter of 2005, we have only approximately 2 years of historical experience with rebates and returns specific to Naglazyme. Until additional historical experience is obtained to serve as a reasonable basis for our estimates of rebates and returns, management will use, to the extent available, current estimated sales mix of which sales will be eligible for rebates, estimated rebate rates for state Medicaid programs and other government programs, as well as experience obtained through the commercialization of Aldurazyme by our joint venture with Genzyme, which is a similar product. Certain of our customers receive distributor fees based on sales volume. 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)* , these fees are presumed to be a reduction of the selling price of Naglazyme and, therefore, are presented as a reduction of revenue on our consolidated statements of operations. The nature and amount of our current estimates of the applicable revenue dilution item that are currently applied to aggregate world-wide gross sales of Naglazyme to derive net sales are described in the table below.

Revenue Dilution Item	Percentage of Gross Sales	Description
Rebates	2-3 %	Rebates payable to state Medicaid, other government programs and certain managed care providers
Distributor fees	2-3 %	Fees paid to authorized distributors
Cash discounts	0-2 %	Discounts offered to customers for prompt payment of accounts receivable
Total	4-8 %	

We maintain a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of Naglazyme customers to make required payments. As of September 30, 2007, we had not experienced any bad debts and had no allowance for doubtful accounts. However, since we cannot predict changes in the financial stability of our customers, we cannot guarantee that allowances will not be required in the future. If we begin to experience credit losses, our operating expenses would increase.

Orapred product sales As a result of our sublicense of North American rights to Sciele in March 2006, we do not expect to record future net product sales related to the Orapred product line. Future revenue streams related to the Orapred product will be realized through recognition of royalty revenue for future sales of Orapred products by Sciele. Prior to the sublicense, we recognized revenue from Orapred product sales when persuasive evidence of an arrangement existed, the product had been shipped, title and risk

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of loss had passed to the customer, the price to the buyer was fixed or determinable and collection from the customer was reasonably assured. Orapred product sales transactions were evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

We established and maintained reserves for amounts payable to managed care organizations and state Medicaid programs for the reimbursement of a portion of the retail price of prescriptions filled that are covered by the respective plans. The amounts estimated to be paid relating to products sold were recognized as revenue reductions and as additions to accrued expenses at the time of the original sale. The rebate reserves were based on our best estimate of the expected prescription fill rate to these managed care organizations and state Medicaid patients, as well as the rebate rates associated with eligible prescriptions. The estimates were developed using the product s rebate history adjusted to reflect known and forecasted changes in the factors that impact such reserves. These factors included changes in the mix of prescriptions that were eligible for rebates, changes in the contract rebate rates and the lag time related to the processing of rebate claims by our customers and managed care organizations. The length of time between the period of prescriptions and the processing of the related rebates was consistent historically at between three and nine months, depending on the nature of the rebate. The length of time between the period of original sale by us and the processing of the related rebate is dependent upon both the length of time that the product is in the distribution channel and the lag time related to rebate processing by third parties. Additionally, we experienced longer than usual rebate processing lag times as a result of the transition of the product from Medicis after the acquisition and high levels of Orapred inventory held by wholesalers. In the first quarter of 2006, our liability for certain rebates was reduced due to the sublicense of North American rights for Orapred to Sciele. The decrease in estimated future rebates resulted in reserve reversals and an increase in net revenue of approximately $1.3 million, which was recorded in the first nine months of 2006. No significant adjustments were made to these reserves in the first nine months of 2007. To the extent actual rebates differ from our estimates, additional reserves may be required or reserves may need to be reversed.

Provisions for sales discounts and estimates for chargebacks and product returns were established as a reduction of product sales at the time such revenues were recognized. These revenue reductions were established by our management as its best estimate at the time of the original sale based on the product s historical experience adjusted to reflect known changes in the factors that impact such reserves. These revenue reductions were generally reflected either as a direct reduction to gross sales and accounts receivable through an allowance or as an addition to accrued expenses. We generally permit product returns only if the product is damaged or if it is returned near or after expiration.

Our estimates for future product returns are primarily based on the actual return history for the product and estimates of future demand related to estimated wholesaler inventory levels. Although we are unable to quantify wholesaler inventory levels of Orapred with any certainty, to the extent necessary based on the expiration date and our estimates of quantity of product in the distribution channel, we adjust our estimate for future returns as appropriate. We estimate wholesaler inventory levels, to the extent possible, based on limited information obtained from certain of our wholesale customers and through other internal analyses. Our internal analyses utilize information such as historical sales to wholesalers, product shelf-life based on expiration dating, estimates of the length of time product is in the distribution channel and historical prescription data, which are provided by a third-party vendor. We also evaluate the current and future commercial market for Orapred and consider factors such as Orapred s performance compared to its existing competitors. Based on increased retail product demand realized during the third quarter of 2006 and the early settlement of product returns with a customer for an amount less than previous estimates, we adjusted our estimates of the return liabilities, which resulted in reserve reductions of approximately $1.0 million, which was recorded as an increase to net revenue of approximately $0.7 million and $0.3 million of reduced expense for returns of product sold by the previous owner for the three-month period ended September 30, 2006. As additional information is obtained regarding retail demand and wholesaler inventory levels, additional reserves may be required or reserves may need to be reversed.

As discussed above and prior to the sublicense of the North American rights to Orapred to Sciele in March 2006, our estimates of revenue dilution items were based primarily on the historical experience for the product, as adjusted to reflect known and forecasted changes in the factors that could impact the revenue dilutions. The nature and amount of our estimates of the applicable effective rates for revenue dilution items that were applied to gross sales of Orapred to derive net sales are described in the table below. There were no additional material revenue dilution items other than those disclosed below.

	Estimated	
Revenue Dilution Item	**Rate**	**Description**
Sales Returns	3-4 %	Provision for returns of product sales, mostly due to product expiration
Rebates	8-9 %	Rebates offered to managed care organizations and state Medicaid programs
Cash Discounts	2%	

	Discounts offered to customers for prompt payment of accounts receivable
Total	13-15 %

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We periodically evaluated the need to maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. When making this evaluation, we made judgments about the creditworthiness of customers based on ongoing credit evaluations and the aging profile of customer accounts receivable and assessed current economic trends that might impact the level of credit losses in the future. The Orapred product had not experienced significant credit losses. We had no allowance for doubtful accounts as of September 30, 2007.

Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue. Nonrefundable up-front license fees where we have continuing involvement through research and development collaboration are initially deferred and recognized as license revenue over the estimated period for which we continue to have a performance obligation. License revenue includes the portion of the $25.0 million up-front license fee received from Merck Serono recognized as revenue during the development period.

Our estimates of the period over which we have an ongoing performance obligation are based on the contractual terms of the underlying arrangement, the level of effort required for us to fulfill our obligation and the anticipated timing of the fulfillment of our obligation. Accordingly, we have deferred the up-front license fee received from Merck Serono and are recognizing it as revenue on a straight-line basis over approximately 3.4 years, which represents our estimate of the time from inception of the agreement until European regulatory approval of Kuvan, for the treatment of PKU, at which point our performance obligations for developing Kuvan for the treatment of PKU will end. Our estimate of the Kuvan commercialization period is based on several underlying assumptions about uncertain events, including actions by European regulatory authorities, results of our ongoing clinical trials and successful commercial scale manufacturing of Kuvan. As Kuvan advances through the clinical development and regulatory process, our estimates of our performance obligation period may change. Changes in our estimates of our performance obligation period will be recognized prospectively over the remaining estimated performance obligation period. We regularly review our estimates of the period over which we have an ongoing performance obligation. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono.

Nonrefundable reimbursements 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 represented 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.

Royalty and license revenues We recognize royalty revenue and royalty receivables in the periods these royalties are earned, in advance of collection. Royalty revenue and receivables are based upon data provided by the sublicensee.

The timing of customer purchases and the resulting product shipments have a significant impact on the amount of royalty revenue that we recognize in a particular period. The majority of Orapred sales are made to wholesalers, which, in turn, resell the product to retail outlets. Inventory in the distribution channel consists of inventory held by wholesalers, who are the principal customers for Orapred, and inventory held by retailers. Royalty revenues from Orapred sales in a particular period will be impacted by increases or decreases in wholesaler inventory levels. If wholesaler inventories continue to substantially exceed the retail demand, we could experience reduced royalty revenue in subsequent periods.

We deferred the up-front license fee of $2.5 million received from Sciele for the North American Orapred rights in March 2006, and recognized it as revenue on a straight-line basis over a period of approximately 5 months, which represented the estimated time from inception of the agreement until commercial launch of Orapred ODT, at which point our performance obligations ended. There are no cost of sales associated with the royalties and license revenues recorded during the period and we do not expect to incur related cost of sales in future periods. The commercial launch of Orapred ODT by our sublicensee occurred in August 2006.

As a result of the FDA approval for the marketing application for Orapred ODT in June 2006 and the commercial launch of Orapred ODT in August 2006, we received milestone payments of $7.5 million and $4.0 million, respectively. We also received a milestone payment of $4.0 million in June 2007 for the one-year anniversary of FDA approval of Orapred ODT. Milestone payments are recognized in full when the related milestone performance goal is achieved and we have no future performance obligations related to that payment.

Inventory

We value inventories at the lower of cost or fair value. We determine the cost of inventory using the average cost method. We analyze our inventory levels quarterly and write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical estimate in this

determination is the estimate of the future expected inventory requirements, whereby we compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and additional inventory write-offs may be required.

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Regulatory approval for Naglazyme was received in the U.S. in May 2005, and costs related to the manufacturing of Naglazyme prior to this date were expensed as research and development expenses. We consider 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 related manufacturing costs for Naglazyme, prior to regulatory approval, were not capitalized as inventory. When regulatory approval was obtained in the U.S. in May 2005, we began capitalizing inventory at the lower of cost or fair value. As of September 30, 2007, Naglazyme inventory includes a small amount of pre-approval manufactured finished goods, which have an insignificant cost basis. The majority of the previously expensed inventory has been sold or used in clinical trials as of September 30, 2007. Stock-based compensation of $0.5 million and $1.5 million was capitalized into Naglazyme inventory for the three and nine months ended September 30, 2007, respectively, as was $0.2 million and $0.9 million for the three and nine months ended September 30, 2006, respectively.

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. Generally, in instances where we enter into agreements with third parties for research and development activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

A critical accounting assumption by our management is that we believe that regulatory approval of our product candidates is uncertain, and do not assume that product manufactured prior to regulatory approval will be sold commercially. As a result, manufacturing costs for product candidates are expensed as research and development expenses until regulatory approval is obtained, at which time inventory is capitalized at the lower of cost or fair value. Historically, there have been no changes to this assumption.

Clinical Trial Accruals

We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CRO s), clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CRO s and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed. No adjustments for material changes in estimates have been recognized in any period presented.

Stock Option Plans

We account for stock-based compensation in accordance with SFAS No. 123R, *Share-Based Payment* . Under the fair value recognition provisions of this statement, share-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 our stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

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

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

If factors change and we employ different assumptions in the application of SFAS No. 123R, the stock-based compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

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Recent Accounting Pronouncements

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

Results of Operations

All of the activities related to the manufacture, distribution and sale of Aldurazyme are reported in the results of the joint venture. Because of this presentation and the significance of the joint venture s results of operations, we have divided our discussion of the results of operations into two sections, BioMarin in total and BioMarin/Genzyme LLC. The discussion of the joint venture s operations includes the total amounts for the joint venture, not just our 50% interest in the operations.

BioMarin Results of Operations

Net Loss

Our net loss for the three and nine months ended September 30, 2007 was $5.2 million and $18.4 million, respectively, as compared to $7.0 million and $18.1 million for the three and nine months ended September 30, 2006, respectively. Net loss for the three months ended September 30, 2007 decreased and for the nine months ended September 30, 2007 increased primarily as a result of the following (in millions):

	Three Months Ended September 30	Nine Months Ended September 30
Net loss for the period ended 2006	$ (7.0)	$ (18.1)
Increased Naglazyme gross profit	5.9	21.0
Decreased collaborative agreement revenues	(1.8)	(3.1)
Decreased net Orapred profits	(5.9)	(11.2)
(Increased) Decreased research and development expense	0.7	(8.6)
Increased selling, general and administrative expense	(7.2)	(18.3)
Increased profits from BioMarin/Genzyme LLC	3.4	7.6
Increased interest income	3.9	10.1
Absence of debt conversion expense	3.3	3.3
Other	(0.5)	(1.1)
Net loss for the period ended 2007	$ (5.2)	$ (18.4)

The increase in Naglazyme gross profit during the third quarter of 2007 as compared to the third quarter of 2006 is primarily the result of additional patients initiating Naglazyme therapy in the U.S., E.U. and other countries. The decrease in net Orapred profits primarily relates to the timing of the milestone payments under the Orapred sublicense. See below for additional information related to the primary net loss fluctuations presented above, including details of our operating expense fluctuations.

Net Product Sales and Gross Profit

Net product sales increased $6.6 million to $21.3 million in the third quarter of 2007 from $14.7 million in the third quarter of 2006. Net product sales in the third quarter of 2007 included only net product sales of Naglazyme. Net product sales in the third quarter of 2006 of $14.7 million included $12.9 million of net product sales of Naglazyme and Orapred net product sales of $1.8 million, which was primarily attributable to sales of raw materials to the sublicensee of $1.0 million and $0.7 million due to reversal of returns reserves during the period. We expect net product sales of Naglazyme to increase in future periods, primarily due to additional patients initiating therapy.

Net product sales increased $27.3 million to $60.6 million in the first nine months of 2007 from $33.3 million in the first nine months of 2006. Net product sales in the first nine months of 2007 of $60.6 million included only net product sales of Naglazyme. Net product sales in the first nine months of 2006 of $33.3 million included $30.2 million of net product sales of Naglazyme and $3.1 million of net product sales of Orapred, which included $1.5 million of net product sales and $1.6 million of net rebate and return reserve reversals.

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We received marketing approval for Naglazyme in the U.S. in May 2005 and began shipping product in June 2005. In January 2006, we received marketing approval for Naglazyme in the E.U. Net product sales for Naglazyme in the third quarter and first nine months of 2007 were $21.3 million and $60.6 million, respectively, of which $17.5 million and $47.9 million, respectively, was from customers based outside of the U.S. The impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. in the third quarter and first nine months of 2007 as compared to foreign currency exchange rates during the third quarter and first nine months of 2006 was an increase to net product sales of approximately $0.9 million and $2.8 million, respectively. Gross profit for the third quarter and first nine months of 2007 was approximately $16.9 million and $47.5 million, representing gross margins of approximately 79% and 78%, respectively. In accordance with our inventory accounting policy, we began capitalizing Naglazyme inventory production costs after U.S. regulatory approval was obtained in May 2005. As a result, some of the product sold in the third quarter of 2007 had an insignificant cost basis and therefore lower cost of goods sold was reported. The majority of inventory with an insignificant cost basis has been sold or used in clinical trials as of September 30, 2007.

Net product sales for Naglazyme for the third quarter and first nine months of 2006 were $12.9 million and $30.2 million, respectively, of which $8.7 million and $19.0 million was from customers based outside of the U.S., respectively. The impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. was insignificant for the third quarter and first nine months of 2006. Gross profit for the third quarter and first nine months of 2006 was approximately $11.1 million and $26.7 million, respectively, representing gross margins of approximately 86% and 88%, respectively. Cost of sales in the first nine months of 2006 includes $0.5 million related to inventory write-offs, which were recognized in the first quarter of 2006. Excluding the inventory write-offs, gross margins for the first nine months of 2006 would have been approximately 90%. A significant portion of the product sold in the third quarter and first nine months of 2006 had an insignificant cost basis and therefore lower cost of goods sold was reported, which contributed to the higher gross margins during the third quarter and first nine months of 2006 as compared to the third quarter and first nine months of 2007.

Commencing with our acquisition of the Ascent Pediatrics business in May 2004 and continuing through the sublicense in March 2006, our net product sales include sales of Orapred. During the third quarter of 2006, we recognized return reserve reversals totaling $1.0 million, of which $0.7 million was recorded as additional net product sales, as a result of increases in retail product demand and the early settlement of product returns with a customer for an amount less than previous estimates realized compared to our previous estimates. For the first nine months of 2006, we recognized net product sales of $3.1 million for the Orapred product line. Net product sales of Orapred were insignificant during both the third quarter and first nine months of 2007, and were only related to adjustments in reserves for previous sales of the Orapred product.

In March 2006, we sublicensed rights to sell and distribute Orapred in North America for up-front and milestone payments of $18.0 million and royalties on future sales of all Orapred products, including Orapred ODT. As a result of the sublicense, we do not expect to record future net product sales related to the Orapred product line. Future revenue streams related to the Orapred product will include royalty revenues for future sales of Orapred product by the sublicensee, which are discussed below.

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 development spending for our Kuvan and 6R-BH4 for other indications program increases or decreases, contract research revenues will also change proportionately following the completion of Phase 2 clinical trials for each indication. The related costs are included in research and development expenses.

Collaborative agreement revenues in the third quarter and first nine months of 2007 were $3.1 million and $10.8 million, respectively, and includes the amortization of $1.7 million and $5.3 million, respectively, of the up-front license fee received from Merck Serono and recognized as revenue during the period, and $1.4 million and $5.5 million, respectively, of reimbursable Kuvan development costs incurred during the period. Collaborative agreement revenues of $4.9 million and $13.9 million for the third quarter and first nine months of 2006, respectively, includes the amortization of $1.8 million and $5.6 million of the up-front license fee received from Serono and recognized as revenue during the period, respectively, and $3.1 million and $8.3 million of reimbursable Kuvan development costs incurred during the period, respectively. Reimbursable Kuvan development costs decreased during the third quarter and first nine months of 2007 compared to the same periods in 2006 due primarily to reductions in Kuvan clinical trial activities.

Royalty and License Revenues

Royalty and license revenues for the first nine months of 2007 include 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 for the first nine months of 2006 include a $7.5 million milestone payment related to FDA approval of the marketing application for Orapred ODT, which was received in June 2006, and a $4.0 million milestone payment related to the commercial launch of Orapred ODT, received in September 2006. Royalty and license revenues also

include royalty revenues from Orapred product sold by the sublicensee of $0.4

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million and $1.2 million in the third quarter and first nine months of 2007, respectively. Royalty and license revenues also include royalty revenues from Orapred product sold by the sublicensee of $0.8 million and $0.9 million in the third quarter and first nine months of 2006, respectively. Royalty and license revenues for the third quarter and first nine months of 2006 also include $0.6 million and $2.5 million related to the amortization of the $2.5 million up-front license fee received from the sublicensee, respectively.

Research and Development Expense

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

Research and development expenses increased to $17.2 million and $54.6 million for the three and nine months ended September 30, 2007, respectively, from $18.1 million and $46.2 million for the three and nine months ended September 30, 2006, respectively. The components of the increase between the three and nine months ended September 30, 2006 and 2007 primarily include the following (in millions):

	Three Months Ended September 30	Nine Months Ended September 30
Research and development expense for the period ended 2006	$ 18.1	$ 46.2
Increased (Decreased) Naglazyme development expenses	0.1	(1.0)
Decreased Kuvan development expenses	(3.5)	(4.3)
Increased 6R-BH4 for other indications development expenses	0.3	5.5
Increased stock based compensation expense	0.8	1.9
Increased Phenylase development expenses	1.2	6.0
Absence of milestone payments to third party co-developer for approval and launch of Orapred ODT	(1.6)	(3.2)
Increase in research and development expense on early stage programs	0.5	0.7
Non-allocated research and development expense and other changes	1.3	2.8
Research and development expense for the period ended 2007	$ 17.2	$ 54.6

The increase in 6R-BH4 development costs is related to increases for the ongoing pre-clinical studies of 6R-BH4 in other indications including endothelial dysfunction and costs related to planning and conducting Phase 2 clinical trials in peripheral arterial disease and sickle cell disease. The increase in Phenylase development costs is related to increases for pre-clinical studies and manufacturing costs. The decrease in Naglazyme development costs is primarily due to decreased clinical trial and manufacturing expenses, after marketing approval was received in May 2005. However, we expect to continue incurring significant Naglazyme research and development costs for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments. The increase in research and development on other programs primarily includes increases in facilities costs, general research costs and research and development personnel. We expect research and development expense to increase in future periods, primarily as a result of spending on our 6R-BH4 program for other indications and on our Phenylase program.

Selling, General and Administrative Expense

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

Selling, general and administrative expenses increased to $19.7 million and $53.6 million for the three and nine months ended September 30, 2007, respectively, from $12.3 million and $35.1 million for the three and nine months ended September 30, 2006, respectively. The components of the increase between the three and nine months ended September 30, 2006 and 2007 primarily include the following (in millions):

	Three Months Ended September 30	Nine Months Ended September 30
Selling, general and administrative expense for the period ended 2006	$ 12.3	$ 35.1
Increased Naglazyme sales and marketing expenses	1.7	6.2
Increased stock-based compensation expense	1.4	4.0
Increased Kuvan commercial preparation costs	1.8	3.9
Net increase in corporate overhead and other administrative costs	2.5	4.4
Selling, general and administrative expense for the period ended 2007	$ 19.7	$ 53.6

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We initiated commercial operations in the E.U. and South America during 2006 and incurred related costs during the third quarter of 2007 primarily related to the commercialization of Naglazyme. We expect additional costs to be incurred in future periods as a result. The increase in stock-based compensation expense is the result of an increased number of options outstanding and a higher average stock price on the related grant date. The increase in corporate overhead and other administrative costs is primarily related to increases in administrative support. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme and preparation for the potential commercial launch of 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 2007 was $1.1 million and $3.3 million, respectively, compared to $1.1 million and $2.6 million for the third quarter and first nine months of 2006, respectively. The increase in amortization expense is due to the change in expected useful life as the amortization period was revised from 15 years to 3.5 years following the sublicense of North American rights to Orapred in March 2006. 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 recurring annual amortization expense associated with the intangible assets will be approximately $4.4 million through the end of the expected useful life in August 2009.

Equity in the Income of BioMarin/Genzyme LLC

Equity in the income of BioMarin/Genzyme LLC includes our 50% share of the joint venture s income for the period. Equity in the income of BioMarin/Genzyme LLC was $8.4 million and $21.2 million in the third quarter and first nine months of 2007, respectively, compared to $5.1 million and $13.6 million in the third quarter and first nine months of 2006. The increase in profit from BioMarin/Genzyme LLC in the third quarter and first nine months of 2007 was principally due to increases in Aldurazyme net revenue, which totaled $32.3 million and $88.3 million in the third quarter and first nine months of 2007, respectively, compared to $25.0 million and $69.9 million in the third quarter and first nine months of 2006, respectively. We expect our equity in the income of BioMarin/Genzyme LLC to increase in future periods, as net revenues for Aldurazyme continue to increase.

Our equity in the income of the BioMarin/Genzyme LLC is presented as non-operating income in the consolidated statements of operations. During the first quarter of 2007, we determined that the significance of the joint venture s operations had decreased on a relative basis compared to our other activities and that presenting the equity in the income of the joint venture as a non-operating income item was now more representative of the Company s operations as a whole. Changes to the proportionate significance of the operating nature of the joint venture to our total operations include the continued world-wide commercialization of Naglazyme, the planned commercial launch of Kuvan pending FDA approval, and the increasing activites related to our ongoing research and development programs. Prior periods have also been reclassified to conform to the current presentation.

See the *BioMarin/Genzyme LLC Results of Operations* section below for further discussion of the joint venture s results of operations.

Interest Income

We invest our cash and short-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income increased to $7.9 million and $18.5 million in the third quarter and first nine months of 2007, respectively, from $4.0 million and $8.7 million in the third quarter and first nine months of 2006, respectively, primarily due to increased levels of cash and short-term investments during the third quarter and first nine months of 2007.

Interest Expense

We incur interest expense on our convertible debt and on our equipment and facility loans. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction. Interest expense was $4.1 million and $10.2 million in the third quarter and first nine months of 2007, respectively, as compared to $3.6 million and $10.5 million in the third quarter and first nine months of 2006, respectively, representing an increase of $0.5 million in the third quarter and a decrease of $0.3 million in the first nine months of 2007. The increase in the third quarter of 2007 is primarily due to the April 2007 convertible debt issuance of approximately $324.9 million of 1.875% Senior Subordinated Convertible Notes due 2017. This increase was partially offset by the lack of interest expense related to our 3.5% Senior Subordinated Convertible Notes due in 2008, which were converted into common stock in two separate transactions in September 2006 and January 2007.

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Imputed interest expense totaled $1.1 million and $3.4 million for the third quarter and nine months ended September 30, 2007, respectively, as compared to $1.2 million and $3.5 million for the third quarter and nine months ended September 30, 2006, respectively.

Debt Conversion Expense

In September 2006, certain holders of our 3.5% Senior Subordinated Convertible Notes due 2008 agreed to convert $73.6 million in aggregate principal amount of the debt to approximately 5.25 million shares of our common stock. As a result of the conversion, we agreed to pay an inducement to the holders of approximately $3.3 million. In January 2007, the remaining outstanding balance of $51.4 million for our 3.5% Senior Subordinated Convertible Notes due 2008 were converted into approximately 3.7 million shares of common stock.

BioMarin/Genzyme LLC Results of Operations

The discussion below gives effect to the inventory capitalization policy that we use for inventory held by the joint venture, which is different from the joint venture s inventory capitalization policy. We began capitalizing Aldurazyme inventory production costs in May 2003, after U.S. regulatory approval was obtained. The joint venture began capitalizing Aldurazyme inventory production costs in January 2002, when inventory production for commercial sale began. The difference in inventory capitalization policies results in a greater operating expense realized by us prior to regulatory approval, and lower cost of goods sold with higher gross profit realized by us post-regulatory approval as the previously expensed product is sold by the joint venture, as well as lower research and development expense when Aldurazyme is used in on-going clinical trials. These differences will be eliminated when all of the product manufactured prior to regulatory approval has been sold or has been used in clinical trials. The majority of the differences have been eliminated as of September 30, 2007. See Note 6(a) to the accompanying consolidated financial statements for further discussion of the difference in inventory cost basis between the joint venture and us.

Revenue and Gross Profit

The joint venture received marketing approval for Aldurazyme in the U.S. in April 2003 and in the E.U. in June 2003. We have subsequently received marketing approval in other countries. Aldurazyme was launched commercially in May 2003 in the U.S. and in June 2003 in the E.U. The joint venture recognized $32.3 million and $88.3 million of net revenue in the third quarter and first nine months of 2007, respectively, and $25.0 million and $69.9 million in the third quarter and first nine months of 2006, respectively. The increase in net revenue of $7.3 million and $18.4 million from the third quarter and first nine months of 2006 to the third quarter and first nine months of 2007, respectively, is primarily attributable to an increase in the number of patients initiating therapy.

Gross profit was $25.4 million and $68.5 million for the third quarter and first nine months of 2007, as compared to $19.0 million and $52.8 million in the third quarter and first nine months of 2006, respectively, representing an increase of $6.4 million and $15.7 million, respectively. Gross margins for the third quarter and first nine months of 2007 were approximately 79% and 78%, respectively, as compared to gross margins for both the third quarter and first nine months of 2006 of 76%. The increase in gross margin during the third quarter of 2007 as compared to the third quarter of 2006 is attributable to improvements in manufacturing yields for Aldurazyme and the effect of foreign currency exchange rate fluctuations on Aldurazyme net sales.

Operating Expenses

Operating expenses of the joint venture include the costs associated with the development and commercial support of Aldurazyme and totaled $8.8 million and $26.7 million for the third quarter and first nine months of 2007, respectively, as compared to $9.1 million and $26.1 million for the third quarter and first nine months of 2006, 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 support of Aldurazyme, respectively, and $3.2 million and $8.9 million of research and development costs, primarily long-term clinical trial and regulatory costs, respectively. Operating expenses in the third quarter and first nine months of 2006 included $6.0 million and $16.0 million of selling, general and administrative expenses associated with the commercial launch of Aldurazyme, respectively, and $3.1 million and $10.1 million of research and development expenses, respectively, primarily long-term clinical trial and regulatory costs.

Changes in Financial Position

September 30, 2007 Compared to December 31, 2006

From December 31, 2006, to September 30, 2007 our inventory increased by approximately $6.5 million. The increase in inventory was attributable to the ongoing manufacturing campaign for Naglazyme. This campaign was completed in the third quarter and the next campaign will start in 2008. Our other assets increased by approximately $8.2 million during that period, primarily as a result of the capitalization and

deferral of offering costs related to the April 2007 convertible note issuance. Our net property, plant

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and equipment increased by approximately $10.8 million from December 31, 2006 to September 30, 2007, primarily as a result of increased purchases of capital equipment, primarily building improvements and equipment, 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.

Liquidity and Capital Resources

Cash and Cash Flow

As of September 30, 2007, our combined cash, cash equivalents and short-term investments totaled $586.7 million, an increase of $297.9 million from $288.8 million at December 31, 2006. During the first nine months of 2007, we received $316.3 million of net proceeds from a public offering of convertible senior subordinated notes, distributions from the joint venture of $17.1 million and $4.0 million in milestone payments for the one-year anniversary of the FDA approval of Orapred ODT. During the first nine months of 2006, we received $127.4 million of net proceeds from a public offering of common stock, $166.9 million of net proceeds from a public offering of convertible senior subordinated notes, distributions from the joint venture of $12.0 million and $14.0 million of proceeds related to our sublicense of North American rights for Orapred.

The $297.9 million increase in cash, cash equivalents, short-term investments and restricted cash during the first nine months of 2007 includes net proceeds from the public offering of convertible debt of $316.3 million. Excluding the net offering proceeds, the decrease in cash, cash equivalents, short-term investments and cash balances related to long-term debt during the first nine months of 2007 was $18.4 million, which was $46.9 million less than the net decrease in cash, cash equivalents, short-term investments and restricted cash during the first nine months of 2006 of $65.3 million, excluding net offering proceeds of $294.3 million. The primary items contributing to the decrease in net cash outflow, excluding the net offering proceeds, in 2007 were as follows (in millions):

Decreased capital asset purchases	$ 8.9
Absence of conversion premium and accrued interest payment	4.1
Decreased license proceeds related to sublicense of North American Orapred rights	(6.0)
Absence of milestone payment for approval and launch of Orapred ODT	1.6
Absence of net repayments of equipment and facility loans	20.9
Increased cash flows from BioMarin/Genzyme LLC	5.2
Net decreased operating spend, including net payments for working capital	12.5
Other	(0.3)
Total decrease in net cash outflow excluding net offering proceeds	$ 46.9

The net decreased operating spend includes increases in cash receipts from net revenues partially offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, as discussed in the *Results of Operations* section above. Decreases in net payments for working capital in 2007 primarily include decreased inventory build of $8.3 million, decreased accounts receivable build of $6.2 million, partially offset by decreased accounts payable and accrued liabilities build of $2.1 million.

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 the Company does 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, 2007, we have not made any draws on the note. We do not anticipate that we will draw funds from this note at this time.

Funding Commitments

We expect to fund our operations with our net product sales, cash, cash equivalents and short-term investments supplemented by proceeds from equity or debt financings, loans or collaborative agreements with corporate partners, to the extent necessary. We expect our current cash, cash equivalents and short-term investments will meet our operating and capital requirements for the foreseeable future based on our current long-term business plans and assuming that we are able to achieve our long-term goals. This expectation could also change depending on the amounts that we elect to spend on our development programs, including potentially multiple indications for 6R-BH4, and potential future business development opportunities.

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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, 2006 and 2007 and for the period since inception (March 1997) represent the following (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Program Inception
	2006	2007	2006	2007	
Naglazyme	$ 2.3	$ 2.4	$ 7.9	$ 6.9	$ 111.1
Kuvan	7.5	4.0	18.0	13.7	72.8
6R-BH4 for other indications, including endothelial dysfunction	3.2	3.5	5.7	10.8	23.2
Phenylase	1.1	2.3	3.3	9.3	16.3
Orapred	1.8	0.1	4.3	0.4	10.9
Not allocated to specific major current projects	2.2	4.9	7.0	13.5	137.9
Total	$ 18.1	$ 17.2	$ 46.2	$ 54.6	$ 372.2

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, 2006 for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in our Form 10-K *If we fail to maintain regulatory approval to commercially market and sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased; To obtain regulatory approval to market our products, preclinical studies and costly and lengthy preclinical and clinical trials are required and the results of the studies and trials are highly uncertain; If we are unable to successfully develop manufacturing processes for our drug products to produce sufficient quantities and at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program; If we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be adversely affected;* and *If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.*

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

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

- our ability to successfully market and sell Naglazyme;
- our joint venture partner 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.

Borrowings and Contractual Obligations

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 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 the common stock.

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In April 2007, we sold approximately $324.9 million of senior subordinated convertible debt due April 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of 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 the common stock. Our $497.4 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 $81.9 million through 2009, of which $1.8 million is payable during the remainder of 2007. 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, 2007 is presented below (in thousands).

	Payments Due by Period					
	Total	Remainder of 2007	2008	2009-2010	2011-2012	2013 and Thereafter
Medicis obligations	$ 81,850	$ 1,750	$ 6,500	$ 73,600	$	$
Convertible debt and related interest	582,008	3,046	10,404	20,808	20,808	526,942
Operating leases	23,149	941	3,815	7,872	7,350	3,171
Research and development and purchase commitments	34,322	12,123	20,791	370	138	900
Total	$ 721,329	$ 17,860	$ 41,510	$ 102,650	$ 28,296	$ 531,013

The purchase commitments above include $11.5 million related to a purchase agreement for an office and laboratory facility in 2008 related to our corporate expansion. We are also subject to contingent payments related to various development activities totaling approximately $32.6 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our market risks at September 30, 2007 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2006, on file with the Securities and Exchange Commission (SEC).

Item 4. Controls and Procedures

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

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

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.
The Company is not party to any legal proceedings not arising in the ordinary course of its business.

Item 1A. Risk Factors
Our risk factors at September 30, 2007 have not changed significantly from those discussed in Part 1, Item 1A of our Annual Report or Form 10-K for the year ended December 31, 2006, on file with the SEC.

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.

Dated: November 2, 2007

BIOMARIN PHARMACEUTICAL INC.

By: /s/ JEFFREY H. COOPER
Jeffrey H. Cooper, Chief Financial Officer
(On behalf of the registrant and as principal financial officer)

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Exhibit Index

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* Filed herewith